

No. 14-55633

**UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT**

TODD SCHUENEMAN, on behalf of himself
and all others similarly situated,

Plaintiff-Appellant,

v.

ARENA PHARMACEUTICALS, INC., et al.,

Defendants-Appellees.

On Appeal from the United States District Court
for the Southern District of California
Hon. Cathy Ann Bencivengo
No. 3:10-cv-01959-CAB-BLM

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INTRODUCTION

This is a class action lawsuit against Arena Pharmaceuticals, Inc. (“Arena” or the “Company”) and several of its executives (collectively “Defendants”) alleging securities fraud. Arena is a pharmaceutical research and development company whose main product throughout the proposed class period (“Class Period”) was a new weight management drug called lorcaserin. In 2009, Arena filed an application with the Food and Drug Administration (“FDA”) seeking approval of lorcaserin (the “Lorcaserin Application”).

In September of 2010, the FDA released a document regarding its assessment of lorcaserin (the “Briefing Document”) revealing that the drug caused significant cancers in rats. Those findings were the result of a study performed by Defendants from 2006 through January of 2009 (the “Rat Study”). It is undisputed that Defendants knew about the negative results of the Rat Study and the FDA’s serious concerns about their relevance to humans *for years*. It is also undisputed that Defendants *never* publicly disclosed that information even though they unfailingly promoted other positive test results and linked them to FDA approval.

Upon release of the Briefing Document, Arena’s share price plummeted by approximately 40 percent. Days later, a panel of FDA scientists recommended against approval of the Lorcaserin Application, and Arena’s stock price fell another 47 percent. This lawsuit followed.

Plaintiff's theory of fraud is straightforward. Defendants engaged in a multi-year campaign of omissions and misleading statements intended to completely suppress negative results of the Rat Study and the serious concerns repeatedly voiced by the FDA about those results. The motivation was to prevent investors from performing their own assessment of whether and when lorcaserin was likely to be approved. Defendants' deception propped up the value of Arena stock and enabled the Company to raise over \$150 million in sorely needed capital. In short, this was a classic fraud on the market perpetrated for classic reasons.

The district court agreed that Defendants made material omissions and misrepresentations. The district court disagreed, however, that Plaintiff's allegations give rise to a "strong inference of scienter" (*i.e.*, the intent to mislead or deliberately reckless disregard for the fact that investors would be misled). Specifically, the district court held that Defendants' omissions and statements were more likely the result of a bona fide scientific disagreement with the FDA than the result of any intent to mislead. With respect, the district court was deeply confused.

Plaintiff's theory of fraud is not that Defendants intentionally misled the market about the safety of lorcaserin. Plaintiff's theory of fraud is that Defendants knew that the negative results of the Rat Study seriously concerned the FDA, and that by failing to disclose those facts, Defendants intentionally deprived the market of material information about whether and when the FDA would likely approve the

drug. That distinction is critical because even a perfectly safe drug cannot be sold until its safety has been demonstrated *to the FDA's satisfaction*. And the value of Arena's stock depended largely on investors' perceptions regarding that issue.

As explained in detail below, Plaintiff's allegations support a compelling inference of scienter. The district court's holding to the contrary is simply untenable. Indeed, if the overwhelming circumstantial evidence in this case of Defendants' intent to mislead is insufficient to avoid dismissal, then no securities plaintiff in the Ninth Circuit will ever obtain access to discovery except in the rare case where he already possesses *non-circumstantial* proof of the specific intent of executives (*i.e.*, admissions). That was not the goal of Congress in passing the Private Securities Litigation Reform Act ("PSLRA"). And it is irreconcilable with precedent interpreting the PSLRA's scienter requirement. Reversal is warranted.

STATEMENT OF THE ISSUES

1. The PSLRA requires a private securities plaintiff to plead facts giving rise to an inference of scienter that is at least as strong as any alternative inference. In ruling on a motion to dismiss for failure to adequately plead scienter, the reviewing court must accept the plaintiff's allegations as true and view them holistically. The first question presented by Appellant is this: did the district court err in dismissing the Second Amended Complaint on the grounds that its allegations do not give rise to a strong inference of scienter?

2. Dismissal without leave to amend is improper unless the pleading cannot possibly be cured. The second question presented by Appellant is this: did the district court err in denying Plaintiff leave to amend the Second Amended Complaint on the grounds that amendment would be futile?

JURISDICTIONAL STATEMENT

This action arises under 28 U.S.C. § 1331 and Section 27 of the Securities Exchange Act of 1934 (the “Exchange Act”), 15 U.S.C. § 78aa. Specifically, Lead Plaintiff Carl Schwartz (“Plaintiff” or “Appellant”) alleges in the Second Consolidated Amended Class Action Complaint (the “Second Amended Complaint”) and in the Proposed Third Consolidated Amended Class Action Complaint (the “Proposed Third Amended Complaint”) violations of Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. § 78j(b) and 15 U.S.C. § 78t(a), and the rules and regulations promulgated thereunder by the U.S. Securities and Exchange Commission (“SEC”), including Rule 10b-5, 17 C.F.R. § 240.10b-5.

This Court has appellate jurisdiction under 28 U.S.C. § 1291 because this is an appeal from a final order, dated March 20, 2014, from the United States District Court for the Southern District of California that disposed of all claims in the proceedings below (“March 20 Order”).¹ The District Court entered Final Judgment

¹ ER-1. “ER-___” refers to Appellant’s Excerpts of Record.

dismissing the action with prejudice on March 21, 2014.² Pursuant to Fed. R. App. P. 4(a), Appellant timely filed his Notice of Appeal on April 18, 2014.³

STATEMENT OF THE CASE

I. Statutory Background

In the aftermath of the stock market crash of 1929, Congress enacted the Securities Act of 1933, 15 U.S.C. §§ 77a *et seq.*, and the Exchange Act to bolster investor confidence in the markets.⁴ Among other provisions, the Exchange Act created a private right of action for defrauded purchasers and sellers of securities.⁵ Plaintiffs were required to prove scienter: “a mental state embracing intent to deceive, manipulate, or defraud.”⁶

In 1995, Congress reaffirmed the importance of private securities litigation as a tool for defrauded investors to recover their losses in enacting the PSLRA. As the House Conference Report explains:

² ER-37.

³ ER-32.

⁴ See, e.g., H.R. REP. NO. 104-369, at 31 (1995) (Conf. Rep.), *available at* <http://www.gpo.gov/fdsys/pkg/CRPT-104hrpt369/pdf/CRPT-104hrpt369.pdf> (“The overriding purpose of our Nation’s securities laws is to protect investors and to maintain confidence in the securities markets . . .”).

⁵ See *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 196 (1976). This model incentivizes individuals to investigate and litigate fraud cases that the SEC may not bring. Bryant Garth et al., *The Institution of the Private Attorney General: Perspectives from an Empirical Study of Class Action Litigation*, 61 S. CAL. L. REV. 353, 360–66 (1988).

⁶ *Hochfelder*, 425 U.S. at 192, 193 n.12.

Private securities litigation is an indispensable tool with which defrauded investors can recover their losses without having to rely upon government action. Such private lawsuits promote public and global confidence in our capital markets and help to deter wrongdoing and to guarantee that corporate officers, auditors, directors, lawyers and others properly perform their jobs. This legislation seeks to return the securities litigation system to that high standard.⁷

To that end, the PSLRA imposed procedural hurdles to obtaining discovery in securities class actions.⁸ And one provision created a heightened pleading standard for scienter requiring plaintiffs to “state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.”⁹

The Supreme Court has since made clear that to effectuate Congressional intent, this “strong inference” requirement must be interpreted and applied in a way that “preserv[es] investors’ ability to recover on meritorious claims.”¹⁰ Accordingly, “[t]he inference that the defendant acted with scienter need not be irrefutable, *i.e.* of the ‘smoking-gun’ genre, or even the ‘most plausible of competing inferences.’”¹¹ A complaint meets the scienter standard whenever “a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged.”¹²

⁷ H.R. REP. NO. 104-369, at 31.

⁸ *See, e.g.*, 15 U.S.C. § 78u-4(b)(3)(B) (staying discovery pending any motion to dismiss).

⁹ 15 U.S.C. § 78u-4(b)(2).

¹⁰ *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007).

¹¹ *Id.* at 324.

¹² *Id.*

II. Factual Background

Defendants are Arena, a pharmaceutical research and development company, and its executives. They include the Company's President and Chief Executive Officer, Jack Lief ("Lief"); Senior Vice President and Chief Scientific Officer, Dominic P. Behan ("Behan"); Senior Vice President and Chief Medical Officer, William R. Shanahan ("Shanahan"); and former Vice President of Clinical Development, Christen "Christy" Anderson ("Anderson").¹³

Defendants developed the weight management drug lorcaserin and shepherded it through the late-stage animal and human testing necessary for FDA approval. The clinical studies on humans went well, but it became clear early in a mandatory long-term animal carcinogenicity study that lorcaserin causes cancer in rats. The FDA required Defendants to prolong the Rat Study to determine whether the carcinogenic mechanism only affects rats, and it requested bimonthly updates.

When Defendants finished the Rat Study in early 2009, they did not publicly announce the results. But they did fire 31 percent of their employees and order other cost-cutting measures. Within fourteen months, they raised over \$150 million through stock issuances and secured a \$100 million loan with a four-year term. By

¹³ Chief Financial Officer Robert E. Hoffman ("Hoffman") was also named as a defendant in the Second Amended Complaint. ER-109 (SAC ¶ 2). To aid the Court, record cites to a specific paragraph of the Second or Proposed Third Amended Complaints are indicated by a parenthetical and, respectively, use the format "SAC ¶ __" and "TAC ¶ __".

the time the FDA rejected the Lorcaserin Application in late 2010, Defendants had acquired enough capital to fund their business through 2012.

Throughout this period, Defendants led the market to believe that FDA approval of lorcaserin would be seamless because the late-stage clinical and nonclinical testing was uniformly encouraging. They promoted the findings of the human studies and represented that those findings satisfied the FDA's safety concerns. Defendants never disclosed either the carcinogenicity data from the Rat Study or the FDA's concerns that those results were germane to humans. When FDA scientists released a Briefing Document describing the results of the Rat Study in September 2010, investors and analysts were shocked, and Arena's stock price collapsed. This lawsuit followed shortly thereafter.

Over the next few years, the parties disputed the sufficiency of Plaintiff's complaints. Plaintiff amended twice and submitted a Proposed Third Amended Complaint, and Defendants argued upon each revision that Plaintiff had failed to sufficiently allege scienter. The district court agreed every time. After granting two motions to dismiss, it concluded that further amendments would be futile because Plaintiff could not plead facts supporting the "strong inference" of scienter necessary to withstand a motion to dismiss. Because this Court reviews the dismissal of Plaintiff's complaint *de novo*, this brief rehearses the key facts.¹⁴

¹⁴ See *infra* pages 9–24.

A. Defendants Conduct the Lorcaserin Human Studies.

Defendants conducted two major late-stage clinical trials of lorcaserin: (1) behavioral modification and lorcaserin for overweight and obesity management (“BLOOM”), and (2) behavioral modification and lorcaserin second study for obesity management (“BLOSSOM”).¹⁵ Both BLOOM and BLOSSOM assessed the cardiovascular safety of lorcaserin,¹⁶ which was important to the FDA because the similar diet drug Phen-Fen had been removed from the market after it was shown to cause heart-valve disease.¹⁷ The results of both BLOOM and BLOSSOM indicated that lorcaserin did not increase cardiovascular risk.¹⁸

B. Defendants Conduct the Lorcaserin Rat Study.

While the clinical trials were ongoing, Defendants conducted the Rat Study, a long-term nonclinical carcinogenicity study required for FDA approval.¹⁹ Such studies are designed to detect the risk that humans will develop cancer as a result of

¹⁵ ER-121 (SAC ¶ 63).

¹⁶ ER-136–37 (SAC ¶ 130) (quoting ER-234) (March 17, 2008 press release). Whenever the Second Amended Complaint quotes or cites press releases, SEC filings, or investor conference calls, the location of the original document in the record will be indicated.

¹⁷ ER-121 (SAC ¶ 66); ER-148–49 (SAC ¶ 182) (quoting ER-253) (September 18, 2009 press release).

¹⁸ ER-145 (SAC ¶ 166) (quoting ER-250) (May 11, 2009 call); ER-148–49 (SAC ¶ 182) (quoting ER-253) (September 18, 2009 press release); ER-152–53 (SAC ¶ 198) (quoting ER-276) (November 9, 2009 press release).

¹⁹ ER-120–22 (SAC ¶¶ 62, 63, 69).

lifetime use of the new drug.²⁰ If the drug causes cancer in rats, its sponsor must demonstrate that the carcinogenic mechanism is not relevant to humans.²¹

As of February 2007, the results of the Rat Study (“Initial Results”) indicated that lorcaserin causes mammary tumors, brain cancer, skin cancer, and cancer in the connective tissue around nerves in rats.²² The incidence of malignant mammary tumors was troubling because lorcaserin would be marketed to overweight women, who are at a higher risk for breast cancer, and the incidence of brain cancer was troubling because lorcaserin targets the central nervous system.²³

On May 31, 2007, Defendants reported the Initial Results of the Rat Study to the FDA.²⁴ Defendants hypothesized that the Initial Results were irrelevant to humans because the carcinogenic mechanism was related to prolactin, a hormone only linked to cancer in rats (the “Prolactin Hypothesis”).²⁵

The FDA had serious concerns. It required Defendants to conduct further studies to substantiate the Prolactin Hypothesis (the “Follow Up Tests”),²⁶ and it took

²⁰ ER-122 (SAC ¶ 69).

²¹ ER-122 (SAC ¶ 70).

²² ER-111 (SAC ¶ 12); ER-122 (SAC ¶ 72).

²³ ER-111 (SAC ¶ 12); ER-123 (SAC ¶ 73).

²⁴ ER-112 (SAC ¶ 15); ER-123 (SAC ¶ 75).

²⁵ ER-3.

²⁶ ER-3. Defendants hoped to show in the Follow Up Tests that lorcaserin causes a significant increase in prolactin production, which has been independently linked to cancer in rats. ER-4.

the highly unusual step of directing Defendants to prepare bimonthly updates on the results of the Follow Up Tests.²⁷ Defendants submitted bimonthly updates to the FDA throughout 2007 and 2008.²⁸

Defendants' March 2008 bimonthly update reported that the incidence and proportion of female rats with cancerous tumors had increased at all doses.²⁹ The FDA requested a meeting with Defendants the next month to discuss the negative results of the Rat Study and their implications for humans, including for participants in the ongoing clinical trials.³⁰ At that April 9, 2008 meeting, the FDA conditionally permitted Defendants to continue clinical studies but requested a draft report of the final results of the Rat Study as soon as it was available.³¹

On February 3, 2009, Defendants submitted a draft report of the final results of the Rat Study to the FDA.³² Consistent with the Initial Results, the report stated that lorcaserin had caused mammary tumors in rats at all doses, and that it had also caused brain and other cancers in rats.³³ With respect to the Follow Up Tests, the report disclosed that lorcaserin had no effect on prolactin in female rats and in fact

²⁷ ER-112 (SAC ¶ 15–16); ER-123–24 (SAC ¶¶ 75–79).

²⁸ ER-113–14 (SAC ¶¶ 19, 23, 25).

²⁹ ER-113 (SAC ¶ 20); ER-124 (SAC ¶ 83).

³⁰ ER-113 (SAC ¶ 21); ER-124 (SAC ¶ 83).

³¹ ER-125 (SAC ¶ 88).

³² ER-126 (SAC ¶ 93).

³³ ER-127 (SAC ¶ 100–01).

reduced prolactin in males by 50 percent.³⁴ The report concluded that lorcaserin did not cause the sustained and robust increase in prolactin that had been observed of drugs that do not cause cancer in humans.³⁵

C. Defendants Promote Seamless FDA Approval of Lorcaserin Based on Results of the Human *and* Animal Studies.

It is undisputed that Defendants knew about the Rat Study and the FDA's serious concerns that its results were relevant to humans *for years* yet never publicly disclosed that information. At the same time, Defendants consistently disclosed positive results of the human trials in detail. And when Defendants mentioned the animal studies, they characterized them as categorically positive.

1. Defendants promote BLOOM and BLOSSOM findings and link them to the likelihood of regulatory approval.

Defendants consistently disclosed the positive cardiovascular data from BLOOM and BLOSSOM. For example, a March 30, 2009 press release described positive BLOOM results in painstaking detail:

Lorcaserin was generally very well tolerated. The most frequent adverse events reported in Year 1 and their rates for lorcaserin and placebo patients, respectively, were as follows: [percentages for headache, upper respiratory tract infection, nasopharyngitis, sinusitis, and nausea]. The most frequent adverse events reported in Year 2 and their rates for lorcaserin and placebo patients, respectively, were as follows: [percentages for upper respiratory tract infection, nasopharyngitis, sinusitis, arthralgia, and influenza].

³⁴ ER-63 (TAC ¶ 67).

³⁵ ER-4.

Adverse events of depression, anxiety and suicidal ideation were infrequent and reported at a similar rate in each treatment group, and no seizures were reported. Serious adverse events occurred with similar frequency in each group throughout the trial without apparent relationship to lorcaserin. One death occurred during the trial, which was a patient in the placebo arm.³⁶

Similar representations were made in May and September of 2009.³⁷ In contrast, Defendants never disclosed the existence of the Rat Study at all.

Defendants also praised the *overall safety profile* of their drug in connection with these disclosures. For example, the day Defendants issued the press release quoted above, Defendant Shanahan represented, “[W]e’re getting support for the excellent safety profile of the drug.”³⁸ Defendant Lief also represented, “I’m really happy that we have such a safe drug without the CNS or cardiovascular side effects that have plagued other drugs potentially in the past.”³⁹ During another conference call coinciding with the release of clinical data, Defendant Lief represented, “We think that this tolerability profile will provide physicians with the confidence to use lorcaserin as a first line therapy for the majority of their patients.”⁴⁰

³⁶ ER-142 (SAC ¶ 153) (quoting ER-243–44) (March 30, 2009 press release).

³⁷ ER-145 (SAC ¶ 166) (quoting ER-54) (May 11, 2009 call); ER-148–49 (SAC ¶ 182) (quoting ER-253) (September 18, 2009 press release).

³⁸ ER-142–43 (SAC ¶ 155) (quoting ER-309, 312) (March 30, 2009 call).

³⁹ ER-142–43 (SAC ¶ 155) (quoting ER-309, 312) (March 30, 2009 call).

⁴⁰ ER-145 (SAC ¶ 166) (quoting ER-250) (May 11, 2009 call).

And Defendants touted the “excellent safety and tolerability profile” of lorcaserin—using that exact phrase four times on September 18, 2009 alone, the day they first reported that the integrated data from BLOOM and BLOSSOM ruled out the risk of valvulopathy.⁴¹ Defendants never qualified their representations about the “excellent safety profile” of lorcaserin by disclosing the negative results of the Rat Study or the FDA’s concerns about their relevance to humans.

On the contrary, Defendants explicitly linked the positive cardiovascular results of BLOOM and BLOSSOM, and the resulting safety profile, to the *FDA’s safety concerns* with lorcaserin. These statements were calculated to confirm investors’ preconceptions that the FDA’s concern with lorcaserin was largely cardiovascular—the problem that caused the FDA to withdraw Fen-Phen from the market.⁴² As Defendant Lief told investors:

Based on results from the BLOOM trial meeting the FDA’s efficacy criteria, and coupled with a strong tolerability profile, that includes no signal of FDA Valvulopathy at any time point over the two-year treatment period, *we believe that lorcaserin is approvable* for weight management, both here in the US, and eventually in Europe as well.⁴³

⁴¹ ER-148–49 (SAC ¶ 182) (quoting ER-253) (September 18, 2009 press release); ER-149–50 (SAC ¶ 186) (quoting ER-260–61, 263, 265–67) (September 18, 2009 call); ER-154 (SAC ¶ 205) (quoting ER-284) (November 10, 2009 call).

⁴² ER-151 (SAC ¶ 188) (quoting ER-267–68) (September 18, 2009 call).

⁴³ ER-145 (SAC ¶ 166) (quoting ER-250) (May 11, 2009 call) (emphasis added).

Defendants drew the same connection for investors later that year, announcing that BLOOM and BLOSSOM data “rules out a risk of valvulopathy in lorcaserin patients *according to criteria requested by the FDA.*”⁴⁴ And Defendant Anderson represented, “I’ll just reiterate that we did rule out the risk of valvulopathy *the way we agreed to with the FDA.* And I think this . . . supports the safety of the drug.”⁴⁵

2. Defendants fail to disclose the FDA’s concerns and represent that there are no safety hurdles to approval.

As noted above, Defendants never publicly disclosed the Initial Results of the Rat Study, the FDA’s reaction, or the existence of the Follow Up Tests. Instead, Defendants affirmatively represented that such data did not exist. For example:

Defendants made unqualified positive statements about the status of the animal studies of lorcaserin. Defendant Lief represented on a March 12, 2009 conference call, “[Our] confidence is based on the Phase II data, the Phase I data, the preclinical studies that was [sic] done, *all the animal studies that have been completed*, as well as how the studies are recruiting, have recruited, the retention in

⁴⁴ ER-148–49 (SAC ¶ 182) (quoting ER-253) (September 18, 2009 press release) (emphasis added). Tellingly, Defendants consistently referred to heart valve disease as “FDA valvulopathy” or “FDA-defined valvulopathy.” ER-144 (SAC ¶ 160) (quoting ER-315) (March 31, 2009 press release); ER-145 (SAC ¶ 166) (quoting ER-250) (May 11, 2009 call); ER-152–53 (SAC ¶ 198) (quoting ER-276) (November 9, 2009 press release).

⁴⁵ ER-151 (SAC ¶ 188) (quoting ER-267–68) (September 18, 2009 call) (emphasis added).

those studies, and that sort of thing.”⁴⁶ Defendants’ public filings with the SEC as of May 2009 likewise represented that “the long-term safety and efficacy” of lorcaserin had been “demonstrated,” in part through “long-term preclinical toxicity and carcinogenicity studies. These preclinical, *animal studies* are required to help us and regulatory authorities assess the potential risk that drug candidates may be toxic or cause cancer in humans.”⁴⁷

Defendants made additional representations that other studies were uniformly encouraging. For example, Defendant Shanahan represented in a March 30, 2009 conference call, “[B]ased on *earlier data* and Lorcaserin-selected mechanism, the topline data has not indicated any significant safety concerns.”⁴⁸ On the same call, Defendant Lief promised, “And you will see *when the full data set* is presented, our drug will be very safe, well-tolerated.”⁴⁹ And on September 18, 2009, Defendant Lief emphasized that “the [hypothalamic] mechanism is very consistent with the

⁴⁶ ER-139–40 (SAC ¶ 144) (quoting ER-387–88) (March 12, 2009 call) (emphasis added).

⁴⁷ ER-153 (SAC ¶ 200) (quoting ER-351–52, 359) (Third Quarter 2009 Form 10-Q) (emphasis added).

⁴⁸ ER-142–43 (SAC ¶ 155) (quoting ER-309, 312) (March 30, 2009 call) (emphasis added).

⁴⁹ ER-143 (SAC ¶ 157) (quoting ER-310–11) (March 30, 2009 call) (emphasis added).

clinical *as well as pre-clinical* experience that we know for lorcaserin” and stated that lorcaserin is “a very effective drug, very safe.”⁵⁰

Finally, Defendants repeatedly represented that the positive results they had disclosed constituted the complete data set accompanying the Lorcaserin Application. On three separate calls between August and November 2009, Defendants represented that they had completed their research:

- August 3, 2009: “The (inaudible) study pretty much finished up that package that we are planning to submit to the FDA as our initial [Lorcaserin Application], so we will have no additional studies that we will be submitting in the initial [Lorcaserin Application] once we complete that study report.”⁵¹
- September 18, 2009: “You know, we’ve, I think put together pretty much all of the data that we now need for this [Lorcaserin Application]. *We have favorable results on everything that we’ve compiled so far.*”⁵²
- November 10, 2009: “I am pleased to report at this time we have all of the data in hand that will be included in the new drug application that we are planning to submit to the FDA next month.”⁵³

Defendants’ statements led investors to believe that Defendants had not only completed their research, but also *disclosed* all the material data to be included in

⁵⁰ ER-149–50 (SAC ¶ 186) (quoting ER-260–61, 263, 265–67) (September 18, 2009 call) (emphasis added).

⁵¹ ER-147 (SAC ¶ 175) (quoting ER-368) (August 3, 2009 call) (response to analyst question, “Are there any other gating studies, preclinical or clinical, that are still needed at the FDA?”).

⁵² ER-151 (SAC ¶ 190) (quoting ER-263) (September 18, 2009 call) (emphasis added).

⁵³ ER-154 (SAC ¶ 204) (quoting ER-282, 284) (November 10, 2009 call).

the Lorcaserin Application. For example, in the September 18, 2009 call, Defendant Behan said, “*As you can see from the data*, we believe that lorcaserin is a game changer.”⁵⁴ At a minimum, these statements falsely suggested that there were no undisclosed *negative* results to be submitted to the FDA.⁵⁵

D. Defendants Reduce Operating Expenses and Procure Capital.

In January 2009, as the Follow Up Tests concluded, Arena directed its purchasing department to suspend all future purchases unless absolutely necessary.⁵⁶ Three months later, Arena announced plans to fire 31 percent of its workforce.⁵⁷ All told, Arena reduced its administrative costs by \$5 million in 2009 after multi-million dollar *increases* in each of the two previous years.⁵⁸ Arena employees understood that these measures were related to uncertainty as to whether lorcaserin would make it to market and, if so, when.⁵⁹

⁵⁴ ER-151 (SAC ¶ 190) (quoting ER-263) (September 18, 2009 call) (emphasis added).

⁵⁵ ER-151 (SAC ¶ 190) (quoting ER-263) (September 18, 2009 call); ER-206 (SAC ¶ 206) (quoting ER-286) (November 10, 2009 call) (“[A]t the present time, we don’t see safety signal [sic] to pursue, so we are going to down [sic] evaluate our data, file the [Lorcaserin Application] and then have discussions with the FDA after that.”).

⁵⁶ ER-114 (SAC ¶ 27).

⁵⁷ ER-438 (First Quarter 2009 Form 10-Q).

⁵⁸ See Arena’s Annual Fiscal Year 2009 Form 10-K, at 47, available at <http://www.sec.gov/edgar.shtml>.

⁵⁹ For example, a Purchasing Manager learned that the suspension of future purchases was due to uncertainty about regulatory approval of lorcaserin. ER-62 (SAC ¶¶ 62–63). Another employee heard that the layoffs were likely linked to

While Arena was implementing cost-cutting measures, it was also fundraising. Arena raised over \$150 million through stock issuances from April 2009 to June 2010 alone.⁶⁰ By comparison, Arena issued under \$2 million worth of new stock in all of 2008.⁶¹ In addition, on July 6, 2009, Arena secured a \$100 million loan from Deerfield.⁶² The loan had a four-year term, with a balloon payment of \$40 million plus interest due at the end of the term.⁶³ Arena raised \$190 million in total,⁶⁴ or enough to fund its operations through 2012.⁶⁵

management's concerns about the future of lorcaserin. ER-114–15 (SAC ¶¶ 27, 29); ER-63–63 (SAC ¶ 72).

⁶⁰ ER-120 (SAC ¶ 60); ER-126 (SAC ¶ 95); ER-127 (SAC ¶ 103); ER- 129 (SAC ¶ 112).

⁶¹ Gurufocus, *Arena Pharmaceuticals Inc (NAS:ARNA) Net Issuance of Stock*, (last visited August 27, 2014), <http://www.gurufocus.com/term/Net%20Issuance%20of%20Stock/ARNA/Net%252BIssuance%252Bof%252BStock/Arena%2BPharmaceuticals%252C%2BInc>.

⁶² ER-222 (Annual Fiscal Year 2009 Form 10-K).

⁶³ ER-222 (Annual Fiscal Year 2009 Form 10-K).

⁶⁴ 150 million is the sum of Arena's stock issuances and the last \$40 million of the Deerfield loan, which Arena did not have to pay back until 2013. ER-222 (Annual Fiscal Year 2009 Form 10-K).

⁶⁵ See generally Arena's First, Second, and Third Quarter 2012 Form 10-Qs, and Annual Fiscal Year 2012 Form 10-K, available at <http://www.sec.gov/edgar.shtml>. If this Court (like the district court) decides to consider events which occurred *after* the Class Period, such as the 2012 FDA approval of lorcaserin, it must examine those events in context. That would require consideration of the information described in this footnote and the accompanying text.

E. Defendants File the Lorcaserin Application with the FDA.

On December 18, 2009, Defendants submitted the Lorcaserin Application to the FDA.⁶⁶ The Lorcaserin Application included both the Initial Results of the Rat Study and the results of the Follow Up Tests, as well as the results of other nonclinical and clinical studies.⁶⁷ The Lorcaserin Application stated that the Follow Up Tests found, among other things, that “malignant mammary tumors were primarily prolactin negative.”⁶⁸ To put it mildly, the Follow-Up Tests failed to conclusively support the Prolactin Hypothesis.

Nonetheless, Defendants continued to promote aggressively the data they had presented to the FDA without ever disclosing the negative results of the Rat Study or the FDA’s concerns that the results were relevant to humans. A few days after submitting the Lorcaserin Application, Defendants issued a press release touting “the robust data package we submitted to the FDA” and specifically describing the results of BLOOM and BLOSSOM.⁶⁹ And a press release issued two months later presented the results of the clinical trials in even greater detail again touting the “excellent safety” of lorcaserin.⁷⁰

⁶⁶ ER-115 (SAC ¶ 30).

⁶⁷ ER-115 (SAC ¶ 30).

⁶⁸ ER-124 (SAC ¶ 79).

⁶⁹ ER-155 (SAC ¶ 209) (quoting ER-231) (December 22, 2009 press release).

⁷⁰ ER-155 (SAC ¶ 211) (quoting ER-288) (February 24, 2010 press release).

Defendants also continued to represent that there was no undisclosed data that would impair the prospects of the Lorcaserin Application. In a March 12, 2010 conference call about the pending FDA review of the Lorcaserin Application, Defendant Lief told investors, “The FDA has said that there is sufficient data to review lorcaserin on its merits. We have also had discussions and meetings around that.”⁷¹ When asked whether the FDA had raised any questions or issues, Defendant Lief responded, “Well, we typically do not go into the details of FDA correspondence. Having said that, we are confident that we have the ability to work with the FDA in the future”⁷² Defendant Lief said on the same call, “Lorcaserin was so well tolerated, and we don’t see any safety signals that require special attention right now.”⁷³

During this period, Defendants retained an independent world-renowned pathologist to make a presentation about the Rat Study to the FDA’s Endocrinology and Metabolic Advisory Committee (“Advisory Committee”) at its meeting to consider whether to recommend lorcaserin for FDA approval, reflecting Defendants’ knowledge that the Rat Study’s negative results were of serious and continued concern to the FDA.⁷⁴ Defendants’ pathologist was an expert in chemical

⁷¹ ER-157 (SAC ¶ 219) (quoting ER-390, 392, 393) (March 12, 2010 call).

⁷² ER-157–58 (SAC ¶ 221) (quoting ER-394) (March 12, 2010 call).

⁷³ ER-157–58 (SAC ¶ 221) (quoting ER-394) (March 12, 2010 call).

⁷⁴ ER-115 (SAC ¶ 32); ER-128 (SAC ¶ 108).

carcinogenesis in animals, and he worked with Defendants to prepare slides explaining the negative results of the Rat Study.⁷⁵ Yet when an analyst asked Defendants what they were focusing on in their preparations, Defendant Shanahan said, “we’re not expecting any surprises associated with the panel,” and Defendant Anderson added only, “Obviously, we’ve always said that the primary focus would be on safety, and we are well prepared to thoroughly address the safety issues, the safety data, as well as the efficacy data with the panel.”⁷⁶ Again, Defendants did not disclose the negative results of the Rat Study or the FDA’s concerns about their relevance to humans.

F. The FDA Discloses Results of the Rat Study, Investors Are Shocked, and Arena’s Stock Price Collapses.

On September 14, 2010, the FDA released a Briefing Document for the Advisory Committee panel.⁷⁷ The Briefing Document publicly disclosed the negative results of the Rat Study and the FDA’s serious concerns about them.⁷⁸

Investors were shocked.⁷⁹ A Summer Street Analyst Report captured the prevailing sentiment: “Yesterday we were *completely blindsided* by preclinical

⁷⁵ ER-115 (SAC ¶ 32); ER-128 (SAC ¶ 108).

⁷⁶ ER-161–62 (SAC ¶ 240) (quoting ER-400) (August 3, 2010 call).

⁷⁷ ER-116 (SAC ¶ 36); ER-129 (SAC ¶ 114).

⁷⁸ ER-116 (SAC ¶ 36); ER-129 (SAC ¶ 114).

⁷⁹ ER-116 (SAC ¶ 37); ER-130 (SAC ¶ 116) (collecting statements).

carcinogenicity data from the two year lorcaserin animal study.”⁸⁰ J.P. Morgan wrote similarly, “The biggest surprise is a preclinical cancer signal. We (and investors we’ve spoken with this morning) were caught off guard by the question relating to lorcaserin-related tumors in rats.”⁸¹

Analysts uniformly cautioned that new information worsened the prospects for imminent FDA approval of lorcaserin. For example, Cowen told investors, “We believe the fact that the FDA believes that lorcaserin increases the risk for malignant breast tumors in rats reduces the likelihood that lorcaserin will receive a positive panel recommendation on Thursday.”⁸² Oppenheimer wrote similarly, “We see the FDA’s rejection of [Defendants’] explanation of pre-clinical cancers in rats as a significant concern.”⁸³ And Summer Street warned, “Most importantly, we do not believe Arena will be able to produce preclinical data and/or design a post-approval trial/registry to rule out a breast cancer risk.”⁸⁴

⁸⁰ ER-130 (SAC ¶ 116) (quoting September 15, 2010 Summer Street Analyst Report) (“Summer Street Analyst Report”) (emphasis added).

⁸¹ ER-130 (SAC ¶ 116) (quoting September 14, 2010 J.P. Morgan *ALERT*) (emphasis removed); *see also* ER-130 (SAC ¶ 116) (quoting September 14, 2010 Jefferies Analyst Report) (“The biggest surprise in the briefing documents is the finding of preclinical cancers.”); ER-130 (SAC ¶ 116) (quoting September 14, 2010 Cowen Analyst Report entitled “Quick Take: Rat Carcinogenicity Data A Surprise In Briefing Docs”) (“Cowen Analyst Report”).

⁸² ER-130 (SAC ¶ 116) (quoting Cowen Analyst Report).

⁸³ ER-130 (SAC ¶ 116) (quoting September 14, 2010 Oppenheimer Analyst Report) (emphasis removed).

⁸⁴ ER-130 (SAC ¶ 116) (quoting Summer Street Analyst Report).

Investors agreed. Arena stock fell from \$6.85 per share at the close of trading the day before to \$4.13 per share at the close of trading on September 14, 2010—a one-day decline of 40 percent that wiped out millions of dollars of shareholder value.⁸⁵ Trading in Arena common stock was halted the next day.⁸⁶

III. Procedural History

A few days later, Arena investors sued Defendants under Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5.⁸⁷ Following his appointment as Lead Plaintiff, Plaintiff filed an amended complaint (“First Amended Complaint”), setting forth facts gleaned from publicly available information and interviews with confidential informants in support of his claim that Defendants artificially inflated the price of Arena stock for over two years by misleading the market about the likelihood and timing of FDA approval of lorcaserin.⁸⁸

The district court dismissed the First Amended Complaint without prejudice on two grounds related to scienter: first, that Plaintiff had not adequately alleged each Defendant’s knowledge of the Rat Study and the FDA’s concerns;⁸⁹ and second,

⁸⁵ ER-116 (SAC ¶ 37); ER-129 (SAC ¶ 115).

⁸⁶ ER-116 (SAC ¶ 37).

⁸⁷ Complaint, Dkt. No. 1.

⁸⁸ First Amended Complaint, Dkt. No. 43.

⁸⁹ In so holding, the district court misapplied the core operations inference. After first noting, “Lorcaserin was Arena’s core product. Defendants were focused on the development of lorcaserin, they discussed lorcaserin in every conference call, press release and periodic report filed by Arena with the SEC, and nearly all of the

that it was “more plausible that [Defendants] knew about the Rat Study data and reasonably believed the results to be *positive* with regard to what the study was designed to test”—whether lorcaserin causes cancer in humans—than that they recklessly disregarded the falsity of their statements.⁹⁰

Plaintiff filed a Second Amended Complaint on May 13, 2013, adding facts to establish each Defendant’s personal knowledge of the Rat Study results and the FDA’s communications with Arena about them.⁹¹ The district court then held a lengthy oral argument on Defendants’ motion to dismiss the Second Amended Complaint.⁹² During that hearing, the district court initially expressed skepticism about Defendants’ position, noting for example that “the company was telling [investors] that they had favorable results on everything and, yet, the fact pattern doesn’t seem to indicate that they were in a favorable position in 2009”⁹³ and that she was inclined “to deny the motion to dismiss based on at least the statements that were made in September of 2009.”⁹⁴ But defense counsel steered the hearing toward

Company’s resources were dedicated to lorcaserin’s development,” the district court continued, “However, the facts presently before the Court do not warrant the application of the ‘core operations’ scienter theory” ER-28. The court’s conclusion does not follow from its premises.

⁹⁰ ER-30 (emphasis added).

⁹¹ ER-106–173.

⁹² Transcript of Proceedings held on October 18, 2013, Dkt. No. 82, 6:16–18 (“October 2013 Hearing Transcript”).

⁹³ October 2013 Hearing Transcript 6:16–18.

⁹⁴ October 2013 Hearing Transcript 7:4–6.

the scientific implications of the Follow Up Tests,⁹⁵ and the judge was led to view this case as a scientific dispute: “Their scientific interpretation of this has to be demonstrated to be wrong”⁹⁶

On November 4, 2013, the district court entered an order (“November 4 Order”) dismissing the Second Amended Complaint without prejudice, again on the grounds that it “fails to meet the Ninth Circuit’s pleading requirements for scienter.”⁹⁷ Specifically, the November 4 Order concluded that Defendant Lief’s March 12, 2009 statement that “confidence is based on . . . the preclinical studies

⁹⁵ October 2013 Hearing Transcript 14:4–11 (“It’s the single most important factor in this case because the FDA . . . mechanistically combined all the data so that it could make a determination with independent pathologists what do these slides show. And when those independent pathologists reviewed the data, it agreed that the data was correct, and in fact, it was less cancer that Arena had suggested.”).

⁹⁶ October 2013 Hearing Transcript at 37:12–14.

⁹⁷ ER-8. The November 4 Order also dismissed Defendant Hoffman from this action on the grounds that Plaintiff did not “sufficiently plead his knowledge of the Rat Study data.” ER-12 (footnote 4). This Court should reverse that dismissal. As noted in *supra* note 89, the district court acknowledged that every public statement made by Arena during the Class Period discussed lorcaserin and nearly all of its resources “were dedicated to lorcaserin’s development.” ER-28. Under these circumstances, the results of the Rat Study were sufficiently prominent “that it would be ‘absurd’ to suggest that management was without knowledge of the matter.” *South Ferry LP, # 2 v. Killinger*, 542 F.3d 776, 786 (9th Cir. 2008) (citing *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 988 (9th Cir. 2008)). In addition, Defendant Hoffman signed the Sarbanes-Oxley certifications that accompanied each regulatory disclosure. ER-138 (SAC ¶ 134). Thus, the Second Amended Complaint contains “specific allegations that [Defendant Hoffman] actually did monitor the data that were the subject of the allegedly false statements. That is sufficient under the PSLRA.” *South Ferry*, 542 F.3d at 785 (citing *In re Daou Sys., Inc.*, 411 F.3d 1006, 1022–23 (9th Cir. 2005)).

that was [sic] done, all the animal studies that have been completed” did not demonstrate recklessness because Defendants reasonably believed lorcaserin’s overall safety profile and potential to be “positive, favorable, or encouraging.”⁹⁸ The court also cited the fact that the FDA had “ultimately [*i.e.*, two years later] accepted and agreed with Arena’s final data” as evidence of an absence of scienter.⁹⁹ Finally, the district court found that Defendant Anderson’s September 18, 2009 statement, “We have favorable results on everything that we’ve compiled so far,” *might* be misleading, but only if Plaintiff could “show this case to be about more than a difference of scientific opinion”¹⁰⁰

The November 4 Order invited Plaintiff to amend with the instruction to “dramatically limit his amended complaint to . . . statements that support Plaintiff’s theory that Defendants knew they had to and failed to substantiate their hypothesis that the tumors found in the Rat Study were due to a rat-specific mechanism”¹⁰¹ For example, the court advised Plaintiff to remove statements limited to the BLOOM and BLOSSOM clinical trials,¹⁰² and cautioned that the allegations relating to stock

⁹⁸ ER-14–15.

⁹⁹ ER-14–15.

¹⁰⁰ ER-15–16.

¹⁰¹ ER-16 (footnote 9).

¹⁰² ER-19 (footnote 13).

sales and budget cuts “do not meaningfully contribute to a strong inference of scienter with respect to the overall safety statements.”¹⁰³

On November 27, 2013, Plaintiff moved for leave to amend the Second Amended Complaint and attached the Proposed Third Amended Complaint, which followed the district court’s instructions to the letter.¹⁰⁴ Nevertheless, the district court denied leave to amend on March 20, 2014 (“March 20 Order”), on the grounds that amendment would be futile because the Proposed Third Amended Complaint still did not adequately plead scienter.¹⁰⁵

The March 20 Order focused on whether Plaintiff adequately alleged that Defendants intentionally misrepresented the safety of lorcaserin because they knew that the Follow Up Tests did not support the Prolactin Hypothesis.¹⁰⁶ The district court concluded that it was “more plausible” that Defendants had a legitimate scientific disagreement with the FDA about the implications of the Follow Up Tests.¹⁰⁷ The district court observed that Plaintiff did not allege that Defendants interpreted the Follow Up Tests unreasonably or that they did not actually believe that the Follow Up Tests supported the Prolactin Hypothesis.¹⁰⁸

¹⁰³ ER-15 (footnote 8).

¹⁰⁴ Motion to Amend, Dkt. No. 73; ER-43 (TAC).

¹⁰⁵ ER-8.

¹⁰⁶ ER-1–7.

¹⁰⁷ ER-6.

¹⁰⁸ ER-6–7.

With respect to Defendants' misrepresentations about the prospects for regulatory approval of lorcaserin, the district court acknowledged in passing that "Defendants may have known that there was a *theoretical risk* that the FDA would disagree" with their assessment of the Follow Up Tests, but emphasized that there were no facts "suggesting Defendants knew they had to show that lorcaserin caused a sustained and robust increase in prolactin to obtain FDA approval."¹⁰⁹ The district court focused on the absence of allegations that Defendants "were on notice that the FDA would opine that the [Follow Up Tests] failed to substantiate the Prolactin Hypothesis."¹¹⁰ Somewhat amazingly, the court concluded that Defendants' scientific disagreement with the FDA was "unanticipated."¹¹¹

On March 20, 2014, final judgment was entered. This appeal followed.

STANDARD OF REVIEW

Plaintiff seeks reversal of the November 4 Order dismissing the Second Amended Complaint and, in the alternative, the March 20 Order denying Plaintiff's motion for leave to amend. This Court reviews both orders *de novo*.¹¹²

¹⁰⁹ ER-4–5 (emphasis added).

¹¹⁰ ER-5.

¹¹¹ ER-6.

¹¹² *Whitman v. Mineta*, 541 F.3d 929, 931 (9th Cir. 2008); *Livid Holdings Ltd. v. Salomon Smith Barney*, 416 F.3d 940, 946 (9th Cir. 2005).

The question presented in a motion to dismiss is whether Plaintiff is entitled to offer evidence to support his claim, not whether Plaintiff will prevail.¹¹³ In answering that question, the Court accepts Plaintiff's allegations as true and draws all reasonable inferences in Plaintiff's favor.¹¹⁴ Even if the chance of recovery is remote, the Court allows Plaintiff to develop his case "unless the complaint fails to 'state a claim to relief that is plausible on its face.'"¹¹⁵

With respect to leave to amend, this Court has "repeatedly held that a district court should grant leave to amend . . . unless it determines that the pleading could not possibly be cured by the allegation of other facts."¹¹⁶ Accordingly, dismissal with prejudice "is improper unless it is clear, upon *de novo* review, that the complaint could not be saved by any amendment."¹¹⁷

SUMMARY OF ARGUMENT

The district court fundamentally misunderstood Plaintiff's theory of fraud. In assessing scienter, it asked whether Plaintiff had adequately alleged that Defendants intentionally misled the market about the *safety* of lorcaserin, and it answered that

¹¹³ See *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974), *overruled on other grounds by Davis v. Scherer*, 468 U.S. 183 (1984).

¹¹⁴ *Usher v. City of Los Angeles*, 828 F.2d 556, 561 (9th Cir. 1987).

¹¹⁵ *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 989 (9th Cir. 2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 554, 570 (2007)); *United States v. City of Redwood City*, 640 F.2d 963, 966 (9th Cir. 1981).

¹¹⁶ *Lopez v. Smith*, 203 F.3d 1122, 1130 (9th Cir. 2000).

¹¹⁷ *Livid Holdings*, 416 F.3d at 946.

Defendants had a legitimate scientific disagreement with the FDA and thus lacked fraudulent intent. But Plaintiff's theory of fraud is that Defendants intentionally misled the market about whether and when the FDA would approve lorcaserin, not its actual safety. That is a critical difference. By depriving investors of the opportunity to independently evaluate how the FDA might act in light of the Rat Study and the FDA's repeatedly expressed concerns, Defendants committed fraud.

Without the benefit of formal discovery, Plaintiff has amassed substantial circumstantial evidence that Defendants intentionally perpetrated this fraud. The evidence shows that: (1) since the beginning of the Class Period, Defendants knew about the Rat Study's negative results and the FDA's concerns about their relevance to human risk; (2) Defendants selectively disclosed and withheld the results of late-stage testing depending on whether they were favorable to the prospects for FDA approval; (3) Defendants misrepresented these results to make FDA approval seem more likely and imminent; and (4) Defendants believed that FDA approval of lorcaserin would be delayed, if not denied altogether. In dismissing these allegations out of hand, the district court failed to read the Second Amended Complaint either holistically or in the light most favorable to Plaintiff.

The district court's application of the PSLRA's requirement that a plaintiff plead scienter was also far too stringent. Indeed, it appears that nothing short of direct evidence showing Defendants' intent to defraud the market would have

satisfied the district court. That is surely not a requirement Congress sought to impose when it enacted the PSLRA. And it is directly contradictory to the Supreme Court’s admonition that the “strong inference” of scienter standard must be applied in a way that “preserv[es] investors’ ability to recover on meritorious claims”¹¹⁸ by “allow[ing] meritorious actions to go forward.”¹¹⁹

ARGUMENT

I. The District Court Misapprehended Plaintiff’s Theory of Fraud.

The district court erred when it dismissed the Second Amended Complaint and, for similar reasons, denied leave to amend the Second Amended Complaint as futile. The district court misapplied the scienter requirement because it erroneously believed that Defendants’ scienter turned on subjective beliefs about lorcaserin’s safety.¹²⁰ In fact, scienter turns on Defendants’ objective awareness of the negative results of the Rat Study and the FDA’s expressed concerns about those results.

A. Plaintiff’s Theory of Fraud Is that Defendants Intentionally Misled Investors about Whether and When the FDA Was Likely to Approve Lorcaserin.

Defendants committed a classic fraud on the market for the classic reasons. According to the Second Amended Complaint, Defendants concealed the negative

¹¹⁸ *Tellabs*, 551 U.S. at 322.

¹¹⁹ *Id.* at 324.

¹²⁰ The court did correctly articulate the standard, which requires Plaintiff to plead facts giving rise to a strong inference that Defendants acted with scienter. ER-9.

results of the Rat Study and the FDA's concerns about their implications for humans with the intent to deprive the market of material information about the likelihood and timing of FDA approval. In this way, Defendants artificially inflated the price of Arena stock for months and raised over \$150 million in capital for the Company. Plaintiff's theory of securities fraud proceeds in three steps.

1. Arena's stock price was based on investor perceptions about whether and when the FDA would approve lorcaserin.

During the Class Period, the business of Arena was focused primarily on lorcaserin.¹²¹ For example, "[a]ccording to the 2009 10-K, approximately 95% and 86% of Arena's total external clinical and preclinical study fees and expenses related to lorcaserin in 2008 and 2009, respectively."¹²²

Investor perceptions regarding the prospects of FDA approval of lorcaserin were, to put it mildly, a significant driver of Arena's stock price. Indeed, the price of Arena stock fluctuated dramatically upon any news that affected those

¹²¹ ER-50–51 (SAC ¶ 50) (citing ER-212) (Fiscal Year 2009 Form 10-K).

¹²² ER-50–51 (SAC ¶ 50) (citing ER-212) (Fiscal Year 2009 Form 10-K).

perceptions.¹²³ And it was not only the likelihood of lorcaserin's approval by the FDA that mattered to investors, but also the *expected timing* of that approval.¹²⁴

The timing of FDA approval was crucial for two reasons. First, the longer Arena was expected to remain in the developmental period for lorcaserin, the more capital the Company would need to raise to remain solvent. The risk of insolvency was significant because pharmaceutical research and development companies consume capital at an astounding rate. Indeed, as Arena noted in 2009:

We do not have any commercially available drugs, and we have substantially less money than we need to develop our compounds into marketed drugs. It takes many years and potentially hundreds of millions of dollars to successfully develop a preclinical or early clinical compound into a marketed drug, and our efforts may not result in any marketed drugs. . . . If adequate funding is not available, we will have to eliminate or further postpone or scale back some or all of our research or development programs or delay the advancement of one or more of such programs, including our lorcaserin program.¹²⁵

¹²³ See, e.g., ER-116 (SAC ¶¶ 36–37); ER-129 (SAC ¶¶ 114–15); ER-165 (SAC ¶ 254) (Arena's share price declined approximately 40 percent upon release of the Briefing Document); ER-116 (SAC ¶¶ 38–39); ER-165 (SAC ¶ 256) (Arena's share price further declined approximately 47 percent upon vote of Advisory Committee).

¹²⁴ See ER-117 (SAC ¶¶ 43–44); ER-135 (SAC ¶¶ 127–28); ER-165 (SAC ¶ 257–58) (Arena's share price declined approximately 19 percent upon disclosure that FDA had recommended lorcaserin studies of at least 12 months). See also ER-117 (SAC ¶¶ 40–44); ER-134–35 (SAC ¶¶ 124–28) (decline in stock price was caused by frustration of widely-held expectation that further lorcaserin studies required by the FDA would be “short in duration”).

¹²⁵ ER-436 (First Quarter 2009 Form 10-Q).

A prolonged approval process would also increase Arena's total expenses to develop lorcaserin without any offsetting increase in expected revenues, further decreasing the value of Arena stock.

Second, basic accounting principles dictate that dollars earned in the future are worth less than dollars earned today.¹²⁶ Thus, the more distant in the future Arena's projected revenues from selling lorcaserin became, the less Arena's stock was currently worth.

2. Investor perceptions about whether and when the FDA would approve lorcaserin turned on investor beliefs about how satisfied the FDA was with the safety of lorcaserin.

As the Second Amended Complaint explains, “a drug sponsor must demonstrate the drug's safety. Safety with respect to diet drugs was highly important because prior FDA-approved diet drugs, including Fen-Phen, were removed from the market because of serious adverse side effects”¹²⁷ It was particularly important for Defendants to demonstrate lorcaserin's lack of side effects because it affects the brain and central nervous system in similar ways as Fen-Phen.¹²⁸

¹²⁶ See e.g., Investopedia, *Definition of Time Value of Money* (last visited August 26, 2014), <http://www.investopedia.com/terms/t/timevalueofmoney.asp>. See also *Donell v. Kowell*, 533 F.3d 762, 772 (9th Cir. 2008) (applying time value of money).

¹²⁷ ER-121 (SAC ¶ 65).

¹²⁸ ER-121 (SAC ¶ 66).

Defendants were keenly aware of this dynamic. “In February 2008, just before the beginning of the Class Period, Defendant Lief acknowledged that focus was on ‘safety, safety, safety, safety . . . and then safety.’”¹²⁹ And Defendant Lief later reiterated, “We have always stated that safety is of paramount importance to the FDA, and that the right profile of efficacy, safety, and tolerability is essential for a weight-management drug.”¹³⁰

3. Defendants concealed the Rat Study’s negative results and the FDA’s concerns about them from the public in order to manipulate investor perceptions.

Plaintiff has alleged that Defendants knew that the negative results of the Rat Study and the FDA’s expressed concerns about them would affect investor perceptions about the prospects for regulatory approval of lorcaserin, and thus would be material to their investing decisions.¹³¹ Defendants engaged in a pattern of misrepresentations and omissions to conceal these facts.¹³²

¹²⁹ ER-121 (SAC ¶ 66).

¹³⁰ ER-161 (SAC ¶ 238) (quoting ER-398) (August 3, 2010 call).

¹³¹ *No. 84 Employer-Teamster Joint Council Trust Fund v. Am. W. Holding Corp.*, 320 F.3d 920, 934 (9th Cir. 2003) (“[A] fact is material if there is a ‘substantial likelihood’ that a reasonable investor would consider it important in his or her decision making.”).

¹³² *See In re Immune Response Sec. Litig.*, 375 F. Supp. 2d 983, 1020 (S.D. Cal. 2005) (“Whether Defendants had to predict the efficacy of [new drug] REMUNE is irrelevant. Defendants are liable under section 10(b) and rule 10b-5 if they made misstatements that a reasonable investor would consider in deciding whether to buy IRC’s stock.”).

The materiality of the negative results of the Rat Study and the FDA's concerns were apparent. The Rat Study was a prerequisite for FDA approval.¹³³ By February 2007, it showed that lorcaserin causes lethal breast, brain, skin and nerve-sheath tumors.¹³⁴ When Defendants reported these adverse results to the FDA,¹³⁵ the agency required Defendants "to warn humans participating in the lorcaserin clinical trials of the mammary and brain cancer risks that were observed in the Rat Study"¹³⁶ and to "provide bi-monthly updates to the FDA regarding the incidence of observed tumors in the Rat Study, including survival and tumor incidence."¹³⁷ As Defendant Lief later admitted, "Arena's bi-monthly updates to the FDA were highly unusual and not part of the normal process with the FDA."¹³⁸

By the beginning of the Class Period, reasonable people in Defendants' position would have disclosed the results of the Rat Study and the FDA's expressed concern about the safety of lorcaserin. Reckless people would have said nothing, allowing investors to draw their own ill-informed conclusions. Defendants' conduct was more than reckless. *For over two years*, Defendants engaged in an affirmative pattern of false and misleading statements intended to suppress the negative results

¹³³ ER-120–22 (SAC ¶¶ 62, 63, 69).

¹³⁴ ER-111 (SAC ¶ 12); ER-122 (SAC ¶ 72).

¹³⁵ ER-112 (SAC ¶ 15); ER-123 (SAC ¶ 75).

¹³⁶ ER-117 (SAC ¶ 41) (citing letters dated June 28, 2007 and August 29, 2007).

¹³⁷ ER-117 (SAC ¶ 47).

¹³⁸ ER-118 (SAC ¶ 48).

of the Rat Study and the serious concerns repeatedly expressed by the FDA. The most likely explanation: Defendants intended to prevent investors from performing their own assessment of whether and when lorcaserin might be approved.¹³⁹ Defendants succeeded, and investors lost.

Plaintiff's theory, that Defendants perpetrated an ordinary fraud by concealing material information about the likelihood of regulatory approval, is hardly novel. This Court recognized and approved that precise theory of relief in *Warshaw v. Xoma Corp.*¹⁴⁰ In *Warshaw*, this Court explained that the complaint sufficiently alleged that the defendant pharmaceutical company's representations about its new drug "were designed to prevent shareholder flight in the aftermath of a damaging report regarding the possible hazards of [the new drug] and the unlikelihood of FDA approval."¹⁴¹ District courts followed suit in *In re Connetics Corp. Securities Litigation*,¹⁴² *In re CV Therapeutics, Inc.*,¹⁴³ and *In re Immune Response Securities Litigation*.¹⁴⁴

¹³⁹ See *infra* pages 42–55 (Argument Section II).

¹⁴⁰ 74 F.3d 955, 959–60 (9th Cir. 1996).

¹⁴¹ *Id.*

¹⁴² No. C 07-02940 SI, 2008 WL 3842938 (N.D. Cal. Aug. 14, 2008).

¹⁴³ No. C 03-03709 SI, 2004 WL 1753241 (N.D. Cal. Aug. 5, 2004).

¹⁴⁴ 375 F. Supp. 2d 983. See also *In re Sepracor, Inc. Sec. Litig.*, 308 F. Supp. 2d 20, 31 (D. Mass. 2004) (denying motion to dismiss where defendants failed to disclose adverse results of animal study in face of FDA concerns known to defendants).

In *Connetics*, for example, the defendant pharmaceutical company and its officers touted the progress of their new acne medication Velac but “failed to inform investors about the results of a pre-clinical test performed on transgenic mice [(“Mouse Study”) that] demonstrated that Velac caused ‘cancerous skin tumors’ in 89 out of approximately 160 mice.”¹⁴⁵ Plaintiffs alleged that defendants’ concealment of the negative results of the Mouse Study and the FDA’s concerns about them for over a year misled the market about the prospects for FDA approval, and the district court denied defendants’ motion to dismiss.¹⁴⁶

Similarly, in *CV Therapeutics*, the district court denied a motion to dismiss allegations that a pharmaceutical company and its officers fraudulently failed to disclose their communications with the FDA about the agency’s safety concerns with their new anti-anginal drug Raxena.¹⁴⁷ The court concluded that the complaint stated a claim for relief because it contained “many particularized allegations of defendants’ representations of [new anti-anginal drug] Raxena’s safety and efficacy, despite their knowledge of the FDA’s specific and serious reservations.”¹⁴⁸

And in *Immune Response*, the district court denied a motion to dismiss allegations that the defendant pharmaceutical company and its executives misled

¹⁴⁵ 2008 WL 3842938, at *1.

¹⁴⁶ *Id.* at *7–8.

¹⁴⁷ 2004 WL 1753241, at *9.

¹⁴⁸ *Id.*

investors about the prospects for FDA approval of their HIV drug by withholding and misrepresenting the negative results of certain clinical studies.¹⁴⁹ The court carefully elucidated the basis for liability:

All investing is based to some degree on investors' perceptions about the future. Plaintiffs presumably bought IRC securities based on their perception of whether REMUNE would have a positive effect on treating HIV and/or be approved by the FDA. . . . Plaintiffs allege that Defendants' misstatements of fact formed a false basis for its investors' perceptions. . . . Where negative clinical study results are fully available to the market, investors can better weigh positive predictions [about FDA approval], and securities are more accurately valued. If, as Plaintiffs allege, Study 806 and its sub-study had shown that REMUNE had no positive effect on secondary markers, then such information would "have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available."¹⁵⁰

As explained below, the district court dismissed Plaintiff's complaint for failure to adequately allege scienter because it fundamentally misunderstood this well-established theory of securities fraud.

B. The District Court Mistakenly Viewed This Case as a Dispute Over Defendants' Subjective Beliefs About Lorcaserin's Safety.

The district court believed that Plaintiff was urging it to infer scienter solely from the fact that the Follow Up Tests did not support the Prolactin Hypothesis.¹⁵¹

¹⁴⁹ 375 F. Supp. 2d at 1023.

¹⁵⁰ *Id.* at 1021 (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 231–32 (1988)).

¹⁵¹ ER-3–5; ER-16 (footnote 9) (granting leave to amend Second Amended Complaint with instruction to limit it to "statements that support Plaintiff's theory that Defendants knew they had to and failed to substantiate their hypothesis that the tumors found in the Rat Study were due to a rat-specific mechanism").

It thus looked in the Second and Proposed Third Amended Complaints only for evidence that Defendants did not honestly or legitimately believe that lorcaserin was safe for humans based on the Follow Up Tests.¹⁵² The district court also took note of the FDA's eventual approval of lorcaserin as evidence that Defendants lacked scienter because they were right.¹⁵³

But Plaintiff's theory of fraud is not that Defendants intentionally misled the market about the objective safety of lorcaserin. Rather, Plaintiff's theory of fraud is that Defendants intentionally withheld information material to the market's assessment of whether and when the FDA would likely approve lorcaserin. That distinction is critical because a drug, regardless of its actual safety, cannot be sold until the FDA believes it is safe. Thus the FDA's *later* approval of lorcaserin, which the district court thought significant, is irrelevant.

The district court's reliance on *In re AstraZeneca, Inc. Securities Litigation*,¹⁵⁴ further illustrates its confusion. The district court cited *AstraZeneca* for the proposition that "a legitimate scientific disagreement alone does not give rise to a strong inference of scienter."¹⁵⁵ To be sure: in *AstraZeneca*, plaintiffs alleged that defendants' drug "Exanta was not as safe or as effective as defendants' public

¹⁵² ER-6–7.

¹⁵³ ER-14–15.

¹⁵⁴ 559 F. Supp. 2d 453 (S.D.N.Y. 2008).

¹⁵⁵ ER-6.

statements made it out to be”¹⁵⁶ But, in that case, defendants had specifically disclosed the existence of the negative side effects that ultimately led to FDA rejection.¹⁵⁷ The district court in *AstraZeneca* concluded that defendants’ characterization of these effects as manageable was not made with scienter simply because the FDA disagreed.¹⁵⁸

Here, Defendants withheld *the very existence of their scientific disagreement with the FDA*, as well as the data that gave rise to it. As the *Immune Response* court explained, Defendants committed securities fraud by intentionally depriving investors of the opportunity to evaluate for themselves the significance of that long-running dispute.¹⁵⁹

II. Plaintiff Alleged Facts Giving Rise to a Strong Inference of Scienter in the Second and Proposed Third Amended Complaints.

The district court erred in holding that the Second and Proposed Third Amended Complaints fail to adequately allege scienter under the heightened pleading requirement of the PSLRA. In *Tellabs*, the Supreme Court explained the relevant inquiry: “The reviewing court must ask: When the allegations are accepted

¹⁵⁶ 559 F. Supp. 2d at 457.

¹⁵⁷ *See id.* at 458.

¹⁵⁸ *Id.* at 470.

¹⁵⁹ Indeed, the district court in *Immune Response* considered and rejected defendants’ argument that they could not be held liable for failing to disclose “data that was not considered fatal by various scientists, or was otherwise subject to scientific dispute” 375 F. Supp. 2d at 1021.

as true and taken collectively, would a reasonable person deem the inference of scienter at least as strong as any opposing inference?”¹⁶⁰ Where the inference of scienter is equally likely as any innocent explanation, the tie goes to the plaintiff.¹⁶¹

As this Court has explained, “the ultimate question [of scienter] is whether the defendant knew his or her statements were false, or was consciously reckless as to their truth or falsity.”¹⁶² Conscious recklessness is:

A highly unreasonable omission, involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it.¹⁶³

Here, the district court found “that Defendants knew the content and Arena’s analysis of [the Initial Results and the results of the Follow Up Tests], as well as communications with the FDA concerning the Rat Study.”¹⁶⁴ To be clear: there is no question about knowledge of the withheld information, the usual focus of the scienter inquiry. Indeed, under this Court’s interpretation of the PSLRA, the district

¹⁶⁰ 551 U.S. at 326.

¹⁶¹ *Sloman v. Presstek, Inc.*, No. 06 Civ. 377, 2007 WL 2740047, at *7 (D.N.H. Sept. 18, 2007).

¹⁶² *Gebhart v. SEC*, 595 F.3d 1034, 1042 (9th Cir. 2010).

¹⁶³ *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 976 (9th Cir. 1999). *See also In re Oracle Corp. Sec. Litig.*, 627 F.3d 376, 390 (9th Cir. 2010) (“[A]n actor is [deliberately] reckless if he had reasonable grounds to believe material facts existed that were misstated or omitted, but nonetheless failed to obtain and disclose such facts although he could have done so without extraordinary effort.”).

¹⁶⁴ ER-3.

court's finding that Defendants had actual knowledge of material information that made their statements false should have ended the scienter inquiry.¹⁶⁵

Even if Plaintiff must plead *more* than knowledge, materiality, and falsity to satisfy the PSLRA, however, he easily satisfies that additional burden. Only by failing to read the Second Amended Complaint “holistically in the light most favorable to the plaintiffs” did the district court conclude otherwise.¹⁶⁶ The district court ignored the obvious materiality of Defendants’ misstatements and omissions as well as overwhelming circumstantial evidence that Defendants’ conduct at least constituted “an extreme departure from the standards of ordinary care.”¹⁶⁷

A. Defendants’ Multi-Year Pattern of Selective Disclosure Gives Rise to a Strong Inference of Scienter.

Defendants’ pattern of disclosing the favorable results of BLOOM and BLOSSOM and linking them to the prospects for regulatory approval while failing to disclose the negative results of the Rat Study or the FDA’s concerns about their relevance to humans strongly suggests scienter. An inference of scienter arises where defendants “affirmatively create[] an ‘impression of a state of affairs that

¹⁶⁵ See, e.g., *South Ferry*, 542 F.3d at 784–86 (“Allegations [regarding management’s role in a company] may independently satisfy the PSLRA where they are particular and suggest that defendants had actual access to the disputed information, as in *Daou* and *Oracle*.”).

¹⁶⁶ *Tellabs*, 551 U.S. at 326.

¹⁶⁷ *Silicon Graphics*, 183 F.3d at 976.

differ[s] in a material way from the one that actually exist[s].”¹⁶⁸ Here, Defendants created a false impression through their “incomplete [disclosures], thus portraying the results of the [lorcaserin] trial[s] in an unduly optimistic light.”¹⁶⁹

Plaintiff does not contend that Defendants were under a generalized duty to disclose the results of the Rat Study, or that their failure to do so is evidence *per se* of scienter. Rather, Plaintiff alleges that having chosen to speak about the status of the lorcaserin studies, and having linked those comments to regulatory approval, Defendants assumed a duty not to mislead.¹⁷⁰ Defendants’ consistency in disclosing the good and withholding the bad demonstrates that they not only violated this duty, but that they did so on purpose to mislead investors.

As discussed in detail above, Arena conducted the BLOOM and BLOSSOM late-stage clinical trials at the same time as the Rat Study.¹⁷¹ While Defendants quickly and specifically announced all results favorable to the prospects for

¹⁶⁸ *Reese v. Malone*, 747 F.3d 557, 570 (9th Cir. 2014) (quoting *Berson*, 527 F.3d at 985).

¹⁶⁹ *Immune Response*, 375 F. Supp. 2d at 1022 (finding strong inference of scienter based on incomplete disclosure of clinical study results).

¹⁷⁰ See, e.g., *Berson*, 527 F.3d at 987 (“Once defendants chose to tout the company’s backlog, they were bound to do so in a manner that wouldn’t mislead investors as to what backlog consisted of.”); *In re Elan Corp. Sec. Litig.*, 553 F. Supp. 2d 187, 208 (S.D.N.Y. 2008) (“By choosing to speak about the safety of [their drug], Defendants assumed a duty to disclose material information regarding adverse events.”) (cited in *Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167, 1181 (9th Cir. 2009)).

¹⁷¹ ER-121 (SAC ¶ 64).

regulatory approval, they withheld all information tending to presage a delay or denial of the Lorcaserin Application.

To take just one example, on the May 11, 2009 conference call (the first call for investors after the BLOOM results had been compiled),¹⁷² Defendant Lief represented, “Based on results from the BLOOM trial . . . *we believe that lorcaserin is approvable for weight management*, both here in the US, and eventually in Europe as well.”¹⁷³ Defendant Lief went on to describe BLOOM’s results (and the significance of those results) in detail,¹⁷⁴ and over the next year, Defendants released four additional press releases touting BLOOM’s success.¹⁷⁵ Not once during this period did Defendants mention the negative results of the Rat Study or the FDA’s expressed concerns—even though Defendants had submitted the final Rat Study report at the FDA’s request earlier that year.

In sum, by choosing to speak about the results of the late-stage testing and the likelihood that the FDA would approve lorcaserin based on those results, “Defendants assumed a duty to disclose material information regarding adverse

¹⁷² ER-139 (SAC ¶ 144) (quoting ER-387–88) (March 12, 2009 call); ER-145 (SAC ¶ 166) (quoting ER-250) (May 11, 2009 call).

¹⁷³ ER-145 (SAC ¶ 166) (quoting ER-250) (May 11, 2009 call) (emphasis added).

¹⁷⁴ ER-145 (SAC ¶ 166) (quoting ER-250) (May 11, 2009 call).

¹⁷⁵ ER-146 (SAC ¶ 168); ER-148–49 (SAC ¶ 182) (quoting ER-253) (September 18, 2009 press release); ER-155 (SAC ¶ 209) (quoting ER-231) (December 22, 2009 press release); ER-155 (SAC ¶ 211) (quoting ER-288) (February 24, 2010 press release).

events.”¹⁷⁶ The facts strongly suggest that they knowingly violated that duty here. Yet the district court completely discounted Defendants’ positive statements about BLOOM and BLOSSOM, and even counseled Plaintiff to remove them from the Third Amended Complaint altogether.¹⁷⁷

B. Defendants’ Multi-Year Pattern of Material Misstatements Gives Rise to a Strong Inference of Scienter.

Defendants did not merely selectively disclose the good and withhold the bad; they affirmatively misrepresented the former and hid the latter. “One of the classic fact patterns giving rise to a strong inference of scienter is that defendants published statements when they knew facts or had access to information suggesting that their public statements were materially inaccurate.”¹⁷⁸ And as this Court has explained, under these circumstances “falsity and scienter are generally inferred from the same set of facts.”¹⁷⁹

As described in detail above, in the nineteen months between the conclusion of the Rat Study and the rejection of the Lorcaserin Application, Defendants

¹⁷⁶ *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1324 (2011); *Elan Corp.*, 553 F. Supp. 2d at 208 (cited in *Siracusano*, 585 F.3d at 1181).

¹⁷⁷ ER-19 (footnote 13).

¹⁷⁸ *Florida State Bd. of Admin. v. Green Tree Fin. Corp.*, 270 F.3d 646, 665 (8th Cir. 2001).

¹⁷⁹ *In re Read-Rite Corp.*, 335 F.3d 843, 845 (9th Cir. 2003); *see also Ronconi v. Larkin*, 253 F.3d 423, 429 (9th Cir. 2001); *Nursing Home Pension Fund, Local 144 v. Oracle Corp.* 380 F.3d 1226, 1230 (9th Cir. 2004).

consistently represented to the public that the data on lorcaserin was uniformly positive.¹⁸⁰ For example, in March 2009, Defendants Lief and Shanahan each independently cited lorcaserin's animal studies as a *positive* factor favoring FDA approval. Defendant Lief offered that “*confidence* [in lorcaserin's FDA approval was] based on the Phase II data, the Phase I data, the preclinical studies that was done, *all the animal studies that have been completed . . .*,”¹⁸¹ and Defendant Shanahan claimed that “[a]nimal studies” provided “a lot of visibility on our safety associated with lorcaserin.”¹⁸² Defendant Anderson later went so far as to say that “we have favorable results on *everything* that we've compiled so far.”¹⁸³

Like Defendants' public statements, the language in the SEC filings was calculated to create an unduly favorable investor impression of the prospects for quick approval of the Lorcaserin Application. For example, Arena's first 10-Q after completing the Rat Study contained some generalized warnings about the possibility that a drug in development may not be approved,¹⁸⁴ but also specifically represented:

¹⁸⁰ See *supra* pages 12–18 (Statement of the Case Section II.C).

¹⁸¹ ER-144 (SAC ¶ 160) (quoting ER-315) (March 31, 2009 press release).

¹⁸² ER-140 (SAC ¶ 146).

¹⁸³ ER-151 (SAC ¶ 190) (quoting ER-263) (September 18, 2009 call) (emphasis added).

¹⁸⁴ The district court held in a footnote that these boilerplate disclosures “sufficiently warned investors of potential risk regarding scientific data interpretation. . . .” ER-5 (footnote 3). But such generic disclosures are inadequate when a more specific risk has already materialized. As one district court vividly put it, “The doctrine of bespeaks caution provides no protection to someone who warns

“To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our drug candidates, except lorcaserin.”¹⁸⁵ That statement repeats in every 10-Q and 10-K until the FDA Advisory Committee voted to recommend not approving the Lorcaserin Application in September 2010.¹⁸⁶

In contrast, less than a month *after* the FDA rejected the Lorcaserin Application, Arena finally disclosed the longstanding material risks of FDA denial or delay:

We conducted long-term carcinogenicity preclinical studies of lorcaserin. The FDA identified [] lorcaserin issues related to such studies. We intend to provide in our response to [the FDA] data and other information to support our view related to such issues, *but the FDA may disagree with our view or impose conditions that could delay or preclude approval of our lorcaserin [Application]*.¹⁸⁷

Defendants knew how to accurately communicate the risk of regulatory delay or denial associated with the negative results from the Rat Study. They simply chose

his hiking companion to walk slowly because there might be a ditch ahead when he knows with near certainty that the Grand Canyon lies one foot away.” *In re Prudential Secs. Inc. P’ships Litig.*, 930 F. Supp. 68, 72 (S.D.N.Y. 1996). Here, Defendants knew that there were specific results of a required nonclinical study that concerned the FDA, but Defendants at best warned of a hypothetical risk.

¹⁸⁵ ER-140–41 (SAC ¶ 148) (quoting ER-205, 209) (Annual Fiscal Year 2008 Form 10-K).

¹⁸⁶ ER-209 (Annual Fiscal Year 2008 Form 10-K); ER-228 (Annual Fiscal Year 2009 Form 10-K); ER-359 (Third Quarter 2009 Form 10-Q); ER-410 (First Quarter 2009 Form 10-Q); ER-422 (Second Quarter 2009 Form 10-Q); ER-432 (Third Quarter 2009 Form 10-Q); ER-443 (First Quarter 2009 Form 10-Q); ER-458 (First Quarter 2010 Form 10-Q); ER-476 (Second Quarter 2010 Form 10-Q).

¹⁸⁷ ER-105 (November 9, 2009 press release) (emphasis added).

to withhold that information until after they had raised sufficient capital to remain in business throughout a more prolonged regulatory process.

In concluding that Defendants lacked scienter, the district court necessarily determined that the pre-September 2010 above statements *were not false*. For example, the order dismissing the First Amended Complaint stated that it was “more plausible that [Defendants] . . . reasonably believed the results [of the Rat Study] to be positive with regard to what the study was designed to test” whether lorcaserin causes cancer in humans—than that they recklessly disregarded the falsity of their statements.¹⁸⁸ The November 4 Order similarly concluded that Defendant Lief’s statement that “confidence is based on . . . all the animal studies that have been completed” was not reckless because he believed lorcaserin’s overall safety profile and potential to be “positive, favorable, or encouraging.”¹⁸⁹

That determination is both wrong and inappropriate at this stage of the proceedings. First, these statements were clearly false. Even if Defendants felt that the Follow Up Tests *mitigated* the highly unfavorable initial results of the Rat Study, no reasonable person would understand or describe the animal studies as “favorable” or inspiring “confidence.”¹⁹⁰ And even if Defendants reasonably believed lorcaserin

¹⁸⁸ ER-30.

¹⁸⁹ ER-14–15.

¹⁹⁰ In addition to those clearly false and misleading statements, Defendants made numerous other general statements about the lack of safety concerns for lorcaserin.

to be completely safe, that belief would not be *based on* “all the animal studies that have been completed.” More to the point, a motion to dismiss is not the appropriate vehicle for making a factual determination about falsity.¹⁹¹ “[O]nly if ‘reasonable minds’ could not disagree that the challenged statements were misleading should the district court dismiss under 12(b)(6).”¹⁹²

C. Defendants’ Actions Evidencing Their Doubts about Seamless FDA Approval Give Rise to a Strong Inference of Scienter.

Scienter may be pled and proven by reference to circumstantial evidence of a company’s activities.¹⁹³ In evaluating that evidence, the reviewing court considers “whether the total of plaintiff’s allegations, even though individually lacking, are sufficient to create a strong inference that defendants acted with deliberate or conscious recklessness.”¹⁹⁴ Any suspicious behavior may contribute to that inference. For example, “[u]nusual trading or trading at suspicious times or in suspicious amounts by corporate insiders has long been recognized as probative of

ER-142–43 (SAC ¶ 155) (quoting ER-309, 312) (March 30, 2009 call); ER-157 (SAC ¶ 219) (quoting ER-390, 392, 393) (March 12, 2010 call); ER-161–62 (SAC ¶ 240) (quoting ER-400) (August 3, 2010 call).

¹⁹¹ *Immune Response*, 375 F. Supp. 2d at 1021 (“At a later stage, the issue of the reasonableness of Defendants’ belief in their statements may be more appropriately raised. At this stage, however, it is simply not within the Court’s authority to make such determinations.”).

¹⁹² *Warshaw*, 74 F.3d at 959.

¹⁹³ See, e.g., *Connetics*, 2008 WL 3842938, at *3; *CV Therapeutics, Inc.*, 2004 WL 1753241, at *3.

¹⁹⁴ *Nursing Home*, 380 F.3d at 1230.

scienter.”¹⁹⁵ While evidence of a specific fraudulent motive is not required, it is often persuasive.¹⁹⁶

In January 2009 or shortly before, Arena completed the supplemental portion of the Rat Study designed to demonstrate to the FDA that lorcaserin’s carcinogenic mechanism does not affect humans.¹⁹⁷ Immediately following the conclusion of the Follow Up Tests, Arena reduced its expenses and rushed to procure additional capital. And before meeting with the FDA Advisory Committee, Arena retained a world-class pathologist to present and explain the results of the Follow Up Tests. In short, Arena began to behave like a company that had discovered that it might need more resources and more time to bring its only drug to market.

As described in detail above, Arena suspended all unnecessary purchases and laid off 31 percent of its workforce in early 2009—changes that Arena employees understood to be linked to uncertainty about the future of lorcaserin.¹⁹⁸ It reduced

¹⁹⁵ *Daou*, 411 F.3d at 1022 (quoting *Greebel v. FTP Software*, 194 F.3d 185, 197 (1st Cir. 1999)).

¹⁹⁶ *See Tellabs*, 551 U.S. at 325 (acknowledging motive as relevant consideration in scienter analysis); *Daou*, 411 F.3d at 1024 (considering personal motive as factor in totality of circumstances); *Reese*, 747 F.3d at 572 (executive’s motive supported compelling inference of scienter).

¹⁹⁷ The FDA was first apprised of the initial Rat Study’s worrisome results on May 31, 2007, and it directed Arena to provide bi-monthly status updates on the Follow Up Tests going forward. ER-112 (SAC ¶ 15). The FDA received at least ten total updates from Arena, so the last update was presumably January 2009. ER-124 (SAC ¶ 79). Arena submitted the final report on the Follow Up Tests to the FDA on February 3, 2009. ER-126 (SAC ¶ 93).

¹⁹⁸ *See supra* pages 18–19 (Statement of the Case Section II.D).

its total operating costs by \$5 million that year after multi-million dollar operating cost increases the two previous years. At the same time, Arena issued new stock to the public at a frantic pace, raising over \$150 million between April 2009 and June 2010, compared to under \$2 million issued in 2008. On July 6, 2009, Arena secured a \$100 million four-year loan with a balloon payment of \$40 million plus interest.

From Defendants' perspective, these measures would be necessary for the Company to remain solvent for two more years if the Lorcaserin Application was not approved in 2010. Arena's cash-raising efforts gave them an extra \$190 million of liquidity: \$150 million in new stock plus the \$40 million portion of the loan that came due in late 2013. That \$190 million amount is *precisely* what Arena might have forecasted needing to withstand a two-year delay in the approval of the Lorcaserin Application. In fact, from the fourth quarter of 2010 (when the Lorcaserin Application was rejected) through lorcaserin's eventual approval in 2012, Arena's operating expenses were slightly over \$190 million.¹⁹⁹

Taken as a whole, the circumstantial evidence supports a compelling inference that Defendants consciously misled the market about material information to ensure that Arena remained solvent pending eventual FDA approval of lorcaserin. This motive differs from the commonplace corporate interest in bolstering stock price

¹⁹⁹ See generally Arena's First, Second, and Third Quarter 2012 Form 10-Qs, and Annual Fiscal Year 2012 Form 10-K, available at <http://www.sec.gov/edgar.shtml>.

because Defendants took specific and uncharacteristic actions to further their specific goal of remaining solvent through 2012.²⁰⁰ Not only did they issue more than 75 times as much stock in a fourteen-month period from 2009 to 2010 as they issued in 2008, but they slashed operating expenses after years of multi-million dollar increases.

Although the district court purported to read the Second and Proposed Third Amended Complaints “holistically in the light most favorable to the plaintiffs,” it instead dismissed this circumstantial evidence altogether. The district court acknowledged that it found the confidential informant testimony unpersuasive, and it considered the remaining evidence irrelevant to Defendants’ state of mind with respect to the *safety* of lorcaserin.²⁰¹ The district court did not even mention Defendants’ retention of a consultant to review their drug, which itself, supports the “cogent and compelling” inference that Defendants elected not to disclose the results

²⁰⁰ In addition, many of Arena’s stock sales were suspiciously timed to coincide with Defendants’ misrepresentations. For example, Arena sold \$60 million in stock on August 6, 2010, just two days after Defendant Shanahan told investors that there would be no surprises at the September 2010 meeting with the FDA Advisory Committee. ER-120 (SAC ¶ 60). The sale was thus “calculated to maximize [the benefit to Arena] from undisclosed inside information.” *In re Apple Computer Sec. Litig.*, 886 F.2d 1109, 1117 (9th Cir. 1989).

²⁰¹ ER-15 (footnote 8).

of the Rat Study “not because [they] believed they were meaningless but because [they] understood their likely effect on the market.”²⁰²

III. The District Court’s Scier Holding Is Unworkable.

If this Court approves the district court’s application of the pleading requirement for scier in this case, then no securities class action lawsuit in the Ninth Circuit will survive a motion to dismiss absent “smoking gun” evidence.²⁰³ That is manifestly not what Congress intended in enacting the PSLRA, and it is contrary to Supreme Court precedent.

A. Plaintiff Has Assembled an Overwhelming Circumstantial Case of Fraud Without the Benefit of Formal Discovery.

In this case, Plaintiff alleged in painstaking detail that Defendants knowingly made specific representations and omissions that misled the market about the likelihood and timing of FDA approval of lorcasein. When investors learned of the information that Arena had misrepresented and withheld, the price of Arena stock fell 40 percent in one day. Plaintiff has further alleged circumstances suggesting that Defendants defrauded investors to further their project of funding Arena’s operations through eventual FDA approval.

It bears emphasis that although this litigation is now nearly four years old, it has yet to transcend the pleading stage. There is still no “evidence” before the Court,

²⁰² *Matrixx Initiatives*, 131 S. Ct. at 1324–25.

²⁰³ *Cf. Tellabs*, 551 U.S. at 324.

only factual allegations and inferences. Yet to decide the very preliminary question of whether Plaintiff has alleged sufficient facts *to warrant the discovery and introduction of evidence* in support of his claim,²⁰⁴ the district court has considered over 1100 pages of documentary material, considered over 375 pages of briefing on the merits, and conducted nearly 2 hours of oral argument. Plaintiff might well prevail in his action on the strength of the existing record alone—surely a sign that something is amiss.²⁰⁵

The persuasiveness of the record as it stands is especially remarkable because, as is usually true of this type of litigation, most of the relevant evidence remains in Defendants’ exclusive possession. Tellingly, Defendants attempted to introduce nine selected pages of the Lorcaserin Application for the district court’s consideration without producing the remaining pages to Plaintiff.²⁰⁶ Without access even to the Lorcaserin Application itself, Plaintiff has assembled an overwhelming circumstantial case of fraud.

²⁰⁴ See *Scheuer*, 416 U.S. at 236.

²⁰⁵ See, e.g., *In re Network Equip. Techs., Inc. Litig.*, 762 F.Supp. 1359, 1368 (N.D. Cal. 1991) (“Court[s] should not . . . generate an evidentiary record and then weigh evidence . . . to dismiss [a] complaint.”); *In re Northpoint Comms. Grp., Inc.*, 221 F. Supp. 2d 1090, 1095 (N.D. Cal. 2002) (consideration of exhibits encourages improper weighing of factual disputes); *Levenstein v. Salafsky*, 164 F.3d 345, 347 (7th Cir. 1998) (judicial notice at pleading stage a “narrow exception” and not license to eliminate distinction between summary judgment and motion to dismiss).

²⁰⁶ ER-4 (footnote 2).

B. If Plaintiff's Allegations Do Not Suffice Here, Then Sophisticated Fraudsters May Act With Impunity.

If Plaintiff's allegations here do not meet the scienter standard, then it is necessary for defrauded investors to produce direct evidence of what companies and their executives were actually thinking merely *to survive the pleading stage*.²⁰⁷ Of course, such evidence will hardly ever be available before formal discovery, especially in the overwhelming majority of cases in which the key actors are sophisticated. And if a company and its representatives do not act with "scienter" whenever the substance of their statements or omissions might reasonably be deemed scientific, technical, or otherwise open to "legitimate disagreement" about its significance, then they are exempt from the disclosure laws altogether.

In practice, the upshot of the district court's interpretation and application of the PSLRA scienter requirement would be to deprive most defrauded purchasers and sellers of securities of any private remedy whatsoever. That is not what Congress intended when it enacted the PSLRA to restore private securities litigation as "an indispensable tool with which defrauded investors can recover their losses without

²⁰⁷ In theory, there might be exception for the exceedingly rare case in which a misrepresentation admits of no conceivable non-fraudulent explanation. *See South Ferry*, 542 F.3d at 786 (citing *Berson*, 527 F.3d at 988). Of course, the Supreme Court in *Tellabs* made clear that to survive the pleading stage, the inference of scienter need not even be "the 'most plausible of competing inferences,'" but merely "at least as compelling as any opposing inference once could draw from the facts alleged." 551 U.S. at 324.

having to rely upon government action.”²⁰⁸ It is also expressly contrary to the Supreme Court’s admonition that the “strong inference” of scienter standard must be applied in a way that “preserv[es] investors’ ability to recover on meritorious claims”²⁰⁹ by “allow[ing] meritorious actions to go forward.”²¹⁰

CONCLUSION

The district court’s November 4 Order dismissing the Second Amended Complaint should be reversed. Alternatively, the district court’s March 20 Order denying Plaintiff’s motion for leave to amend should be reversed.

Dated: August 27, 2014

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²⁰⁸ H.R. REP. NO. 104-369, at 31.

²⁰⁹ *Tellabs*, 551 U.S. at 322.

²¹⁰ *Id.* at 324.

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STATEMENT OF RELATED CASES

There are no known related cases pending in this Court.

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(C), I certify that:

1. The brief complies with the length limits set forth at Fed. R. App. P. 32(a)(7)(B) because it has 14,000 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. The brief's type size and type face comply with Fed. R. App. P. 32(a)(5) and (6) because the brief is proportionately spaced using 14-point Times New Roman type.

Dated: August 27, 2014

/s/ Peter K. Stris
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CERTIFICATE OF SERVICE

I hereby certify that, on August 27, 2014, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system. Participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system.

I further certify that some of the participants in the case are not registered CM/ECF users. Upon acceptance by the Clerk of the Court of the electronically filed document, one copy of the foregoing will be served, via U.S. Mail, postage prepaid on:

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Dated: August 27, 2014

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No. 14-55633

**UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT**

TODD SCHUENEMAN, on behalf of himself
and all others similarly situated,

Plaintiff-Appellant,

v.

ARENA PHARMACEUTICALS, INC., et al.,

Defendants-Appellees.

On Appeal from the United States District Court
for the Southern District of California
Hon. Cathy Ann Bencivengo
No. 3:10-cv-01959-CAB-BLM

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VOLUME 1 OF 3
(PAGES 1-31)**

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**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA**

Todd Schueneman,

Plaintiff,

vs.

Arena Pharmaceuticals, Inc. et al.,

Defendants.

CASE NO. 10cv01959-CAB (BLM)

ORDER DENYING LEAD
PLAINTIFF'S MOTION TO AMEND
SECOND CONSOLIDATED
AMENDED CLASS ACTION
COMPLAINT

[Doc. No. 73]

Presently before the Court is Lead Plaintiff's Motion to Amend Second Consolidated Amended Complaint. On November 4, 2013, the Court granted Lead Plaintiff leave to file the instant motion to amend to determine whether a third amended complaint would be futile on the issue of scienter. As such, the briefing focuses on whether Lead Plaintiff could sufficiently allege Defendants' contemporaneous knowledge of or deliberate disregard for facts that seriously undermined their statements relating to lorcaserin's safety or the sufficiency of the data for its New Drug Application ("NDA"). The Court concludes that because Lead Plaintiff's proposed complaint fails to sufficiently plead scienter, amendment would be futile. The motion to amend is therefore DENIED.

FACTUAL BACKGROUND

The Court dispenses with a recitation of the facts as the factual background for this case is set forth in the Court's prior orders.

STANDARD OF REVIEW

Although parties are generally allowed to amend pleadings “when justice so requires,” Fed. R. Civ. P. 15(a)(2), denial is appropriate “where the amended complaint would also be subject to dismissal.” *Saul v. United States*, 928 F.2d 829, 843 (9th Cir. 1991). Futility alone can justify the denial of a motion to amend. *See Eminence Capital, LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1052 (9th Cir. 2003); *DCD Programs, LTD. v. Leighton*, 833 F.2d 183, 186 (9th Cir. 1987) (“Futile amendments should not be permitted.”) (citations omitted).

ANALYSIS

The pleading requirements for scienter under Section 10(b) of the Exchange Act are set forth in 15 U.S.C. § 78u-4(b)(2) as follows:

(2) Required state of mind

(A) In general

... in any private action arising under this chapter in which the plaintiff may recover money damages only on proof that the defendant acted with a particular state of mind, the complaint shall, with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a **strong inference** that the defendant acted with the required state of mind.

15 U.S.C. § 78u-4(b)(2) (emphasis added). In the Ninth Circuit, the required state of mind is that “the plaintiffs must show that defendants engaged in ‘knowing’ or ‘intentional’ conduct.” *South Ferry LP, No. 2 v. Killinger*, 542 F.3d 776, 782 (9th Cir. 2008) (quoting *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 975 (9th Cir. 1999)). “We have held that reckless conduct can also meet this standard ‘to the extent that it reflects some degree of intentional or conscious misconduct,’ or what we have called ‘deliberate recklessness.’” *Id.* “The absence of a motive allegation, though relevant, is not dispositive.” *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1324 (2011). Finally, the parties agree that to show scienter, Lead Plaintiff must demonstrate an “extreme departure” from standards of ordinary care.

In this action, the hurdle to overcome for Lead Plaintiff’s proposed complaint

1 was to show that Defendants knew or were deliberately reckless in making certain
2 statements about Arena's drug lorcaserin because the statements were seriously
3 undermined by scientific data concerning Arena's Rat Study. As discussed in the
4 Court's November 4, 2013 order, the Court infers that Defendants knew the content
5 and Arena's analysis of this data, as well as communications with the FDA
6 concerning the Rat Study. [See Doc. No. 71 at 5 (discussing core operations
7 inference).] However, as previously explained by the Court, Lead Plaintiff needed
8 to show more for the Court to infer that Defendants' statements were seriously
9 undermined by this data concerning the Rat Study. Importantly, Lead Plaintiff
10 needed to show that this case is about more than a difference of scientific opinion
11 between Defendants and the FDA on the relevant data.

12 Lead Plaintiff contends that this action is not about a legitimate difference of
13 scientific opinion. Rather, according to Plaintiff, Defendants knew throughout the
14 class period that Arena had not yet obtained all the required favorable safety data
15 for the FDA to approve Arena's NDA.¹ Defendants allegedly knew that lorcaserin's
16 Rat Study results included high incidences of tumors. Defendants also knew that, as
17 a result, Arena would need to show the tumor results were irrelevant to humans to
18 achieve the FDA's approval of Arena's NDA. To make this showing, the FDA
19 required Defendants to provide study data from mechanistic studies that would
20 substantiate Arena's hypothesis that the high incidences of tumors were due to a rat-
21 specific mechanism involving prolactin. This hypothesis is referred to by Lead
22 Plaintiff and herein as the Prolactin Hypothesis.

23 Between July 2007 and December 2008, Defendants conducted six
24 mechanistic studies to support Arena's Prolactin Hypothesis. Arena designed these
25 studies to show that lorcaserin increased prolactin and caused tumors in rats, a
26 mechanism that arguably was not relevant to humans. Arena submitted the data

27
28 ¹ The class period set forth in the proposed complaint is May 11, 2009 through
January 27, 2011.

1 from the mechanistic studies to the FDA in February 2009. [Doc. No. 73-2,
2 proposed TAC ¶¶42-44, 65.] The data did not show a sufficient increase in
3 prolactin for the FDA to timely approve the NDA. According to the FDA, in
4 contrast with study data on other drugs, like haloperidol, lorcaserin did not robustly
5 increase prolactin in all circumstances. Thus, Lead Plaintiff's central theory is that
6 a strong inference of scienter arises from Defendants' contemporaneous knowledge
7 of or deliberate disregard for the data available during the class period that showed
8 Arena's mechanistic studies failed to support the Prolactin Hypothesis.

9 This central theory is based on Lead Plaintiff's reading of FDA-generated
10 documents in the record. The parties dispute whether Plaintiff pleads a reasonable
11 interpretation of these documents. Defendants contend that Lead Plaintiff
12 mistakenly bases his proposed complaint on reported results from a different study
13 (the exploratory arm of the Rat Study, referred to as the TK Arm) and that those
14 results do not reflect the mechanistic studies' results. Lead Plaintiff disputes this
15 contention. Assuming without deciding that the documents describe the relevant
16 mechanistic study data, the Court concludes Plaintiff fails to sufficiently plead a
17 strong inference of scienter.

18 Read holistically in the light most favorable to Plaintiff, the proposed
19 complaint and the documents incorporated therein create the more plausible
20 inference that Defendants had a legitimate scientific opinion that their data
21 supported both the Prolactin Hypothesis and Arena's NDA when making statements
22 about lorcaserin during the class period.² From the facts pled, Defendants may have
23 known that there was a theoretical risk that the FDA would disagree because
24 lorcaserin did not cause a "sustained and robust" increase in prolactin in the
25
26

27 ² The Court does not consider the 9 pages of the NDA, as the NDA is not publicly
28 available and Defendants have not produced any of the other pages of the NDA to Lead Plaintiff.

1 mechanistic studies conducted (like other relevant drugs studied had).³ However,
2 there are no facts before the Court suggesting Defendants knew they had to show
3 that lorcaserin caused a sustained and robust increase in prolactin to obtain FDA
4 approval.

5 In addition, there are no facts pled that suggesting that the FDA commented
6 about the mechanistic study data or results prior to its Advisory Committee's
7 September 2010 public meeting, which was held to consider whether to recommend
8 lorcaserin's approval to the FDA. There are also no facts pled showing Defendants
9 presented the FDA with an unreasonable scientific interpretation of the mechanistic
10 studies. There are also no facts pled suggesting Defendants must have believed the
11 mechanistic studies failed to support the Prolactin Hypothesis. In sum, the
12 proposed complaint and the documents incorporated therein fail to give rise to a
13 strong inference that the scientific data seriously undermined Defendants'
14 statements such that it was an "extreme departure" from standards of ordinary care
15 for Defendants to make positive statements about lorcaserin's safety and NDA,
16 including Christy Anderson's statement on September 18, 2009 that "[w]e have
17 favorable results on everything we've compiled so far." [TAC ¶109.]

18 Distinguishing this action from the cases argued by Lead Plaintiff, there are
19 no facts before the Court that the FDA or anyone else expressed any concern to
20 Defendants about the design or results of the prolactin mechanistic studies prior to
21 their relevant statements. There is nothing in the record showing Defendants were
22 on notice that the FDA would opine that the mechanistic studies failed to
23 substantiate the Prolactin Hypothesis. And again, contrary to Lead Plaintiff's
24 assertion otherwise, the facts do not give rise to an inference that Defendants should
25

26 ³ Under the facts of this case, Defendants sufficiently warned investors of
27 potential risk regarding scientific data interpretation by providing specific risk
28 warnings to investors, including warnings that the FDA may not view favorably
Arena's preclinical studies and may determine that the data is not enough to support
approval by the FDA.

1 have understood that absent data showing lorcaserin causes a “sustained and robust”
 2 increase in prolactin, the NDA would be considered incomplete or that its approval
 3 would delayed or denied. The record gives rise to the more plausible inference that
 4 Defendants believed that Arena’s scientific opinion was legitimate – the
 5 mechanistic studies contained favorable data that supported the Prolactin
 6 Hypothesis. Even the FDA described the relevant mechanistic studies’ results as
 7 **supporting** Defendants’ hypothesis, despite the fact that the FDA opined that it was
 8 “weak support for the hypothesis.” [See, e.g., Doc. No. 44-5 at 63.]

9 With respect to the proposed complaint’s remaining scienter allegations –
 10 e.g., confidential witnesses, stock sales, Arena’s capital needs and budget cuts, and
 11 an FDA inspection – these are retreads of allegations and arguments the Court
 12 already ruled do not meaningfully contribute to the Court’s scienter analysis. The
 13 new allegations of the proposed complaint do not change this conclusion.

14 Ultimately, the more plausible inference is that Defendants had a legitimate
 15 and unanticipated scientific disagreement with the FDA. As the district court
 16 observed in *AstraZeneca*, a legitimate scientific disagreement alone does not give
 17 rise to a strong inference of scienter:

18 As of the time when the FDA Advisory Committee met . . .
 19 AstraZeneca had its side of the case and the FDA staff had its side. The
 20 FDA staff view prevailed before the Advisory Committee. This does
 21 not mean that AstraZeneca was not conscientious in advocating [its]
 drug . . . before the FDA, nor does it mean that the information issued
 publicly over the course of more than a year was dishonest or
 recklessly disseminated.

22 *In re AstraZeneca Sec. Litig.*, 559 F. Supp. 2d 453, 471 (S.D.N.Y. 2008). *See also*
 23 *DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212, 1225 (S.D. Cal. 2001) (while
 24 plaintiffs “may have established a legitimate difference in opinion as to the proper
 25 statistical analysis, they have hardly stated a securities fraud claim”).

26 In conclusion, the Court has determined that amendment of Lead Plaintiff’s
 27 complaint is futile as it does not give rise to a strong inference of scienter. Plaintiff
 28 has not come forward with alleged facts that give rise to an inference that

1 Defendants made statements knowing or turning a blind-eye to facts showing the
2 NDA for lorcaserin lacked, or that the FDA would reject, the scientific data that was
3 specifically requested by the FDA. The more cogent and compelling inference is
4 that Defendants had a legitimate scientific reason to believe that the final Rat Study
5 data, including the mechanistic studies' data, was sufficient to address the FDA's
6 safety concerns.

7 Lead Plaintiff's claim under Section 20(a) of the Exchange Act requires a
8 primary violation of Section 10(b), and must show that each defendant "directly or
9 indirectly" controlled the violator. *Paracor Fin., Inc. v. Gen. Elec. Capital Corp.*,
10 96 F.3d 1151, 1161 (9th Cir. 1996). As the proposed third amended complaint fails
11 to plead a strong inference of scienter for purposes of establishing a primary
12 violation of Section 10(b), the Section 20(a) claim also fails. *See Lipton v.*
13 *Pathogenesis Corp.*, 284 F.3d 1027, 1035 (9th Cir. 2002).

14 CONCLUSION

15 The Court concludes that amendment of the complaint in this action would be
16 futile as the allegations of the proposed third amended complaint fail to give rise to
17 a strong inference of scienter. The motion to amend [Doc. No. 73] is therefore
18 DENIED. The case is dismissed with prejudice.

19
20 DATED: March 20, 2014

21
22 
23 **CATHY ANN BENCIVENGO**
24 United States District Judge
25
26
27
28

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA**

Todd Schueneman,

Plaintiff,

vs.

Arena Pharmaceuticals, Inc. et al.,

Defendants.

CASE NO. 10cv01959-CAB (BLM)

ORDER GRANTING MOTION TO
DISMISS WITHOUT PREJUDICE and
DENYING MOTION TO STRIKE
[Doc. Nos. 60, 62]

Defendants’ motion to dismiss the Second Amended Complaint (“SAC”) challenges whether Plaintiff sufficiently pleads a material misrepresentation and scienter. The Court held oral argument on Friday, October 25, 2013, and Defendants focused their argument on the reasons they contend the SAC fails to meet the Ninth Circuit’s pleading requirements for scienter. For the reasons stated on October 25, 2013 and below, the Court agrees. Under the unique facts of this case, the SAC fails to raise a strong inference of scienter.

PARTIAL FACTUAL BACKGROUND

The facts set forth herein are taken from the SAC or documents incorporated therein, and are accepted as true for purposes of this procedural juncture only. The SAC supplements the allegations of the Consolidated Amended Class Action Complaint already outlined by this Court’s prior order, [Doc. No. 56]. Accordingly, this order does not fully recite the facts before the Court.

Plaintiff alleges that Arena Pharmaceuticals, Inc. (“Arena” or the “Company”) and its most senior executives violated Section 10(b) and 20(a) of the Securities Exchange Act of 1934 (“Exchange Act”) and Rule 10b-5 promulgated thereunder by making materially false statements and/or omitting to disclose material facts concerning the safety and the completeness of the data needed for FDA approval of Arena’s weight loss drug, lorcaserin – Arena’s most important developmental drug.¹

The Rat Study of lorcaserin at issue in this case was a key, long-term carcinogenicity study on rats designed to approximate a lifetime of human use, and to assess risk to humans. [¶6; *see also* ¶69.]² By February 2007, the interim results of the ongoing Rat Study indicated that lorcaserin caused mammary, brain, skin and nerve-sheath tumors, including lethal, malignant mammary and brain tumors. [¶12; Doc. No. 61-5 at 8, Ex. D.] Starting in September 2007, the FDA told Arena its concern that the Rat data reflected potential effects in humans and that Arena needed to dispel this concern with data on animals and humans exposed to lorcaserin. [Doc. No. 61-5 at 7, Ex. D.]³

The FDA and Arena representatives, including defendants Shanahan, Anderson and Behan, met in April 2008 to discuss, *inter alia*, the causes of mammary tumors in rats and the FDA’s concern about the tumors’ significance to humans. During this meeting, the FDA approved Arena’s written warning to humans in the clinical trials and told Arena that animal mechanistic studies and continued clinical study of humans exposed to lorcaserin could dispel its concern about the Rat data. At that time, Arena

¹ The “Defendants” are Arena Pharmaceuticals, Inc. (“Arena” or the “Company”); Jack Lief (“Lief”), Arena’s President, CEO and Chairman; Robert E. Hoffman (“Hoffman”), Arena’s CFO; Dominic P. Behan (“Behan”), Arena’s Senior Vice President and Chief Scientific Officer; William R. Shanahan, Jr. (“Shanahan”), Arena’s Senior Vice President and Chief Medical Officer; and Christy Anderson (“Anderson”), Arena’s Vice President of Clinical Development.

² “¶_” refers to paragraphs in the SAC, Doc. No. 59.

³ Page references to documents filed on the docket of this case refer to the ECF-generated page numbers.

1 representatives hypothesized that the tumors were attributable to a rodent-specific
2 mechanism. [Doc. No. 61-5 at 8.]

3 The FDA allowed Arena to continue the ongoing phase 3 clinical trials on
4 humans despite the tumor data because 1) the Rat Study data was incomplete, and thus,
5 “the interim tumor incidence data would change (e.g., might be less worrisome) as full
6 histopathology assessments became available after completion of the study”; 2) the
7 “drug exposure in rats was nearly twice as high as predicted, which increased the safety
8 margin to clinical exposure”; 3) “prolactin was a reasonable explanation of mode of
9 action” based on “preliminary data,” which would mean that the mammary tumors were
10 due to a “rodent-specific mechanism”; 4) “there were no mammary tumors in mice”
11 studied; 5) “only with continued clinical study was it possible to assess whether
12 long-term dosing with lorcaserin increased serum prolactin levels in humans”; 6) “only
13 with continuation of clinical dosing would we [the FDA] obtain an accurate assessment
14 of lorcaserin’s weight-loss efficacy and safety in diabetics”; and 7) “given that
15 lorcaserin is non-genotoxic, we [the FDA] believed that cancer risk was low under the
16 conditions of use in the ongoing clinical trials (not the case with chronic or indefinite
17 use).” [Doc. Nos. 61-4 at 7, 14, 20, Ex. C; 61-5 at 5, 7-8, Ex. D.]

18 To support the hypothesis that the mammary tumors were due to a “rodent-
19 specific mechanism”, the FDA 1) “asked for mechanistic studies exploring the role of
20 prolactin”; 2) “requested a draft report of the rat and mouse carcinogenicity studies as
21 soon as possible”; and 3) “requested changes to the clinical protocol to include analysis
22 of human serum prolactin.” [*Id.*; ¶88.] Further, the FDA requested from the Company
23 that the “updated informed consent forms [for the clinical trial] included the nonclinical
24 breast and brain cancer findings.” [Doc. No. 61-5 at 8, Ex. D.] In addition, “the FDA
25 directed Defendants to prepare bi-monthly updates on the Rat Study’s results as data
26 became available for both mammary and brain tumors.” [¶¶15-16, 19, 23, 25, 77-78,
27 83, 88.]

28 The bimonthly updates continued until the Rat Study was completed and draft

report of the Rat Study was submitted to the FDA on February 3, 2009. [Doc. No. 61-4 at 14, Ex. C.] “The Rat Study found that breast tumors developed at all doses, and that lorcaseerin caused brain tumors as well as many other malignant tumors.” [¶¶28, 101.] “[T]he final Rat Study data . . . was further revised from the data that Defendants reported to the FDA in April 2008 to show an increase in benign tumors and a decrease in malignant tumors.” [¶100.] The data Defendants submitted to the FDA failed to sufficiently demonstrate that the results of the Rat Study were irrelevant to humans. [¶101.]

STANDARD OF REVIEW

The pleading requirements for scienter under Section 10(b) of the Exchange Act are set forth in 15 U.S.C. § 78u-4(b)(2) is as follows:

(2) Required state of mind

(A) In general

. . . in any private action arising under this chapter in which the plaintiff may recover money damages only on proof that the defendant acted with a particular state of mind, the complaint shall, with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a **strong inference** that the defendant acted with the required state of mind.

15 U.S.C. § 78u-4(b)(2) (emphasis added). In the Ninth Circuit, the required state of mind is that “the plaintiffs must show that defendants engaged in ‘knowing’ or ‘intentional’ conduct.” *South Ferry LP, No. 2 v. Killinger*, 542 F.3d 776, 782 (9th Cir. 2008) (quoting *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 975 (9th Cir. 1999)). “We have held that reckless conduct can also meet this standard ‘to the extent that it reflects some degree of intentional or conscious misconduct,’ or what we have called ‘deliberate recklessness.’” *Id.* “The absence of a motive allegation, though relevant, is not dispositive.” *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1324 (2011).

In determining whether Plaintiffs have adequately pled scienter on a motion to dismiss, the Court must 1) accept all factual allegations as true, 2) consider the

complaint and “other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions” to determine “whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard,” and 3) take into account plausible opposing inferences. *Tellabs*, 551 U.S. at 322-23.

ANALYSIS

Plaintiff argues that Defendants, as members of the Lorcaserin Team,⁴ made statements that the results of animal testing were positive despite the fact that they “did not reasonably believe that the results of the Rat Study posed no threat to human use.” [See Doc. No. 61 at 1.] At oral argument, Plaintiff focused on Defendants’ failure to disclose that they had failed to dispel a material risk that had come to fruition – the FDA’s concern that the rats in the Rat Study experienced a drug-related increase in tumors that could be relevant to humans using lorcaserin.

The allegations of the SAC give rise to a core operations inference of knowledge about the lorcaserin Rat Study for defendants Arena, Lief, Behan, Shanahan, and Anderson.⁵ Specifically, the SAC provides “additional detailed allegations about the defendants’ actual exposure to information” that gives rise to the inference that these defendants knew about the Rat Study data and Arena’s communications with the FDA about it. *See South Ferry LP*, #2, 542 F.3d at 784-85.

A. March 12, 2009 Statement

Having reviewed the alleged false and materially misleading statements, the Court begins its analysis of Defendants’ alleged scienter on March 12, 2009. Prior thereto, the allegations of this case fail to show that Defendants had a duty to disclose interim information about the Rat Study or their dialogue with the FDA about it or that

⁴ Defendant Hoffman is not alleged to be part of the Lorcaserin Team.

⁵ The SAC does not sufficiently plead a core operations inference for defendant Hoffman. Defendant Hoffman is **dismissed** from this action as a result of Plaintiff’s failure to sufficiently plead his knowledge of the Rat Study data.

they made deliberately reckless misleading statements about the Rat Study.⁶ *Matrixx*, 131 S. Ct. at 1321-22 (“companies can control what they have to disclose under these [securities law] provisions by controlling what they say to the market”).

In 2009, Defendants knew in order to obtain FDA approval to market lorcaserin, Arena needed to demonstrate the Rat Study supported lorcaserin’s safety profile with respect to potential carcinogenicity. Specifically, in light of interim Rat Study data showing “a high incidence of mammary tumors in female” rats and “an apparent dose-dependent increase in incidence of malignant mammary tumors” in female rats, the FDA had told Defendants in 2008 that Arena needed to show that the drug’s mechanism or tumorigenic mode of action for mammary tumors is not relevant to humans. [Doc. No. 61-4 at 14, Ex. C; ¶¶70, 101.] To do so, the FDA requested that the Company complete animal mechanistic studies, among other things, exploring whether mammary tumors found in the Rat Study were attributable to a rat-specific mechanism. The FDA considered Defendants’ hypothesis that the tumors were the result of a rat-specific mechanism to be plausible, but required more data to support this hypothesis.

Plaintiff pleads that, by February 2009, “[t]he final Rat Study data that Defendants submitted to the FDA showed that tumors in female rats occurred at *all* doses and increased multiple tumor types in male rats, and that tumors occurred early and were very aggressive, leading to premature deaths.” [See, e.g., ¶101 (emphasis in SAC).] Plaintiff pleads that Defendants knew the purportedly adverse results undermined the long-term safety and sufficiency of the data needed for Arena’s New

⁶ For example, Defendants’ March 17, 2008 press release is about cardiovascular safety. The press release announces a specific cardiovascular safety milestone and limits its content to the implications of achieving that milestone. While Defendants may have possessed unfavorable carcinogenicity information at the time, the press release did not address or even allude to lorcaserin’s carcinogenicity or overall safety profile. Nor are there any facts to infer that like the human trials there were safety milestones for the Rat Study that should have been disclosed. As such, Defendants’ statements did not mislead investors about safety or the Company’s carcinogenicity studies.

1 Drug Application (“NDA”). Plaintiff also pleads that Defendants knew or deliberately
2 disregarded the fact that Arena had not satisfied the FDA’s request for scientific
3 evidence showing the mammary tumors were caused by rat-specific mechanism, which
4 was required to address the FDA’s concern that the Rat Study was relevant to humans.
5 Plaintiff pleads that satisfying this request was especially important because, with
6 respect to the Rat Study, “[n]o safety margin was identified for the mammary tumors
7 and the safety margin for brain tumors was uncertain.” [¶101.]

8 According to the SAC, Defendants would have known that “[w]hen safety
9 margins are absent or uncertain in a carcinogenicity study, it is critical that a drug
10 sponsor demonstrate that the drug’s mechanism or tumorigenic mode of action is not
11 relevant to humans.” [¶70.] Again, Plaintiff contends that Defendants failed to make
12 this demonstration. Plaintiff therefore argues “considering the facts alleged in the
13 Complaint, it is at least as likely than not that the Defendants knew of the Rat Study’s
14 adverse results, knew that the FDA had concerns about the Rat Study’s adverse results
15 and that the FDA believed that there was risk to humans, and that Defendants
16 deliberately chose to hide this material information from investors.” [Doc. No. 61 at
17 10.]

18 Plaintiff argues that with this factual backdrop, on March 12, 2009, defendant
19 Lief made the following statement: “Well, the confidence [on lorcaserin’s potential] is
20 not just based on the blinded data, of course, the confidence is based on the Phase II
21 data, the Phase I data, *the preclinical studies that was done, all the animal studies that*
22 *have been completed.*” [¶144 (emphasis added).] According to Plaintiff, when
23 Defendants made statements about lorcaserin’s safety Defendants should have
24 disclosed the adverse results observed in the Rat Study and the FDA’s concerns that
25 they were relevant to humans and could not have reasonably believed that the results
26 of the Rat Study were positive, favorable, or encouraging.

27 Based on a holistic view, the Court concludes Plaintiff has not established that
28 Defendants’ statement to the market about their increasing confidence in lorcaserin’s

1 overall safety profile in March 2009 (and thereafter), demonstrates as strong inference
 2 of deliberate recklessness. Despite the SAC's negative characterization of the Rat data,
 3 the documents relied upon by the SAC tell a more complete story that the Court
 4 considers for purposes of its scienter analysis.

5 By the time Defendants finalized the Rat Study data, the number of malignant
 6 tumors identified by the interim data were revised downward through the peer-review
 7 process.⁷ The final Rat Study data showed there was no significant cancer in any of the
 8 groups that would be clinically relevant to an assessment of human risk or use. The
 9 facts alleged do not persuasively show that Defendants were or should have been
 10 suspicious of this cancer data. Thus, the Court concludes the record supports the more
 11 plausible inference that Defendants, when speaking about lorcaserin's overall safety
 12 profile and potential, reasonably believed it to be positive, favorable, or encouraging.
 13 In addition, the FDA ultimately accepted and agreed with Arena's final data on the
 14 amount of cancer, which further supports an absence of scienter regarding the accuracy
 15 of the favorable cancer data. [See Doc. Nos. 44-6 at 10; 44-6 at 59; 60-4 at 17.]⁸

16 **B. September 18, 2009 Statement**

17 Whether defendant Anderson's September 18, 2009 gives rise to a strong
 18 inference of scienter is a closer question. Defendant Anderson made the following
 19 alleged materially false and misleading statement on September 18, 2009: "We've I
 20 think put together pretty much all of the data that we now need for this NDA. We have
 21 *favorable results on everything* that we've compiled so far. . . ." [¶190 (emphasis
 22 added); Doc. No. 44-5 at 23, Ex. J.] This statement, having been made by the
 23 Company's Vice President for Lorcaserin Development and the person in charge of
 24

25 ⁷ The FDA contemplated such a downward revision might occur in allowing
 26 human trials to go forward. [¶¶100, 123; Doc. No. 61-5 at 9, Ex. D.]

27 ⁸ Considered holistically in the context of the current allegations before the
 28 Court, Plaintiff's other allegations related to scienter, e.g. the FDA inspection,
 confidential witnesses, insider sales and budget cuts, do not meaningfully contribute
 to a strong inference of scienter with respect to the overall safety statements.

1 putting together the NDA, communicated to investors that Arena had checked all the
2 boxes that it needed to for its NDA submission. Plaintiff alleges that Defendants had
3 not checked all the boxes and they knew it.

4 According to Plaintiff, this statement was materially false and misleading
5 because Defendants knew they had to and failed to substantiate their hypothesis that
6 the tumors found in the Rat Study were due to a rat-specific mechanism with data on
7 prolactin levels in animals exposed to lorcaserin. The Court concludes that the record
8 before the Court may contain enough facts to show a strong inference of scienter for
9 defendant Anderson based on her September 2009 statement. Specifically, Plaintiff
10 may be able to show facts from the current record supporting a conclusion that it was
11 more than just a difference of scientific opinion that led to the FDA's conclusion that
12 Defendants failed to demonstrate that the Rat Study was irrelevant to humans. The
13 factual record may give rise to the more plausible inference that defendant Anderson
14 knew or deliberately disregarded facts that seriously undermined any belief Defendants
15 may have had regarding the sufficiency of the data.

16 However, in coming to this conclusion, the Court finds itself combing through
17 portions of the record that the SAC does not specifically identify, or that the parties
18 have not sufficiently briefed for purposes of this motion to dismiss. To fairly conduct
19 a holistic analysis of scienter, Plaintiff should amend to set forth the portions of the
20 record that show this case to be about more than a difference of scientific opinion
21 between the Company and the FDA on the sufficiency of the mechanistic studies
22 regarding lorcaserin's mechanism or tumorigenic mode of action. By allowing for such
23 an amendment, Defendants can properly respond to whether they made an affirmative
24 misrepresentation regarding the completeness, sufficiency or favorableness of Arena's
25 results.⁹

27 ⁹ Should Plaintiff choose to amend, Plaintiff is directed to dramatically limit
28 his amended complaint to the alleged materially false and misleading statements that
support Plaintiff's theory that Defendants knew they had to and failed to substantiate

1 The Company presented the FDA with an analysis of the Rat Study's mammary
 2 tumors that combined cancer data with non-cancer data.¹⁰ "[C]ombining mammary
 3 tumors in rats is an accepted practice used by other sponsors and [Arena]." [Doc. No.
 4 61-4 at 6.] Like the Company's interim Rat Study data, the final, combined data
 5 showed an unusually high and dose dependent incidence of mammary tumors in female
 6 rats. Plaintiff pleads with respect to this data that, "[n]o safety margin was identified
 7 for the mammary tumors and the safety margin for brain tumors was uncertain."
 8 [¶101.] As a result, defendant Anderson would have known that "[w]hen safety
 9 margins are absent or uncertain in a carcinogenicity study, it is critical that a drug
 10 sponsor demonstrate that the drug's mechanism or tumorigenic mode of action is not
 11 relevant to humans." [¶70.]

12 Further, as pled, defendant Anderson knew that the FDA had directed the
 13 Company in 2008 to substantiate their hypothesis that the mammary tumors were due
 14 to a rat-specific mechanism. The Company had been directed to complete animal
 15 mechanistic studies, among other things, to substantiate their hypothesis.¹¹ In the end,
 16 the FDA concluded "the mechanistic studies provided by the sponsor thus far have
 17 failed to persuasively demonstrate a link between lorcaserin emergent mammary
 18 tumors and prolactin, as it has been demonstrated for haloperidol." [Doc. No. 61-4 at
 19 7, Ex. C; *see also* Doc. No. 61-5 at 5, Ex. D ("Drs. Alavi and Bourcier do not believe
 20 that the totality of data provided by the sponsor support the hypothesis that lorcaserin

21
 22 their hypothesis that the tumors found in the Rat Study were due to a rat-specific
 mechanism with data on prolactin levels in animals exposed to lorcaserin.

23 ¹⁰ Defendants incorrectly suggested at oral argument that the FDA
 24 unexpectedly chose to perform this combined analysis.

25 ¹¹ Despite Defendants' argument otherwise, it does not appear that this
 direction was contingent on the clinical significance of the study's cancer findings.
 26 [See, e.g., Doc. Nos. 61-4 at 7 ("mammary tumor development in rodents is generally
 27 recognized to progress from hyperplasia to benign to malignant"), Ex. C; 61-5 at 5, Ex.
 28 D ("while fibroadenomas may not represent a life-threatening risk to humans, a drug
 that increased the incidence of these breast tumors would add at least a temporary
 emotional burden to women following detection of a breast mass of unknown
 histology").]

1 increases prolactin levels in rats to an extent commensurate with the increase in the
2 incidence of mammary tumors observed in the 2-year carcinogenicity study”).]

3 The SAC does not plead what Defendants should have understood to be the
4 threshold showing in order to satisfy the FDA’s request that Arena substantiate its
5 hypothesis that the mammary tumors found in the Rat Study were due to a rat-specific
6 mechanism. The FDA concludes in detail why the mechanistic study results failed to
7 connect the mammary tumors to a rat-specific mechanism. The details provided may
8 show that the mechanistic studies failed to substantiate Arena’s hypothesis, regardless
9 of what threshold standard applied. There also may be a generally accepted standard
10 to which this Court is unaware.

11 The FDA outlined the following observations, among others, about the
12 mechanistic studies’ results:

- 13 • Lorcaserin had no effect on serum prolactin in female rats and reduced
14 prolactin in males by 50% in the rat carcinogenicity study; and
- 15 • The single and multiple doses of lorcaserin (10 to 100 mg/kg) consistently
16 failed to show a significant rise in serum prolactin levels in female rats at
17 any time period;

18 [See Doc. No. 61-4 at 7, 21, Ex. C.] The FDA expressed concern that lorcaserin did not
19 robustly increase serum prolactin under all circumstances, which would demonstrate
20 a link between lorcaserin emergent mammary tumors and prolactin. [*Id.* at 8.] While
21 Defendants argue this is a matter of scientific opinion, facts such as the ones set forth
22 above may tip the scales of the Court’s scienter analysis in favor of sustaining
23 Plaintiff’s complaint on this issue.

24 In conclusion, the Court has determined that amendment of Plaintiff’s complaint
25 may not be futile. Plaintiff may be able to persuade the Court that defendant Anderson
26 (and/or other defendants) knew the NDA would not include the scientific evidence that
27 was specifically requested by the FDA and was deliberately reckless in conveying to
28 the market that the Company had completed the tasks necessary for the NDA. Further,

Anderson (and/or other defendants) may have hoped the final Rat Study data was sufficient to address the FDA's safety concerns regarding the statistically significant development of mammary tumors. Plaintiff may, however, persuade the Court that it is equally plausible that Anderson, as Arena's Vice President of Clinical Development, knew the scientific evidence related to the Rat Study did not sufficiently establish a correlation between lorcaserin emergent mammary tumors and prolactin, such that the Rat Study could be characterized as having favorable results in light of this unresolved safety concern.¹²

C. Section 20(a)

Plaintiff's claim under Section 20(a) of the Exchange Act requires a primary violation of Section 10(b), and must show that each defendant "directly or indirectly" controlled the violator. *Paracor Fin., Inc. v. Gen. Elec. Capital Corp.*, 96 F.3d 1151, 1161 (9th Cir. 1996). As currently pled, the SAC fails to plead a strong inference of scienter for purposes of establishing a primary violation of Section 10(b). Accordingly, the Section 20(a) claim also fails. *See Lipton v. Pathogenesis Corp.*, 284 F.3d 1027, 1035 (9th Cir. 2002).

CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss [Doc. No. 60] is **GRANTED WITHOUT PREJUDICE** to Plaintiff filing a motion to amend the complaint for a putative class period not to exceed May 11, 2009¹³ through January 27, 2011. Any motion to amend shall be filed on or before **November 27, 2013** and

¹² The Court declines to address whether other defendants can be held liable for defendant Anderson's September 2009 statement.

¹³ The alleged materially false and misleading statement set forth in ¶162 that long-term safety has been demonstrated for lorcaserin is the first statement that may be actionable depending on the strength of any amended complaint. Again, statements should be reduced to those that tie into Plaintiff's theory that Defendants knew they had to and failed to substantiate their hypothesis that the tumors found in the Rat Study were due to a rat-specific mechanism with data on prolactin levels in animals exposed to lorcaserin. For example, statements limited to the BLOOM and BLOSSOM clinical trials should be removed from any amended complaint.

1 limited to addressing whether the amended complaint sufficiently pleads a strong
2 inference of scienter. Any such motion may bring to the Court's attention any new
3 facts supporting scienter and any facts in the current record that Plaintiff believes
4 bolsters the SAC with respect to scienter. Any motion to amend shall not include
5 defendant Hoffman as a defendant in the proposed amended complaint. **Defendant**
6 **Hoffman is dismissed from this action with prejudice** as a result of Plaintiff's failure
7 to sufficiently plead his knowledge of the Rat Study data. Finally, **no extensions of**
8 **the motion to amend deadline will be granted.** Any opposition to Plaintiff's motion
9 to amend shall be limited to scienter, and Defendants do not waive any arguments by
10 limiting their opposition papers to the issue of scienter. Plaintiff shall not file a
11 separate motion to strike in response to any opposition to Plaintiff's motion to amend.

12 To the extent the Court, for purposes of conducting its scienter analysis, pointed
13 to materials complained of in Plaintiff's Motion to Strike, the Motion [Doc. No. 62] is
14 **DENIED.** The Court otherwise did not rely on the materials complained of and,
15 therefore, the Motion is otherwise denied as moot.

16 IT IS SO ORDERED.

17
18 DATED: November 4, 2013

19
20 
21 **CATHY ANN BENCIVENGO**
22 United States District Judge
23
24
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28

MINUTES OF THE UNITED STATES DISTRICT COURT**SOUTHERN DISTRICT OF CALIFORNIA**

Case Name: **Schueneman v. Arena Pharmaceuticals, Inc. et al** Case Number: **10cv1959-CAB (BLM)**

Hon. Cathy Ann Bencivengo Ct. Deputy Lori Hernandez Rptr. Tape:

The Court hereby confirms that the October 25, 2013 hearing in this matter shall go forward as scheduled, [*see* Doc. No. 66]. The Court does not have a tentative decision for the parties. However, the Court directs the parties to focus their arguments on the sufficiency of the second amended complaint, [Doc. No. 59], with respect to the time period of March 12, 2009 through January 27, 2011.

Date: October 22, 2013

Initials: smm

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA**

Todd Schueneman,

Plaintiff,

vs.

Arena Pharmaceuticals, Inc. et al.,

Defendants.

CASE NO. 10cv01959-CAB (BLM)

ORDER GRANTING MOTION TO
DISMISS WITHOUT PREJUDICE and
DENYING MOTION TO STRIKE AS
MOOT
[Doc. Nos. 44, 45, 47]

Before the Court is Defendants' Motion to Dismiss Consolidated Amended Class Action Complaint [Doc. Nos. 44, 45]. Upon consideration of the briefing, the motion is **GRANTED WITHOUT PREJUDICE**.

I. BACKGROUND

The Consolidated Amended Class Action Complaint (the "Complaint") alleges that Arena Pharmaceuticals, Inc. ("Arena" or the "Company") and its most senior executives violated Section 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act") and Rule 10b-5 promulgated thereunder by making materially false statements and/or omitting to disclose material facts concerning the safety of lorcaserin, Arena's most important developmental drug.¹

¹ The "Defendants" are Arena; Jack Lief ("Lief"), Arena's President, CEO and Chairman; Robert E. Hoffman ("Hoffman"), Arena's CFO; Dominic P. Behan ("Behan"), Arena's Senior Vice President and Chief Scientific Officer; William R. Shanahan, Jr. ("Shanahan"), Arena's Senior Vice President and Chief Medical Officer; and Christy Anderson ("Anderson"), Arena's Vice President of Clinical Development.

1 Lorcaserin is intended for weight loss and maintenance of weight loss,
 2 representing “the first in a new class of selective serotonin 2C receptor agonists.”
 3 [¶44.] Lorcaserin’s safety profile was important to investors, in part, because prior
 4 FDA-approved diet drugs, including Fen-Phen, were removed from the market after it
 5 was shown that they caused heart-valve disease (valvulopathy). [¶48.]

6 In order to obtain FDA approval to market lorcaserin, Arena needed to
 7 demonstrate lorcaserin’s safety and efficacy based on nonclinical/pre-clinical animal
 8 studies and clinical trials on humans. [¶45.] For example, as part of lorcaserin’s new
 9 drug application (“NDA”) to the FDA, Arena was required to conduct a long-term
 10 study of potential carcinogenesis on rats (the “Rat Study”). [¶51.] As pled, the Rat
 11 Study was a two year nonclinical/pre-clinical study that commenced in 2007 and was
 12 designed to help determine the potential risk that lorcaserin may be toxic or cause
 13 cancer in humans.

14 Plaintiff alleges that unknown to investors, Defendants knew by the beginning
 15 of the Class Period (March 17, 2008 through January 27, 2011) that the Rat Study
 16 showed that lorcaserin caused cancer. Plaintiff alleges that by late 2007, Defendants
 17 learned that the Rat Study showed the following risks: lorcaserin caused tumors in rats,
 18 including malignant mammary (breast) tumors in both male and female rats, malignant
 19 astrocytomas (brain cancer), squamous carcinomas of the subcutis (skin cancer),
 20 malignant schwannomas (cancer of connective tissue surrounding nerves or nerve
 21 sheath tissue), liver and thyroid. [¶53.] High percentages (56%-70%) of female rats
 22 in the study developed mammary cancer, which was “outside the historical range.”
 23 [¶¶8-9, 76.]²

24 So, by March 2008, Arena is alleged to have notified the U.S. Food and Drug
 25 Administration (“FDA”) about the Rat Study’s data. [¶¶ 8-9, 55, 72.] *See also* 21

26
 27 Lief, Hoffman, Behan, Shanahan and Anderson are referred to as the “Individual
 28 Defendants.”

² “¶” refers to paragraphs in the Complaint.

1 C.F.R. § 312.32(c). In response, the FDA did not halt lorcaserin's ongoing human
2 clinical trials. Rather, the FDA requested bi-monthly updates. [¶ 55.] See 21 C.F.R.
3 § 312.32(c)(1)(v)(3) ("FDA may require a sponsor to submit IND safety reports in a
4 format or at a frequency different than that required under this paragraph."). This
5 request was atypical. [¶¶ 9-10; 76.] Defendants did not publicly disclose facts about
6 the Rat Study or the FDA's request related thereto.

7 Arena provided the FDA with the requested bi-monthly updates until the
8 conclusion of the Rat Study in March 2009. Because of the ongoing nature of the Rat
9 Study, the bi-monthly updates only included "initial reads" of data, not reviewed by
10 outside pathologists. [¶ 76.] When Arena submitted its final report to the FDA, it
11 included a peer-reviewed analysis by "three [non-Arena] veterinary pathologists" who
12 concluded there were fewer malignant tumors than Arena initially reported to the FDA.
13 [¶¶ 12, 76.] The Rat Study showed an "apparent increase in aggressiveness of
14 adenocarcinoma in rats administered lorcaserin." [¶ 74.] Defendants did not publicly
15 disclose these facts to investors at the time.

16 In December 2009, Defendants filed lorcaserin's NDA, and the FDA appointed
17 the Advisory Committee, comprised of physicians and scientists, to discuss and vote
18 on whether to recommend that the FDA approve lorcaserin. [¶ 13.] The FDA Advisory
19 Committee was scheduled to meet on September 16, 2010. [¶ 14.]

20 In September 2010, investors first learned about the Rat Study data and that this
21 data caused the FDA's Advisory Committee to vote 9-5 against recommending
22 approval of lorcaserin. [¶¶ 18-20, 67-69, 71.] In October 2010, Arena publicly
23 disclosed that the FDA completed its review of the NDA and found that it could not
24 approve the NDA "in its present form." [¶ 73.] Defendants explained the FDA's
25 reasons to be, among other things, that the NDA failed to demonstrate that the Rat
26 Study was irrelevant to humans. [¶¶ 73-76.]

27 Plaintiff alleges that the negative results of the Rat Study and the FDA's
28 concerns over the rat data constituted material facts that should have been, but were

1 not, disclosed to investors. Plaintiff alleges that instead of disclosing, Defendants
2 repeatedly falsely represented that lorcaseirin was safe and made materially false and
3 misleading representations about non-clinical study results. Plaintiff further alleges
4 that when Defendants' prior misrepresentations were disclosed and became apparent
5 to the market, the price of Arena's securities declined precipitously as the prior
6 artificial inflation came out of Arena's stock price. As a result of their purchases of
7 Arena securities during the Class Period, Plaintiff and other members of the putative
8 class suffered economic loss, *i.e.*, damages under the federal securities laws. [¶¶179-
9 185.]

10 II. LEGAL STANDARD

11 Plaintiffs allege that Defendants violated § 10(b) of the 1934 Securities Act, and
12 Rule 10b-5 promulgated thereunder, and that the individual defendants acted as
13 controlling persons of Arena within the meaning of § 20(a) of the 1934 Act. In
14 enacting the Private Securities Litigation Act ("PSLRA"), congress imposed a
15 heightened pleading standard for cases alleging securities fraud, requiring that "the
16 complaint shall specify each statement alleged to have been misleading, the reason or
17 reasons why the statement is misleading, and, if an allegation regarding the statement
18 or omission is made on information and belief, the complaint shall state with
19 particularity all facts upon which that belief is formed." 15 U.S.C. § 78u-4(b)(1)(B).
20 *In re Cutera Securities Litigation*, 610 F.3d 1103, 1107 (9th Cir. 2010). To meet this
21 standard, "Plaintiffs must allege with particularity both the facts constituting the
22 alleged violation, and the facts evidencing scienter, *i.e.*, the defendant's intention to
23 deceive, manipulate, or defraud." *Id.* at 1107-08, *quoting Tellabs, Inc. v. Makor Issues*
24 *& Rights, Ltd.*, 551 U.S. 308, 313 (2007) (internal quotations omitted). In considering
25 a Rule 12(b)(6) motion to dismiss a § 10(b) action, the Court must, as with any motion
26 to dismiss, accept all factual allegations in the complaint as true. *Tellabs, Inc.*, 551
27 U.S. at 322.

III. ANALYSIS

Rule 10b-5 makes it unlawful “to make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statement made, in the light of the circumstances under which they were made, not misleading.” 17 C.F.R. § 240.10b-5(b). To adequately state a claim under Section 10(b), Plaintiffs must allege: (1) a misstatement or omission (2) of material fact (3) made with scienter (4) on which they relied (5) which proximately caused their injury. *DSAM Global Value Fund v. Altris Software, Inc.*, 288 F.3d 385, 388 (9th Cir. 2002). Defendants challenge the adequacy of the Complaint with regard to elements (1) and (3) above. The Court addresses scienter first.

A. Scienter

To plead scienter, Plaintiff must, as to each act or omission, “state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.” 15 U.S.C. § 78u-4(b)(2)(A). “[T]he ultimate question is whether the defendant knew his or her statements were false, or was consciously reckless as to their truth or falsity.” *Gebhart v. SEC*, 595 F.3d 1034, 1042 (9th Cir. 2010). The PSLRA requires that the Court dismiss the complaint if the Plaintiffs do not meet this standard. 15 U.S.C. § 78u-4(b)(3).

In determining whether Plaintiffs have adequately pled scienter on a motion to dismiss, the Court must 1) accept all factual allegations as true, 2) consider “whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard,” and 3) take into account plausible opposing inferences.” *Tellabs*, 551 U.S. at 322-23. “To determine whether the plaintiff has alleged facts that give rise to the requisite ‘strong inference’ of scienter, a court must consider plausible, nonculpable explanations for the defendant’s conduct, as well as inferences favoring the plaintiff. . . . The inference of scienter must be more than merely ‘reasonable’ or ‘permissible’—it must be cogent and compelling, thus strong in light of other explanations. A complaint will survive, we

1 hold, only if a reasonable person would deem the inference of scienter cogent and at
2 least as compelling as any opposing inference one could draw from the facts alleged.”
3 *Id.* at 323-24.

4 Here, Plaintiff argues that Defendants made statements about lorcaserin intended
5 to deceive or with deliberate recklessness as to the possibility of misleading investors.
6 Plaintiff identifies three categories of purported materially false and misleading
7 statements: (1) representations concerning lorcaserin’s safety, including statements that
8 lorcaserin was different from current and developmental diet drugs because it is both
9 safe and effective (¶¶84, 95, 97, 99, 103, 105, 108, 110, 113, 115, 118, 120, 132, 134,
10 136, 141, 144, 146, 148, 152, 154, 156, 167); (2) representations concerning the results
11 and progress of Defendants’ non-clinical animal safety studies on lorcaserin, including
12 the carcinogenicity studies like the Rat Study (¶¶86, 89, 92, 97, 99, 120, 128, 138, 156,
13 159, 173); and (3) certifications signed by Hoffman and Lief that represented Arena’s
14 periodic SEC filings (10-Ks and 10-Qs) did not contain any untrue statements of a
15 material fact or omit a material fact necessary to make the statements made, in light of
16 the circumstances under which such statements were made, not misleading (¶¶87, 90,
17 93, 100, 111, 139, 157, 160).³

18 Plaintiff argues that Defendants knew or consciously disregarded the danger that
19 the above statements would mislead investors because the statements omitted the
20 following facts:

- 21 (i) that by late 2007, Defendants learned that the findings of the Rat Study
22 included mammary tumors (¶¶ 8, 53-54);
23 (ii) that in approximately March 2008, Defendants alerted the FDA of the
24 adverse findings from the Rat Study and the FDA instructed that Arena provide

25 ³ Plaintiff’s opposition also identifies representations concerning
26 Defendants’ “end-of-review” meeting with the FDA in December 2010 as a fourth
27 category of false statements. However, the Court declines to analyze scienter for the
28 fourth category of statements because there is no factual support for the allegation that
defendants omitted information about their “end of review” meeting. As pled, the
allegedly omitted information was not learned by Defendants until “[s]ubsequent to the
end-of-review meeting.” [¶ 79.]

1 updates every two months to the FDA, an unusual request that is not part of the
2 normal FDA process for development of new drugs (§§ 8-9, 55-56, 72, 76);
3 (iii) that starting in March 2008, Arena provided bi-monthly updates to the FDA
4 on the Rat Study (§§ 9, 56, 76);
5 (iv) that Defendants were not able to demonstrate to the FDA that the Rat Study
6 results were irrelevant to humans (§§ 9-10, 57, 76); and
7 (v) by March 2009, the Rat Study was concluded and in or around March 2009
8 Defendants sent the final report to the FDA concerning the results of the Rat
9 Study. The final report's results changed prior findings regarding mammary
10 tumors. Specifically, the number of benign mammary tumors increased and the
11 number of malignant tumors decreased (§§ 11-12, 58, 76).

12 Therefore, according to Plaintiff, scienter is demonstrated because Defendants knew
13 or were deliberately reckless in not knowing about the Rat Study data and Arena's
14 communications with the FDA about it.

15 As an initial matter, the Court is not persuaded that the Complaint sufficiently
16 pleads each Defendant knew or were deliberately reckless in not knowing about the Rat
17 Study data or Arena's communications with the FDA about it. Lorcaserin was Arena's
18 core product. Defendants were focused on the development of lorcaserin, they
19 discussed lorcaserin in every conference call, press release and periodic report filed by
20 Arena with the SEC, and nearly all of the Company's resources were dedicated to
21 lorcaserin's development. [See ¶34.] However, the facts presently before the Court do
22 not warrant the application of the "core operations" scienter theory, wherein may be
23 inferred that facts critical to a business's "core operations" or important transactions
24 are known to key company officers. *See South Ferry LP, #2 v. Killinger*, 542 F.3d 776,
25 784-85 (9th Cir. 2008).

26 Indeed, allegations suggesting a core operations inference, standing alone, will
27 generally not support a strong inference of scienter absent "additional detailed
28 allegations about the defendants' actual exposure to information." *Id.* at 784. Here,

1 there are no detailed allegations showing how each Defendant would have been
2 exposed to the Rat Study data or FDA communications about it. The Complaint's
3 generic conclusions are insufficient – that based on the defendants' "positions" at
4 Arena each "received and/or had access to data concerning lorcaserin, including the
5 results of the Rat Study." [See ¶¶ 40, 42.] Without details showing how each
6 Defendant's job responsibilities or interactions with others would have put them on
7 notice of the omitted facts, there is no factual basis for the Court to begin its scienter
8 analysis.

9 Where unusual circumstances are present, courts depart from the general rule
10 that scienter based on the core operations inference requires detailed allegations about
11 the defendants' exposure to the type of information at issue. However, there are no
12 such unusual circumstances here. For example, there are no factual allegations about
13 how any Defendant interpreted or reacted to the Rat Study data or the FDA's request
14 for bi-monthly updates on the data during the Class Period. The FDA's opinion did not
15 characterize the data as suggesting a risk in humans. And, as pled, Defendants only
16 learned of the FDA's opinion on the Rat Study data two days before the September 16,
17 2010 Advisory Committee meeting. Further, while the FDA's March 2008 request for
18 bi-monthly updates was unusual, there are no facts pled to infer that each Defendant
19 should have known about these updates, that they were unusual, or that the updates
20 suggested a risk to humans (or even to the NDA). In sum, the facts alleged do not
21 demonstrate that there was a red flag that Defendants knew or deliberately disregarded
22 when they chose to speak about lorcaserin's safety.

23 Arguably, the Complaint plausibly shows that Defendant Lief and Defendant
24 Anderson knew about the Rat Study data by March 12, 2009 and September 18, 2009,
25 respectively. [See ¶97 (Lief's explaining that he is "encouraged by the overall
26 emerging [risk/benefit] profile" because of "... the preclinical studies that was [*sic*]
27 done, all the animal studies that have been completed. . . ."; ¶128 (Anderson stating,
28 "... all of the data that we now need for this NDA. We have favorable results on

1 everything that we've compiled so far.”.)] Viewed holistically with other facts alleged,
2 Lief’s statement was sufficiently specific and Anderson’s statement was sufficiently
3 sweeping to attribute knowledge of the Rat Study to them. Therefore, the question for
4 Defendants Lief and Anderson becomes whether each knew their “statements were
5 false, or was consciously reckless as to their truth or falsity.” *Gebhart*, 595 F.3d at
6 1042. The Court is not persuaded.

7 As currently pled, the Court finds it more plausible that Defendants Lief and
8 Anderson knew about the Rat Study data and reasonably believed the results to be
9 positive with regard to what the study was designed to test. Namely, “the potential risk
10 that drug candidates may be toxic or cause cancer *in humans*.” [See, e.g., ¶¶86, 89, 92,
11 99, 100, 123, 138, 159 (emphasis added).] The facts alleged do not show a nexus
12 between the increased tumors found in the Rat Study to human use or risk. For
13 example, there are no allegations that, during the Class Period, anyone suspected that
14 the cancerous tumors found in the rats resulted from dosage amounts that were
15 scientifically relevant to human use. Instead, the Complaint alleges that Arena promptly
16 notified the FDA in March 2008 about the rat data, and that in response, the FDA did
17 not halt lorcaserin’s ongoing human clinical trials. This makes it more plausible that
18 Arena’s reporting to the FDA did *not* concern any suspected risk in humans. There is
19 nothing to suggest that Lief or Anderson should have known the Rat Study data could
20 negatively impact lorcaserin’s safety profile or its NDA timeline. There is nothing to
21 suggest that it would have been unreasonable for Lief and Anderson to interpret the Rat
22 Study results as favorably contributing to lorcaserin’s safety profile for humans and
23 NDA. Therefore, under the facts alleged, the omissions about which Plaintiff complains
24 do not raise an inference of scienter.

25 B. Falsity

26 As stated above, the Complaint fails to plead that Defendants’ representations
27 about the “end-of-review” meeting with the FDA in December 2010 were false or
28 misleading. However, because the Court finds that the Complaint does not meet the

1 requisite pleading standard to allege scieinter, it does not reach Defendants' additional
2 arguments as to falsity here.

3 Should Plaintiff choose to amend, he is directed to better identify which
4 statements within the block-quotes provided he believes were false and misleading
5 when made and why. Further, the Court encourages Plaintiff to narrow the scope of his
6 alleged false and misleading statements to include only statements for which
7 Defendants, under a different set of facts, may have had a duty to disclose information
8 about the Company's preclinical studies. [See ¶¶97, 99, 110, 123, 128, 138, 156, 159,
9 173.] Despite this guidance, the Court makes no findings as to duty to disclose at this
10 time.

11 **IV. CONCLUSION**

12 For the foregoing reasons, Defendants' Motion to Dismiss [Doc. Nos. 44, 45] is
13 **GRANTED WITHOUT PREJUDICE** to Plaintiff filing an amended complaint on or
14 before **April 25, 2013**.

15 As the Court did not find it necessary to rely on the materials complained of in
16 Plaintiff's Motion to Strike, the Motion [Doc. No. 47] is **DENIED as MOOT**.

17 **IT IS SO ORDERED.**

18
19 DATED: March 28, 2013

20
21 
22 **CATHY ANN BENCIVENGO**
23 United States District Judge
24
25
26
27
28

No. 14-55633

**UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT**

TODD SCHUENEMAN, on behalf of himself
and all others similarly situated,

Plaintiff-Appellant,

v.

ARENA PHARMACEUTICALS, INC., et al.,

Defendants-Appellees.

On Appeal from the United States District Court
for the Southern District of California
Hon. Cathy Ann Bencivengo
No. 3:10-cv-01959-CAB-BLM

**APPELLANT'S EXCERPTS OF RECORD
VOLUME 2 OF 3
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*Lead Counsel for Lead Plaintiff Carl Schwartz
 and the Proposed Class*

**UNITED STATES DISTRICT COURT
 SOUTHERN DISTRICT OF CALIFORNIA**

TODD SCHUENEMAN, on behalf of
 himself and all others similarly situated,

Plaintiff,

vs.

ARENA PHARMACEUTICALS, INC.,
 JACK LIEF, DOMINIC P. BEHAN,
 WILLIAM R. SHANAHAN, and
 CHRISTY ANDERSON,

Defendants.

Case No. 3:10-cv-01959-CAB

NOTICE OF APPEAL

Judge: Hon. Cathy Ann Bencivengo

Additional captions on following page

1 WILLIAM SUTLIFF and JEAN SUTLIFF,
2 on behalf of themselves and all others
3 similarly situated,

4 Plaintiff,

5 vs.

6 ARENA PHARMACEUTICALS, INC.,
7 JACK LIEF and WILLIAM SHANAHAN,
8 JR.

9 Defendants.

Case No. 3:10-cv-01961-CAB

10 WILLIAM PRATT, Individually and on
11 Behalf of All Others Similarly Situated,

12 Plaintiff,

13 vs.

14 ARENA PHARMACEUTICALS, INC.,
15 JACK LIEF, DOMINIC P. BEHAN,
16 WILLIAM R. SHANAHAN, JR. and
17 CHRISTY ANDERSON,

18 Defendants.

Case No. 3:10-cv-01977-CAB

19 CRAIG RUBENSTEIN, Individually and
20 on Behalf of All Others Similarly Situated,

21 Plaintiff,

22 vs.

23 ARENA PHARMACEUTICALS, INC.,
24 JACK LIEF, DOMINIC P. BEHAN,
25 WILLIAM R. SHANAHAN, JR. and
26 CHRISTY ANDERSON,

27 Defendants.

Case No. 3:10-cv-01984-CAB

28 *captions continue on next page*

1 RODNEY VELASQUEZ, on behalf of
2 himself and all others similarly situated,

3 Plaintiff,

4 vs.

5 ARENA PHARMACEUTICALS, INC.,
6 JACK LIEF, DOMINIC P. BEHAN,
7 WILLIAM R. SHANAHAN, JR. and
8 CHRISTY ANDERSON,

9 Defendants.

Case No. 3:10-cv-02026-CAB

10 THONG VU, individually and on behalf of
11 all others similarly situated,

12 Plaintiff,

13 vs.

14 ARENA PHARMACEUTICALS, INC.,
15 JACK LIEF, DOMINIC P. BEHAN,
16 WILLIAM R. SHANAHAN, and
17 CHRISTY ANDERSON,

18 Defendants.

Case No. 3:10-cv-02086-CAB

19 ARIC D. JACOBSON, individually and on
20 behalf of all others similarly situated,

21 Plaintiff,

22 vs.

23 ARENA PHARMACEUTICALS, INC.,
24 JACK LIEF, DOMINIC P. BEHAN,
25 WILLIAM R. SHANAHAN, JR., and
26 CHRISTY ANDERSON,

27 Defendants.

Case No. 3:10-cv-02335-CAB

1 Notice is hereby given that Lead Plaintiff Carl Schwartz, in the above-
2 captioned matters, hereby appeals to the United States Court of Appeals for the
3 Ninth Circuit from: (1) the Judgment in a Civil Case, entered March 21, 2014
4 (ECF No. 78); (2) the Order Denying Lead Plaintiff's Motion to Amend Second
5 Consolidated Amended Class Action Complaint, entered March 21, 2014 (ECF
6 No. 77); and (3) the Order Granting Motion to Dismiss Without Prejudice and
7 Denying Motion to Strike, entered November 4, 2013 (ECF No. 71).

8 DATED: April 18, 2014

KAPLAN FOX & KILSHEIMER LLP

9
10 By: /s/ Laurence D. King
Laurence D. King

11 Laurence D. King (SBN 206423)
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20 *Lead Counsel for Lead Plaintiff Carl Schwartz*
21 *and the Proposed Class*
22
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28

CERTIFICATE OF SERVICE

I, Laurence D. King, hereby declare that on April 18, 2014, I caused the foregoing to be filed electronically using the Court's CM/ECF system which sent notifications of the filing to counsel of record.

/s/ Laurence D. King

Laurence D. King



United States District Court
SOUTHERN DISTRICT OF CALIFORNIA

Todd Schueneman on behalf of himself
and all others similarly situated;
**See Attachment for additional
plaintiffs**

Plaintiff,

V.

Arena Pharmaceuticals, Inc.;

**See Attachment for additional
defendants**

Defendant.

Civil Action No. 10CV1959-CAB-BLM

JUDGMENT IN A CIVIL CASE

Decision by Court. This action came to trial or hearing before the Court. The issues have been tried or heard and a decision has been rendered.

IT IS HEREBY ORDERED AND ADJUDGED:

The Court concludes that amendment of the complaint in this action would be futile as the allegations of the proposed third amended complaint fail to give rise to a strong inference of scienter. The motion to amend [Doc. No. 73] is therefore denied. The case is dismissed with prejudice.

Date: 3/21/14

CLERK OF COURT

JOHN MORRILL, Acting Clerk of Court

By: s/ Y. Barajas

Y. Barajas, Deputy

United States District Court

SOUTHERN DISTRICT OF CALIFORNIA

(ATTACHMENT)

Civil Action No. 10CV1959-CAB-BLM

Todd Schueneman, on behalf of himself and all others similarly situated; William Sutliff; Jean Sutliff; Arena Investors Group; Anthony Caravella; Carl Schwartz

Plaintiffs

v.

Arena Pharmaceuticals, Inc.; Jack Lief; Robert E. Hoffman; Dominic P. Behan; William R. Shanahan; Christy Anderson;

Defendants

Chris Georgakopoulos; Larry Sprowl; Maxat Amankossov; David Prince; Ford L. Williams; Carl Schwartz; John Lee; Babak Ghayour;

Movants

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*Lead Counsel for Lead Plaintiff Carl Schwartz
 and the Proposed Class*

**UNITED STATES DISTRICT COURT
 SOUTHERN DISTRICT OF CALIFORNIA**

TODD SCHUENEMAN, on behalf of
 himself and all others similarly situated,

Plaintiff,

vs.

ARENA PHARMACEUTICALS, INC.,
 JACK LIEF, DOMINIC P. BEHAN,
 WILLIAM R. SHANAHAN, and
 CHRISTY ANDERSON,

Defendants.

Case No. 3:10-cv-01959-CAB

**DECLARATION OF
 LAURENCE D. KING IN
 SUPPORT OF LEAD
 PLAINTIFF'S MOTION TO
 AMEND SECOND
 CONSOLIDATED AMENDED
 CLASS ACTION COMPLAINT**

Judge: Hon. Cathy Ann Bencivengo
 Courtroom: 4C
 Hearing Date: January 3, 2014
 Hearing Time: 2:00 p.m.

[Oral argument requested, subject to
 Court approval]

captions continue on next page

1 WILLIAM SUTLIFF and JEAN SUTLIFF,
2 on behalf of themselves and all others
3 similarly situated,

4 Plaintiff,

5 vs.

6 ARENA PHARMACEUTICALS, INC.,
7 JACK LIEF and WILLIAM SHANAHAN,
8 JR.

9 Defendants.

Case No. 3:10-cv-01961-CAB

10 WILLIAM PRATT, Individually and on
11 Behalf of All Others Similarly Situated,

12 Plaintiff,

13 vs.

14 ARENA PHARMACEUTICALS, INC.,
15 JACK LIEF, DOMINIC P. BEHAN,
16 WILLIAM R. SHANAHAN, JR. and
17 CHRISTY ANDERSON,

18 Defendants.

Case No. 3:10-cv-01977-CAB

19 CRAIG RUBENSTEIN, Individually and
20 on Behalf of All Others Similarly Situated,

21 Plaintiff,

22 vs.

23 ARENA PHARMACEUTICALS, INC.,
24 JACK LIEF, DOMINIC P. BEHAN,
25 WILLIAM R. SHANAHAN, JR. and
26 CHRISTY ANDERSON,

27 Defendants.

Case No. 3:10-cv-01984-CAB

28 *captions continue on next page*

1 RODNEY VELASQUEZ, on behalf of
2 himself and all others similarly situated,

3 Plaintiff,

4 vs.

5 ARENA PHARMACEUTICALS, INC.,
6 JACK LIEF, DOMINIC P. BEHAN,
7 WILLIAM R. SHANAHAN, JR. and
8 CHRISTY ANDERSON,

9 Defendants.

Case No. 3:10-cv-02026-CAB

10 THONG VU, individually and on behalf of
11 all others similarly situated,

12 Plaintiff,

13 vs.

14 ARENA PHARMACEUTICALS, INC.,
15 JACK LIEF, DOMINIC P. BEHAN,
16 WILLIAM R. SHANAHAN, and
17 CHRISTY ANDERSON,

18 Defendants.

Case No. 3:10-cv-02086-CAB

19 ARIC D. JACOBSON, individually and on
20 behalf of all others similarly situated,

21 Plaintiff,

22 vs.

23 ARENA PHARMACEUTICALS, INC.,
24 JACK LIEF, DOMINIC P. BEHAN,
25 WILLIAM R. SHANAHAN, JR., and
26 CHRISTY ANDERSON,

27 Defendants.

Case No. 3:10-cv-02335-CAB

1 I, Laurence D. King, declare as follows:

2 1. I am a partner with the law firm of Kaplan Fox & Kilsheimer LLP,
3 counsel for Lead Plaintiff Carl Schwartz and the Proposed Class. I have personal
4 knowledge of the following facts and, if called upon to testify, I could and would
5 testify competently thereto.

6 2. Attached hereto as Exhibit A is a true and correct copy of the clean
7 version of the proposed Third Consolidated Amended Class Action Complaint
8 (“proposed Amended Complaint”).

9 3. Attached hereto as Exhibit B is a true and correct copy of the redlined
10 version of the proposed Amended Complaint reflecting Lead Plaintiff’s
11 amendments to the Second Consolidated Amended Class Action Complaint (ECF
12 No. 56).

13 I declare under penalty of perjury under the laws of the United States that the
14 foregoing is true and correct. Executed this 27th day of November, 2013, in San
15 Francisco, California.

16
17 /s/ Laurence D. King
18 Laurence D. King
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EXHIBIT A

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*Lead Counsel for Lead Plaintiff Carl Schwartz
 and the Proposed Class*

**UNITED STATES DISTRICT COURT
 SOUTHERN DISTRICT OF CALIFORNIA**

TODD SCHUENEMAN, on behalf of
 himself and all others similarly situated,

Plaintiff,

vs.

ARENA PHARMACEUTICALS, INC.,
 JACK LIEF, DOMINIC P. BEHAN,
 WILLIAM R. SHANAHAN, and
 CHRISTY ANDERSON,

Defendants.

Case No. 3:10-cv-01959-CAB

**THIRD CONSOLIDATED
 AMENDED CLASS ACTION
 COMPLAINT**

JURY TRIAL DEMANDED

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1 WILLIAM SUTLIFF and JEAN SUTLIFF,
2 on behalf of themselves and all others
3 similarly situated,

4 Plaintiff,

5 vs.

6 ARENA PHARMACEUTICALS, INC.,
7 JACK LIEF and WILLIAM SHANAHAN,
8 JR.

9 Defendants.

Case No. 3:10-cv-01961-CAB

10 WILLIAM PRATT, Individually and on
11 Behalf of All Others Similarly Situated,

12 Plaintiff,

13 vs.

14 ARENA PHARMACEUTICALS, INC.,
15 JACK LIEF, DOMINIC P. BEHAN,
16 WILLIAM R. SHANAHAN, JR. and
17 CHRISTY ANDERSON,

18 Defendants.

Case No. 3:10-cv-01977-CAB

19 CRAIG RUBENSTEIN, Individually and
20 on Behalf of All Others Similarly Situated,

21 Plaintiff,

22 vs.

23 ARENA PHARMACEUTICALS, INC.,
24 JACK LIEF, DOMINIC P. BEHAN,
25 WILLIAM R. SHANAHAN, JR. and
26 CHRISTY ANDERSON,

27 Defendants.

Case No. 3:10-cv-01984-CAB

28 *captions continue on next page*

1 RODNEY VELASQUEZ, on behalf of
2 himself and all others similarly situated,

3 Plaintiff,

4 vs.

5 ARENA PHARMACEUTICALS, INC.,
6 JACK LIEF, DOMINIC P. BEHAN,
7 WILLIAM R. SHANAHAN, JR. and
8 CHRISTY ANDERSON,

9 Defendants.

Case No. 3:10-cv-02026-CAB

10 THONG VU, individually and on behalf of
11 all others similarly situated,

12 Plaintiff,

13 vs.

14 ARENA PHARMACEUTICALS, INC.,
15 JACK LIEF, DOMINIC P. BEHAN,
16 WILLIAM R. SHANAHAN, and
17 CHRISTY ANDERSON,

18 Defendants.

Case No. 3:10-cv-02086-CAB

19 ARIC D. JACOBSON, individually and on
20 behalf of all others similarly situated,

21 Plaintiff,

22 vs.

23 ARENA PHARMACEUTICALS, INC.,
24 JACK LIEF, DOMINIC P. BEHAN,
25 WILLIAM R. SHANAHAN, JR., and
26 CHRISTY ANDERSON,

27 Defendants.

Case No. 3:10-cv-02335-CAB

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1 Lead Plaintiff Carl Schwartz, through Lead Counsel Kaplan Fox &
2 Kilsheimer LLP, individually and on behalf of all other persons and entities
3 similarly situated that purchased the securities of Arena Pharmaceuticals, Inc.
4 (“Arena” or the “Company”), makes the following allegations, which are based
5 upon the investigation conducted by Lead Plaintiff’s counsel, which included,
6 among other things, a review of the public statements made by defendants, Arena’s
7 filings with the United States Securities and Exchange Commission (“SEC”),
8 transcripts of conference calls with investors and research analysts and a public
9 meeting before the FDA’s Endocrinology and Metabolic Advisory Committee
10 (“Advisory Committee”) on September 16, 2010, the Briefing Document prepared
11 by Food and Drug Administration (“FDA”) scientists for the September 2010
12 Advisory Committee meeting (the “FDA Briefing Document”), the
13 Pharmacology/Toxicology New Drug Application (“NDA”) Review and Evaluation
14 of lorcaserin by the FDA, the Summary Review for Regulatory Action by the FDA
15 concerning lorcaserin, the FDA’s Division for Scientific Investigation’s March 3,
16 2010 Consult Request for Nonclinical Site Inspections for lorcaserin, press releases,
17 analyst reports and media reports regarding Arena, this Court’s November 4, 2013
18 Orders (ECF. Nos. 71-72), and interviews with confidential informants.

19 **I. NATURE OF THE CLAIMS**

20 1. This is a securities class action brought under Sections 10(b) and 20(a)
21 of the Securities Exchange Act of 1934 (“Exchange Act”), 15 U.S.C. §§ 78j(b) and
22 78t(a), and the rules and regulations promulgated thereunder by the SEC, including
23 Rule 10b-5, 17 C.F.R. § 240.10b-5, on behalf of purchasers of Arena securities
24 between May 11, 2009 through January 27, 2011 (the “Class Period”).

25 2. “Defendants” are the Company; Jack Lief (“Lief”), the Company’s
26 President, Chief Executive Officer and Chairman of the Company’s board of
27 directors; Dominic P. Behan (“Behan”), the Company’s Senior Vice President and
28 Chief Scientific Officer and a member of the Company’s board of directors;

1 William R. Shanahan (“Shanahan”), the Company’s Senior Vice President and
2 Chief Medical Officer; and Christen “Christy” Anderson (“Anderson”), the
3 Company’s former Vice President of Lorcaserin Development.

4 **II. JURISDICTION AND VENUE**

5 3. This Court has jurisdiction over the subject matter of this action
6 pursuant to Section 27 of the Exchange Act.

7 4. Venue is proper in this District pursuant to Section 27 of the Exchange
8 Act and 28 U.S.C. §§ 1391(b) and (c). Substantial acts in furtherance of the wrongs
9 alleged and/or their effects have occurred within this District and Arena maintains
10 its headquarters in San Diego, California.

11 5. In connection with the facts and omissions alleged in this complaint,
12 Defendants, directly or indirectly, used the means and instrumentalities of interstate
13 commerce, including, but not limited to, the mails, interstate telephone
14 communications, and the facilities of the national securities markets.

15 **III. THE PARTIES**

16 6. Lead Plaintiff purchased Arena securities as detailed in the
17 certification previously filed with the Court and was damaged thereby.

18 7. Defendant Arena is incorporated in Delaware and has executive offices
19 in San Diego, California. The Company’s common stock trades on the NASDAQ
20 under the symbol “ARNA”. Arena purports to be a clinical-stage
21 biopharmaceutical company focused on discovering, developing and
22 commercializing drugs for cardiovascular, central nervous system, inflammatory
23 and metabolic diseases. During the Class Period, the Company did not sell any
24 products.

25 8. During the Class Period, Arena, a small company, focused on the
26 development of lorcasein. Arena’s 2009 annual report filed with the SEC on
27 March 16, 2010 on Form 10-K (the “2009 10-K”) stated that “we are focusing our
28 activities and resources on our lorcasein program.” According to the 2009 10-K,

1 approximately 95% and 86% of Arena's total external clinical and preclinical study
2 fees and expenses related to lorcaserin in 2009 and 2008, respectively.

3 9. Defendant Lief was, at all relevant times, the Company's President and
4 Chief Executive Officer, and Chairman of the Company's board of directors. Lief
5 is a co-founder of the Company. During the Class Period, Lief made false
6 statements in the Company's reports filed with the SEC and in conference calls
7 with investors and research analysts.

8 10. Defendant Behan was, at all relevant times, the Company's Senior
9 Vice President and Chief Scientific Officer and a member of the Company's board
10 of directors. Behan is a co-founder of the Company. During the Class Period,
11 Behan made false statements in the 2009 10-K and made false statements in
12 conference calls with investors and research analysts.

13 11. Defendant Shanahan was, at all relevant times, the Company's Senior
14 Vice President and Chief Medical Officer. During the Class Period, Shanahan
15 made false statements in conference calls with investors and research analysts.

16 12. Defendant Anderson was the Company's Vice President of Lorcaserin
17 Development during the Class Period and left Arena after the Class Period. During
18 the Class Period, Anderson made false statements in conference calls with investors
19 and research analysts.

20 13. Defendants Lief, Shanahan, Behan, and Anderson are referred to
21 herein as the "Individual Defendants". The Individual Defendants, because of their
22 positions with the Company, possessed the power and authority to control the
23 contents of Arena's press releases and presentations to securities analysts, money
24 and portfolio managers and institutional investors, *i.e.*, the market. Each Individual
25 Defendant was provided with copies of the Company's press releases and/or filings
26 with the SEC alleged herein to be misleading prior to or shortly after their issuance
27 and had the ability and opportunity to prevent their issuance or cause them to be
28 corrected. Because of their positions and access to material, non-public information

1 available to them but not investors, each of the Individual Defendants knew that the
2 adverse material facts specified herein had not been disclosed to and were being
3 concealed from the public and that the positive representations which were being
4 made were materially false and misleading at that time. Defendants Lief,
5 Shanahan, Anderson and Behan attended meetings with the FDA and corresponded
6 with the FDA concerning lorcaserin, including meetings at which the FDA
7 discussed the adverse results of a key, long-term carcinogenicity study on rats (the
8 “Rat Study”) designed to approximate a lifetime of human use, and to assess safety
9 and risk to humans. During the Class Period, each of the Individual Defendants
10 knew of the Rat Study results, received and/or had access to data concerning
11 lorcaserin, including the results of the clinical and nonclinical studies of lorcaserin
12 safety, and made false statements and/or omitted to disclose material facts to
13 investors.

14 **IV. BACKGROUND AND BASIS OF DEFENDANTS’ LIABILITY**

15 **A. Background on Arena’s Development of Lorcaserin.**

16 **1. Arena’s Animal (Non or Pre-Clinical) and Human (Clinical)** 17 **Studies of Lorcaserin.**

18 14. Lorcaserin is intended for weight management, including weight loss
19 and maintenance of weight loss. Lorcaserin is described by Arena as “a novel
20 single agent that represents the first in a new class of selective serotonin 2C
21 receptor agonists. The serotonin 2C receptor is located in areas of the brain
22 involved in the control of appetite and metabolism, such as the hypothalamus.
23 Stimulation of this receptor is strongly associated with feeding behavior and
24 satiety.” Because lorcaserin’s mechanism affected the central nervous system in
25 the brain, any signal of brain tumors would be a red flag of a safety risk in humans.

26 15. Arena has been developing lorcaserin since at least 2003. To market
27 lorcaserin, Arena needed approval from the FDA. Approval by the FDA of a new
28

1 drug requires a new drug sponsor to submit data demonstrating the drug's safety
2 and efficacy based on nonclinical animal studies and clinical trials on humans.

3 16. Human clinical trials are referred to as phases 1, 2, and 3. Phase 1
4 trials are mainly aimed at determining if the metabolic and pharmacologic actions
5 of the drug in humans are safe enough to proceed to Phase 2 studies. Phase 2
6 studies are controlled clinical studies that involve a limited population infected with
7 the disease the drug proposes to treat. Phase 3 studies usually involve many more
8 people than Phase II studies and are intended to gather additional information on
9 the drug's efficacy and safety that will be used in evaluating its overall risks and
10 benefits. Nonclinical animal studies include long-term studies on animals of a
11 drug's toxicity and carcinogenicity.

12 17. Between 2006 and 2009, Arena concurrently conducted nonclinical
13 animal studies and human studies, including two "pivotal" Phase 3 trials—BLOOM
14 (Behavioral modification and Lorcaserin for Overweight and Obesity Management)
15 and BLOSSOM, all of which were intended to be submitted with the lorcaserin
16 New Drug Application ("NDA").

17 18. BLOOM started in September 2006 and was completed in February
18 2009. BLOSSOM was conducted between January 2008 and July 2009.

19 19. During the Class Period, Arena had a Lorcaserin Team that conducted
20 and/or supervised clinical and nonclinical tests required for approval by the FDA.
21 According to Confidential Informant 1 ("CI 1"),¹ and Confidential Informant 2
22 ("CI 2"),² the Lorcaserin Team was led by Defendants Lief, Anderson, Shanahan
23 and Behan, as well as other Arena senior management.

24 ¹ CI 1 was a Senior Manager for Regulatory Affairs at Arena between February
25 2008 through June 2010, who handled correspondence with the FDA and prepared
26 meeting packages, safety reports and carcinogenicity updates for the lorcaserin
27 project.

28 ² CI 2 was a Senior Director of Drug Safety Evaluation at Arena between October
2007 through May 2009 who was responsible for monitoring the quality and
standards used in animal studies of lorcaserin.

20. As members of the Lorcaserin Team, Defendants Lief, Shanahan, Anderson and Behan supervised the tests required for FDA approval of lorcaserin, including the Rat Study. Further, Defendants Lief, Shanahan, Anderson and Behan were privy to, and knowledgeable about the protocols and results of the Rat Study and other studies of lorcaserin, and attended meetings with the FDA at which the Rat Study and the FDA's concerns about the Rat Study's results and its significance to humans were discussed, and corresponded with the FDA concerning the Rat Study.

21. By 2006, Defendants were conducting advanced human studies of lorcaserin (Phase 3 studies) and, at the same time, they were conducting other essential studies for lorcaserin's NDA, including nonclinical carcinogenicity and toxicity studies in animals, and the Rat Study to assess clinical (human) risk.

22. As members of the Lorcaserin Team, Defendants Shanahan and Anderson, were tasked as the team leaders for lorcaserin's nonclinical and clinical studies. Shanahan and Anderson were responsible for collecting and analyzing all preclinical/animal and clinical data, including the Rat Study data, for lorcaserin's NDA, which data they discussed and shared with the other members of the Lorcaserin Team.

23. According to CI 1, the Rat Study data was collected by Bruce Ennis ("Ennis"), Arena's Associate Director and Head Toxicologist, who reported to Defendant Shanahan. Tina Leakakos, Arena's Associate Director of Drug Safety Evaluation, assisted Ennis. According to CI 1, Ennis received the data from the Rat Study from outside companies that ran the nonclinical trials. Ennis reported results to Shanahan who shared them with the other members of the Lorcaserin Team.

24. According to CI 1, Mark Brunswick ("Brunswick"), Arena's Senior Director of Regulatory Affairs during the Class Period (who reported to Defendant Lief), and Terri Heyward, Arena's Regulatory Manager, were the Regulatory Project Managers for lorcaserin.

25. Brunswick was responsible for sending and receiving communications with the FDA on behalf of the Lorcaserin Team.

2. Lorcaserin's Safety Was Critical to the FDA and Investors.

26. As with all new drugs, a drug sponsor must demonstrate the drug's safety. Safety with respect to diet drugs was highly important because prior FDA approved diet drugs, including Fen-Phen, were removed from the market because of serious adverse side effects after it was shown that they cause heart-valve disease (valvulopathy).

27. Fen-Phen, like lorcaserin, was a "serotonin agonist", and affects the brain and central nervous system in similar ways. As such, it was important for Arena to demonstrate that lorcaserin did not cause negative side effects. Indeed, before the beginning of the Class Period, Defendant Lief acknowledged that focus was on "safety, safety, safety, safety...and then safety."

28. Further, lorcaserin's safety profile was of paramount importance to investors. Vivus and Orexigen, competitors of Arena, were developing competing weight-loss drugs (qnexa and contrave, respectively), and the results of certain clinical studies for qnexa and contrive that had been publicly disclosed showed potential adverse side effects, like birth defects and cardiovascular risks.

29. Accordingly, Defendants represented that lorcaserin was different from the drugs being developed by Vivus and Orexigen because, according to Defendants, lorcaserin was purportedly *both* safe and effective.

3. The Individual Defendants knew of the Rat Study results, and received and/or had access to data concerning lorcaserin, including the results of the Rat Study.

30. As noted above, Arena was required to conduct a long-term study of potential carcinogenesis relating to lorcaserin, including the Rat Study. Carcinogenicity studies, like the Rat Study, are highly relevant to humans because they are designed to approximate results of lifetime use of a drug in humans and to detect tumor risks in humans.

31. Pursuant to FDA protocols, during a carcinogenicity study, rats are observed on a daily basis for signs of departure from normal activity, morbidity and mortality. If tumors develop, the time of onset, location, dimensions, appearance and progression are recorded.

B. Defendants' Rat Study Shows Lorcaserin Causes Tumors and is Carcinogenic.

1. Arena's Rat Study Reveals to Defendants Alarming Findings.

32. By February 2007, the Lorcaserin Team learned that the Rat Study showed lorcaserin caused tumors in rats, including malignant mammary (breast) tumors in both male and female rats, malignant astrocytoma (brain cancer), squamous carcinomas of the subcutis (skin cancer), malignant schwannomas (cancer of connective tissue surrounding nerves or nerve sheath tissue), liver and thyroid.

33. According to Confidential Informant 3 ("CI 3")³, at a meeting with David Unett ("Unett") in 2006 or 2007, Unett who at the time was Arena's Senior Director, Receptor Pharmacology & Screening, told CI 3 that "massive tumors in breast tissues in rats" were discovered. According to CI 3, Unett knew this because he had just left a meeting with the Lorcaserin Team that included Defendant Behan at which the findings of the ongoing Rat Study were discussed.

34. According to CI 3, updates on lorcaserin were discussed several times during this meeting and in subsequent meetings. CI 3 and other team members warned Unett that the "FDA is going to look into this" (cancer findings). Based on conversations with Unett, CI 3 believes that Arena executives withheld disclosing the cancer findings to the FDA "for several months, maybe longer." Further, CI 3 told Unett that even if the findings were not relevant to humans, "it still has to be

³ CI 3 was a Senior Manager in Arena's Pharmacology and Screening Department between 2000 and April 2009.

1 addressed to the FDA and investors”, who were going to “take a poor view of
2 where the data stands.” According to CI 3, Unett concurred and responded that
3 based on what he had learned at meetings with Arena executives, “the last thing
4 they (Arena executives) want to do is raise awareness about them” (cancer
5 findings).

6 **2. Defendants Inform the FDA of Lorcaserin’s Risks and the**
7 **FDA Directs Defendants to Provide Bi-Monthly Updates on**
8 **the Results of the Rat Study.**

9 35. On May 31, 2007, Defendants submitted a safety report informing the
10 FDA of increased mortality of female rats due to breast cancers and tumors
11 (mammary adenocarcinoma and fibroadenoma) at all doses of lorcaserin by week
12 55 of the ongoing Rat Study. Additionally, Defendants described a higher
13 incidence of brain cancer (astrocytoma). The cancer observed in the Rat Study was
14 unusual because cancer occurred very early in the Rat Study and the cancers
15 observed were aggressive.

16 36. Because cancer occurred at all doses, no margin of safety for lorcaserin
17 existed, and the results at 55 weeks therefore indicated that lorcaserin was
18 carcinogenic. Mammary tumors (mammary adenocarcinoma and fibroadenoma)
19 were of particular concern to the FDA because potential lorcaserin users—
20 overweight and obese women—were a group that was already at high risk for breast
21 cancer. Brain tumors (astrocytomas) were a concern to the FDA because
22 lorcaserin’s mechanism affects the central nervous system in the brain.

23 37. According to FDA protocols and procedures for NDAs, in order to
24 demonstrate that the tumors observed in the Rat Study were irrelevant to human
25 risk, a drug sponsor would have to demonstrate either a safety margin (*i.e.*, a
26 showing that the drug exposure level needed to cause the tumor in rodents is
27 substantially greater than human exposure at recommended dose), or a rodent-
28 specific mechanism.

1 38. According to Defendants, the *International Conference on*
2 *Harmonization of Technical Requirements for Registration of Pharmaceuticals for*
3 *Human Use*, to which the FDA is a party, and FDA Guidance, a safety margin
4 should be approximately 25 times clinical exposure.

5 39. According to Dr. Coleman's Deputy Division Director Summary
6 Review, based on the Rat Study data, the FDA's Division of Metabolism and
7 Endocrinology Products ("DMEP") and Dr. Fred Alavi, the FDA's lead reviewer,
8 believed that lorcaserin was carcinogenic and that no safety margin had been
9 demonstrated, and that the Rat Study was relevant to humans.

10 40. During his discussions within DMEP on and around June 20, 2007,
11 Dr. Alavi notified the FDA clinical team that interim histological examination of
12 rats that died prematurely during a 2-year carcinogenicity study revealed the
13 development of astrocytomas in 2 mid-dose animals and 3 high-dose animals, facts
14 that show Dr. Alavi understood the Rat Study's adverse results were relevant to
15 human risk.

16 41. Representatives of the FDA corresponded with Defendants through
17 letters on June 28, 2007 and August 29, 2007 about the Rat Study's adverse results
18 and required Defendants' to warn humans participating in the lorcaserin clinical
19 trials of the mammary and brain cancer risks that were observed in the Rat Study—
20 red flags that put Defendants on notice that the FDA believed that the Rat Study
21 was relevant to humans.

22 **3. Defendants Hypothesize that Lorcaserin's Mode of Action**
23 **Causes an Increase in Prolactin, a Known Carcinogen in**
24 **Rats.**

25 42. In mid-2007, Defendants hypothesized that the Rat Study's adverse
26 results were caused by increases serum prolactin levels based on studies of other
27 drugs (the "Prolactin Hypothesis"). The Prolactin Hypothesis was based on
28 academic studies involving drugs unrelated to lorcaserin, that caused an increase in

1 prolactin and caused tumors in rats, a mechanism that arguably was not relevant to
2 humans.

3 43. The FDA told Defendants that they needed to provide supporting data
4 that showed lorcaserin caused an increase in prolactin in rats. Defendants, as
5 proponents of the Prolactin Hypothesis, knew that they would have to obtain data
6 that demonstrated lorcaserin's mechanism mode of action caused an increase in
7 prolactin in order to demonstrate the Rat Study's adverse results were not relevant
8 to humans.

9 44. Between July 3, 2007 and December 19, 2008, Defendants' conducted
10 six mechanistic studies to test the Prolactin Hypothesis.

11 45. In mid-2007, according to Confidential Informant 4 ("CI 4")⁴, CI 4
12 was told by Barbara Koozer ("Koozer"), Arena's Purchasing Director that
13 Defendant Arena's Chief Financial Officer Robert E. Hoffman ("Hoffman") stated
14 "they are trying to work on this cancer thing with the rats." Koozer told her team
15 and CI 4 to "cross their fingers."

16 **4. The FDA Requires Defendants to Send Bi-Monthly Updates**
17 **on the Rat Study's Results.**

18 46. Starting in September 2007, the DMEP and Defendants exchanged
19 numerous communications related to the nonclinical tumor data and the assessment
20 of serum prolactin levels, adverse events related to hyperprolactinemia, and breast
21 cancer risk, in subjects taking part in the ongoing clinical trials.

22 47. The high incidence of mortality and palpable tumors in female rats
23 observed during the course of the Rat Study, as well as the incidents of brain
24 cancer, prompted the FDA in September 2007 to direct that Defendants provide bi-
25 monthly updates to the FDA regarding the incidence of observed tumors in the Rat
26 Study, including survival and tumor incidence.

27 ⁴ CI 4 was a Purchasing Assistant at Arena from July 2006 through February 2009.
28

1 48. This direction by the FDA for bi-monthly updates was very unusual
2 and was not part of the FDA's normal and customary process for new drug
3 approval. As Defendant Lief admitted after the Class Period, Arena's bi-monthly
4 updates to the FDA were highly unusual and not part of the normal process with the
5 FDA.

6 49. The bi-monthly updates were reviewed by the FDA and the findings
7 were periodically discussed with the FDA's Executive Carcinogenicity Assessment
8 Committee (eCAC).

9 50. The FDA considered the Rat Study's findings relevant to humans.
10 According to CI 1 and FDA records, at least 10 carcinogenicity updates were sent
11 by Defendants to the FDA between September 2007 and March 2009.

12 51. The FDA's request for bi-monthly updates put the Defendants on
13 notice and was a red flag that the FDA had concerns about the findings of breast,
14 brain and other tumors in the Rat Study and that they were relevant to humans.

15 52. In October 2007, through conversations with Shanahan, CI 2 learned
16 of tumor findings during the Rat Study and that Arena senior management had
17 discussions with the FDA about the Rat Study. According to CI 2, the findings of
18 the ongoing Rat Study revealed unusual toxicology findings of tumors.

19 **5. The Ongoing Rat Study Results Reveal Increases in Tumors**
20 **and Cancer.**

21 53. By March 2008, week 96 of the Rat Study had been reached. The
22 number of deaths and the incidence of malignant and benign mammary tumors
23 *increased* at all doses of lorcaserin in each bi-monthly update, and therefore there
24 was no margin of safety. This was reported to the FDA by Defendants.

25 54. Based on Dr. Alavi's report and Dr. Coleman's report, Defendants'
26 March 2008 bi-monthly update to the FDA set off alarm bells at the FDA because
27 cancer and mortality materially increased at all doses, and as the dose increased, so
28 did mortality and cancer. The increase in cancer found in the ongoing Rat Study

1 concerned the FDA and the FDA directed that Defendants attend a special meeting
2 with the FDA in Silver Spring, Maryland.

3 55. On April 9, 2008, members of the Lorcaserin Team, including
4 Defendants Shanahan, Behan, and Anderson, as well as Brunswick (a senior Arena
5 executive who reported to Defendant Lief), met with the FDA in Silver Spring,
6 Maryland for the sole purpose of discussing the FDA's concerns about the Rat
7 Study's adverse results and its nexus to human risk.

8 56. Further, at that meeting, Defendants Shanahan, Behan, and Anderson,
9 as well as Brunswick were informed that the FDA continued to believe that the Rat
10 Study's adverse results were relevant to humans, and required Defendants to
11 monitor Arena's clinical trials for risks observed in the Rat Study, another red flag
12 to Defendants that showed the FDA believed that there was a nexus between the
13 Rat Study's adverse results and human risk.

14 57. At this juncture, all the evidence indicated that lorcaserin was
15 carcinogenic and Defendants had failed to establish a margin of safety for
16 lorcaserin. The FDA told Defendants that data supporting the Prolactin Hypothesis
17 were required to dispel the FDA's concern that the Rat Study was relevant to
18 humans.

19 58. In addition to the mechanistic studies that Defendants were conducting
20 in hopes of supporting the Prolactin Hypothesis, the FDA requested a draft report of
21 the Rat Study as soon as possible.

22 59. Thus by April 9, 2008, Defendants were on notice that the FDA put the
23 burden on Defendants to demonstrate the Prolactin Hypothesis with supporting data
24 that showed the lorcaserin caused an increase in prolactin in rats.

25 60. Further, Defendants were on notice that without such data supporting
26 the Prolactin Hypothesis, they could not demonstrate that the mode of action that
27 caused the tumors in the Rat Study was irrelevant to human safety.
28

61. According to CI 2, in mid-2008, Defendants Anderson, Shanahan, Behan, and Brunswick as well as other Arena employees, including CI 2, met with FDA officials at the FDA headquarters in Silver Spring, Maryland to discuss the lorcaserin NDA at which one of two topics on the agenda was the ongoing Rat Study.

62. In or around October 2008, according to Confidential Informant 5 (“CI 5”)⁵, CI 5 learned of the Rat Study and the tumor findings from conversations with Koozer.

63. In January 2009, CI 5 was instructed by Koozer that Lief and CFO Hoffman gave the directive to all finance departments, including purchasing, to suspend any future purchases unless absolutely necessary. Based on discussions with Koozer and other Arena employees, CI 5 believed that management’s directive to halt purchases was directly connected to growing uncertainty on whether lorcaserin would ever make it to market.

64. For the first few months on 2009, CI 5 had “nothing to do”. There was mounting concern within the Company that layoffs were forthcoming.

6. Defendants’ Mechanistic Studies on Rats Fail to Show Lorcaserin Causes an Increase in Prolactin.

65. On February 3, 2009, with the Rat Study and the mechanistic studies completed, Brunswick, on behalf of Defendants, submitted a draft of the final Rat Study to the FDA, per the FDA’s request at the April 9, 2008 meeting.

66. Defendants’ mechanistic studies did not show an increase in prolactin as required by the FDA. In Defendants’ mechanistic studies on rats, haloperidol, an antipsychotic drug that is a serotonin agonist, like lorcaserin, increased prolactin levels in male rats by 15 fold and in females by as much as 80 fold, which were a sustained and robust increase in prolactin.

⁵ CI 5 was a Purchasing Manager for Arena from July 2002 through April 2009.

1 67. In sharp contrast, Defendants' mechanistic studies showed that
2 lorcaserin had *no effect* on serum prolactin in female rats, and *reduced* prolactin in
3 males by 50% in the rat carcinogenicity study. Further, the single and multiple
4 doses of lorcaserin (10 to 100 mg/kg) consistently failed to show a significant rise
5 in serum prolactin levels in female rats at any time period.

6 68. Thus, by February 3, 2009, Defendants knew that they failed to
7 develop data required by the FDA to substantiate the Prolactin Hypothesis as
8 required by the FDA.

9 69. Furthermore, the Rat Study final results showed no safety margin was
10 identified for the mammary tumors, and the safety margin for brain tumors was
11 uncertain. The Rat Study data that Defendants submitted to the FDA showed that
12 tumors in female rats occurred at *all* doses and increased multiple tumor types in
13 male rats, and that tumors occurred early and were very aggressive, leading to
14 premature deaths.

15 70. In females, the incidence of mammary fibroadenoma alone, or in
16 combination with adenocarcinoma, were increased at every dose level at
17 statistically significant amounts with no safety margin. The incidence of
18 adenocarcinoma in low dose and mid-dose females was higher than control and
19 historical background. In males, the combined incidence of mammary
20 fibroadenoma and adenocarcinoma was also significantly increased in mid-dose and
21 high-dose groups.

22 71. Without data showing lorcaserin caused an increase in prolactin, and
23 with no margin of safety, Defendants did not have evidence to show that the Rat
24 Study's adverse results were irrelevant to humans.

25 72. In April 2009, CI 5 was called into Hoffman's office along with 10-12
26 finance staff and was informed by Hoffman that their respective positions at Arena
27 were being eliminated. Based on discussions with other Arena employees, CI 5
28

1 believed that the layoffs were directly linked to management's concerns
2 surrounding the future of lorcaserin.

3 73. On July 8, 2009, Arena issued 12,500,000 shares of its common stock
4 at a public offering price of \$4.17 per share for proceeds of over \$52.1 million.

5 74. On August 9, 2009, Defendants Shanahan, Anderson, Behan and
6 Brunswick conducted a pre-NDA meeting with the FDA to discuss lorcaserin at
7 which representatives of the FDA told Defendants that breast neoplasms, an
8 adverse event of special interest, should be analyzed in the NDA. The FDA's
9 continued discussion of breast neoplasm was a red flag to Defendants that the FDA
10 continued to have concerns that lorcaserin presented a risk to humans and that
11 Defendants had not demonstrated that adverse tumors observed in the Rat Study
12 were irrelevant to human use.

13 75. On September 18, 2009, on a conference call with investors,
14 Defendant Anderson represented to investors on a conference call that "[w]e've, I
15 think, put together pretty much all of the data that we now need for this NDA. *We*
16 *have favorable results on everything that we've compiled so far. . . .*" (emphasis
17 added).

18 76. This statement, having been made by the Company's Vice President
19 for Lorcaserin Development and the person in charge of putting together the NDA,
20 falsely communicated to investors that Arena had checked all the boxes that it
21 needed to for its NDA submission. But Defendants had not checked all the boxes
22 and Anderson knew it.

23 77. Anderson knew that the FDA required Defendants to substantiate the
24 Prolactin Hypothesis with data that showed an increase in prolactin. Anderson
25 further knew that Defendants had not collected all of the required scientific data for
26 lorcaserin's NDA to demonstrate that lorcaserin was safe for use in humans as
27 required by the FDA. Accordingly, it was an extreme departure from ordinary
28

standards of conduct for Anderson to represent to investors that all of the data regarding lorcaserin was favorable, when internally, she knew it was not.

78. On December 18, 2009, Brunswick, on behalf of Arena, submitted the NDA for lorcaserin. The NDA included the final Rat Study data.

79. Defendants NDA stated that Defendants failed to show that lorcaserin caused an increase in prolactin as requested by the FDA:

[t]he mammary gland lobular hyperplasia with atypia, benign and malignant mammary tumors *were primarily prolactin negative*. There *was no correlation* between incidence of mammary gland prolactin stain and the incidence of pituitary gland prolactin stain in females at all dose levels.

(Emphasis added.)

80. Thus, Defendants admitted in the NDA that they did not meet their burden to show that lorcaserin caused an increase in prolactin in rats as required by the FDA. Defendants were not successful in establishing the Prolactin Hypothesis or any other mechanism for the mammary tumor formation induced by lorcaserin as observed in the Rat Study. Therefore, it was not possible to dismiss the mammary tumors as irrelevant to humans based on the data in the NDA and Defendants knew this.

81. Further, in the lorcaserin NDA, Defendants presented the FDA with an analysis of the Rat Study's mammary tumors that combined cancer data with non-cancer data, a standard practice used by the FDA and NIH. Like Defendants' interim Rat Study data, the final, combined data that Defendants submitted with the NDA showed an unusually high and dose dependent incidence of mammary tumors in female rats. No safety margin was identified for the mammary tumors.

82. With respect to brain cancer (astrocytomas), Defendants did not conduct any studies and therefore Defendants had no data to support their assertion that the astrocytoma findings in rats were not relevant to humans.

1 83. Finally, the final Rat Study data showed the tumor classification
2 changed several times by the time of the final Rat Study, which reduced confidence
3 in the integrity of the data.

4 **7. Defendants Mislead Investors Prior to the September 16,**
5 **2010 Advisory Committee Meeting.**

6 84. After Defendants filed the lorcaserin NDA, investors repeatedly asked
7 Defendants about the status of the NDA application and about any FDA concerns
8 with lorcaserin. Despite knowing of the material, negative results of the Rat Study,
9 that the FDA was concerned about the results and their applicability to humans, and
10 Defendants failed to show lorcaserin caused an increase in prolactin. Defendants
11 misled investors by failing to disclose these material risks.

12 85. On March 8, 2010, while knowing of the Rat Study and its relevance
13 to humans and the FDA's concerns about such, or at least ignoring all of these risks
14 with deliberate recklessness, Defendants caused Arena to sell approximately
15 8.3 million Arena shares at an artificially inflated price (\$2.96 per share) for
16 proceeds of approximately \$24.5 million.

17 86. Defendants' repeated lies concerning lorcaserin's safety misled
18 investors in Arena stock, including sophisticated research analysts. On May 7,
19 2010, a Cowen & Co. analyst observed that lorcaserin's "**Modest Efficacy Plus**
20 **Clean Safety Carves Out Niche**".

21 87. On June 2, 2010, Arena disclosed that it had been notified that the
22 FDA Advisory Committee would meet publicly on September 16, 2010 to consider
23 whether to recommend lorcaserin's approval to the FDA.

24 88. Defendants knew that the Rat Study and its relevance to humans and
25 the FDA's concerns about the Rat Study were issues for the Advisory Committee.
26 Notably, Arena retained Dr. Gary Williams ("Dr. Williams"), a New York Medical
27 College Pathologist with a focus on the mechanisms of carcinogenesis and the
28 metabolic and genetic effects of chemical carcinogenesis, to present a slide

1 presentation to the Advisory Committee, a fact indicating that Defendants knew
2 that the results of the Rat Study were materially important to the FDA and would be
3 important to the Advisory Committee's and FDA's consideration of Arena's NDA
4 for lorcaserin.

5 89. On June 2, 2010, an Oppenheimer analyst stated "we do not see
6 negative read-through for the lorcaserin NDA . . . we believe lorcaserin's clean
7 safety profile in trials to date, including minimal cardiovascular side effects, should
8 sway the [Advisory Committee] panel to recommend approval . . .".

9 90. Defendants knew that the FDA continued to have concerns about the
10 integrity of the Rat Study data. At the request of the Dr. Alavi, on June 7-11, 2010,
11 the FDA's Division of Scientific Inspections inspected Arena and a facility where
12 the Rat Study was conducted. The inspections concerned, in part, the change in
13 tumor classification in the Rat Study, and the quality and integrity of the data
14 compiled in the Rat Study.

15 91. Dr. Alavi sought the inspection in order to examine "nearly
16 everything" in the Rat Study "from brain to breast tumor incidence to how the drug
17 levels were measured."

18 92. As late as August 3, 2010, Defendant Shanahan represented in a
19 conference call with investors and research analysts that he did not expect any
20 "surprises" at the September 16 FDA Advisory Committee meeting. But,
21 internally, Defendants knew about the negative results of the Rat Study, the FDA's
22 concern about those results, and that Defendants' failed to show that lorcaserin
23 caused an increase in prolactin in rats as required by the FDA, and therefore had not
24 demonstrated that the Rat Study was irrelevant to humans. Indeed, Defendants
25 were preparing for the September 16, 2010 Advisory Committee meeting by
26 preparing slides and statements to address the negative results of the Rat Study.

27
28

93. On August 5, 2010, Defendants caused Arena to sell 9 million shares of Arena common stock at an artificially inflated price (\$6.70 per share) for proceeds of \$60 million.

94. As late as August 2010, based on Defendants' false representations, analysts continued to believe that lorcaserin was safe: "lorcaserin appears relatively well positioned with two years of controlled safety data, no clear adverse safety signal, and a robust clinical trial design" (J.P. Morgan); "We believe that lorcaserin's profile is fundamentally approvable." (Jefferies); and "We expect Additional Upside on a Positive Lorcaserin Ad Com Mtg The company reported that no new issues have emerged ahead of the 9/16 FDA Ad Com meeting for lorcaserin . . . **Safety is lorcaserin's defining characteristic, in our view.**" (Oppenheimer) (emphasis added).

8. The Truth Begins to be Revealed.

95. On September 14, 2010, the FDA Briefing Document, the negative results from the Rat Study, the FDA's concern about the Rat Study's adverse results, and Defendants' failure to show lorcaserin caused an increase in prolactin as required by the FDA, causing Arena's stock price to decline.

96. On September 14, 2010, the price of Arena shares declined from a close on September 13, 2010 of \$6.85 per share, to close at \$4.13 per share, a decline of \$2.72 per share or approximately 40% on heavy volume.

97. Investors and analysts, without exception, were shocked and surprised:

- September 14, 2010 J.P. Morgan ALERT: "**The biggest surprise is a preclinical cancer signal.** We (and investors we've spoken with this morning) were caught off guard by the question relating to lorcaserin-related tumors in rats. In the FDA's question alone, the agency specifically notes that the neoplasms involve breast, brain, peripheral nerve, skin, and subcutis. . . ." (emphasis in original);
- September 14, 2010 Jefferies Analyst Report: "The biggest surprise in the briefing documents is the finding of preclinical cancers";

- September 14, 2010 Oppenheimer Analyst Report – **“We see the FDA's rejection of ARNA's explanation of pre-clinical cancers in rats as a significant concern”** (emphasis in original);
- September 15, 2010 Canaccord Analyst Report: **“Cancer risk in the briefing document was unforeseen; presents another challenge for lorcaserin, especially since it is a new chemical entity”** (emphasis added); and
- September 15, 2010 Summer Street Analyst Report: **“Yesterday we were completely blindsided by preclinical carcinogenicity data from the two year lorcaserin animal study Most importantly, we do not believe Arena will be able to produce preclinical data and/or design a post-approval trial/registry to rule out a breast cancer risk”** (emphasis added).

98. On September 16, 2010, the Advisory Committee met and heard statements from FDA scientist Dr. Fred Alavi, who authored a report on the Rat Study that was part of the FDA Briefing Document, and Dr. Williams, on behalf of Arena, who gave a presentation concerning the Rat Study.

99. After hearing statements and presentations from Arena, FDA scientists, and others, the Advisory Committee voted 9-5 against recommending approval of lorcaserin, in material part, because of safety concerns raised by the Rat Study and Defendants failure to show that the Rat Study was not relevant to humans.

100. On September 17, 2010, Lief and Shanahan participated in a conference call with investors and research analysts to discuss the Advisory Committee meeting and Lief made the following admissions:

Karen Jay – JPMorgan – Analyst

I had a question about the pre-clinical cancer signals. I was wondering when—I guess you're aware of them pretty early and the cancer, you had potentially underestimated the FDA's concern on that topic.

Jack Lief – Arena Pharmaceuticals Inc. - President & CEO

Well, what we can say, as we stated in our presentation yesterday, is that *when we learned of the data, we promptly discussed it with the FDA.*

* * *

Bill Tanner – *Lazard Capital Markets – Analyst*

And just—and I don't know if you were there, I'm sure you would have been debriefed. How much of an in depth discussion was it? How much of it was back and forth? You may not wish to comment on it, but was there any kind of inkling, any kind of thought that perhaps the FDA reviewers would have been in agreement? Or are they just cursorily looking at your data, making a cursory decision to proceed without any real hard analytical processes being done?

Jack Lief – *Arena Pharmaceuticals Inc. – President & CEO*

Yes, you know we can't provide more details on that at this time. But I appreciate your question.

(Emphasis added.)

9. The FDA Rejects Arena's NDA.

101. On October 23, 2010, Arena disclosed that it received a Complete Response Letter ("CRL") from the FDA that indicated that the FDA completed its review of the NDA and the FDA could not approve Arena's NDA "in its present form." The CRL, according to Arena, outlined the reasons for the FDA's decision, including the following:

The non-clinical issues identified by the FDA included diagnostic *uncertainty in the classification of mammary masses in female rats, unresolved exposure-response relationship for lorcaserin-emergent mammary adenocarcinoma, and unidentified mode of action and unclear safety margin for lorcaserin-emergent brain astrocytoma.*

(Emphasis added.)

102. Further, the FDA requested that Defendants provide the following evidence to address the FDA's concern that the Rat Study was relevant to humans—concerns that the Defendants knew about by the beginning of the Class Period: (1) provide a valid explanation for the mysterious reclassification of tumors between week 96 and week 104 of the Rat Study ("provide a detailed accounting of all slides prepared from female rats that contributed to mammary tumor incidence data in each update to the FDA and to the final study report; in consultation with the FDA, identify an independent pathologist or group of pathologists to re-

1 adjudicate all mammary and lung tissues (neoplastic and nonneoplastic lesions)
 2 from all female rats”); and (2) show that the Rat Study is not relevant to humans
 3 (“demonstrate that the apparent increase in aggressiveness of adenocarcinoma in
 4 rats administered lorcaserin is reasonably irrelevant to human risk assessment,” and
 5 “provide additional data/information regarding the distribution of lorcaserin to the
 6 central nervous system in animals and human subjects that would clarify or provide
 7 a better estimate of astrocytoma exposure margins.”)

8 103. On October 25, 2010, Lief, Shanahan and Behan conducted a
 9 conference call with investors and research analysts concerning the CRL and Lief
 10 made the following statements:

11 **Bill Tanner** – *Lazard Capital Markets – Analyst*

12 Can you help us understand a little bit the first sentence
 13 on the fourth paragraph about detailed accounting of
 14 slides prepared? Is there a snafu here, or what's the gist of
 15 that? It says, provide a detailed accounting of all
 16 slides prepared from female rats [contribute] to
 17 [mammary] tumor incidence, and each update to FDA in
 18 the final report. Is there an accounting issue with the
 19 slides or with the data?

20 **Jack Lief** – *Arena Pharmaceuticals – President & CEO*

21 As the FDA indicated in their briefing document, what
 22 they were concerned about were the changes between the
 23 initial readings by a single veterinary pathologist as part
 24 of the normal process, and then the final peer-reviewed,
 25 adjudicated diagnoses for each of these slides. *We, at the*
 26 *FDA's request, got into an out-of-process type of*
 27 *procedure whereby we updated, every two months, the*
 28 *Agency with the results...* some of these diagnoses
 changed from when the final peer review process with—I
 believe that included three veterinary pathologists
 reviewed the slides and came to a consensus view on
 them. So that’s how that changed. Normally, the only data
 submitted to the Agency would be the final peer reviewed
 data

[Question:] I was wondering if the panel of three vet
 pathologists that you used to review the mammary tumors
 at the end of the study were also retained to go back and
 review the earlier slides. Did they indeed come up with
 different diagnoses than the earlier reports?

Jack Lief – *Arena Pharmaceuticals – President & CEO*

The process was that we had a single pathologist ma[k]e
the initial reads as the study was ongoing. At the request

1 *of the FDA we provided these data every two months as*
 2 *the study was unfolding. And then the normal process is*
 3 *you never submit those data. Everyone gets together and*
 4 *makes a final reading on these tissues, and then that's*
what gets accounted for in the study report. So it's just
the change from an initial reading from one pathologist.
And so that's the process.

5 **Steve Byrne** – Banc of America – Analyst

6 Okay, and just an overall question about the rat study.
 7 *Almost half of the female rats in the control study had*
 8 *mammary tumors, and that just seems to be outside the*
historical range. Do you have any hypotheses as to why
there was such prevalence of rat tumors in the females?

9 **Jack Lief** – Arena Pharmaceuticals – President & CEO

10 Yes, we *don't*. It was slightly—I believe the upper range
 11 on the lab was around 40%, and we were, I think, around
 12 43% or 44% in the control group. So outside the range,
 13 very high FDN. But no, we *don't have an explanation for*
 14 *that. . . .*

15 **Jim Birchenough** – Barclays Capital – Analyst

16 I just wanted to follow up on the pre-clinical data and the
 17 request by FDA for the slides. How difficult is it to
 18 distinguish between adenocarcinoma and fibroid
 19 adenoma? *And I ask the question because, between week*
 20 *96 and week 104 it seemed like there were several*
 21 *animals that were reclassified, or at least that was the*
 22 *question that FDA raised in their briefing documents.*
 23 And I just wanted confirmation that in animals that were
 24 reclassified as fibroadenoma from adeno, they had no
 25 evidence of lung metastases. And then I have a follow-up.

26 **Jack Lief** – Arena Pharmaceuticals – President & CEO

27 We'll have to review all those data, but we have the data,
 28 and we will review it. . . .

(Emphasis added.)

104. On January 27, 2011, after the close of trading, in a report filed with
 the SEC on Form 8-K, Arena disclosed that the FDA required the Company to
 perform additional long-term studies to demonstrate lorcaserin was safe for
 humans:

[T]he FDA requested that we consider performing a
 separate 12-month study in female rats that would test
 whether transient prolactin elevation mediated by short-
 term exposure to lorcaserin can result in mammary tumors
 in rats

1 105. On January 28, 2011, the price of Arena's common stock closed at
2 \$1.63 per share, a decline of \$0.37 per share or approximately 19% from the closing
3 price on January 27, 2011, on heavy volume.

4 **C. Defendants' Materially False and Misleading Statements and**
5 **Material Omissions.**

6 106. On May 11, 2009, Defendants caused Arena to file its quarterly report
7 with the SEC on Form 10-Q for the period ended March 31, 2009. The 10-Q was
8 signed by Lief and represented to investors *for the first time* that "[t]o date, long-
9 term safety and efficacy have not yet been demonstrated in clinical trials for any of
10 our drug candidates, *except lorcaserin*." (Emphasis added.)

11 107. Lief's representations communicated to investors that Defendants had
12 demonstrated that lorcaserin was safe for use in humans. But this was not true
13 because Defendants did not have data to support the Prolactin Hypothesis. As
14 alleged above, Lief, as a member of the Lorcaserin Team, knew through
15 correspondence and meetings with the FDA that the FDA required Defendants to
16 show that lorcaserin caused an increase in prolactin in rats in order to show that the
17 Rat Study's adverse results were not relevant to humans. Lief also knew that by the
18 beginning of the Class Period, Defendants' mechanistic studies on rats failed to
19 substantiate the Prolactin Hypothesis with supporting data showing an increase in
20 prolactin levels in rats, and therefore Defendants had failed to show that the Rat
21 Study was not relevant to humans. In fact, Defendants' mechanistic studies showed
22 that lorcaserin had *no effect* on serum prolactin in female rats, and *reduced*
23 prolactin in males by 50% in the rat carcinogenicity study. Further, the single and
24 multiple doses of lorcaserin (10 to 100 mg/kg) consistently failed to show a
25 significant rise in serum prolactin levels in female rats at any time period.

26 108. In light of these facts that were known to Lief at that time, it was an
27 extreme departure from ordinary standards of conduct for Lief to represent that
28 Defendants had demonstrated lorcaserin was safe for use in humans.

1 109. On September 18, 2009 on a conference call with investors.
2 Defendant Anderson represented to investors that “[w]e’ve, I think, put together
3 pretty much all of the data that we now need for this NDA. We have favorable
4 results on everything that we’ve compiled so far. . . .”

5 110. This statement, having been made by the Company’s Vice President
6 for Lorcaserin Development and the person in charge of putting together the NDA,
7 falsely communicated to investors that Arena had checked all the boxes that it
8 needed to for its NDA submission. But Defendants had not checked all the boxes
9 and Anderson knew it. As alleged above, Anderson knew through correspondence
10 and meetings with the FDA that the FDA required Defendants to show that
11 lorcaserin caused an increase in prolactin in rats in order to show that the Rat
12 Study’s adverse results were not relevant to humans. Anderson also knew that by
13 the beginning of the Class Period, Defendants’ mechanistic studies on rats failed to
14 substantiate the Prolactin Hypothesis with supporting data showing an increase in
15 prolactin levels in rats, and therefore Defendants had failed to show that the Rat
16 Study was not relevant to humans. In fact, Defendants’ mechanistic studies showed
17 that lorcaserin had *no effect* on serum prolactin in female rats, and *reduced*
18 prolactin in males by 50% in the rat carcinogenicity study. Further, the single and
19 multiple doses of lorcaserin (10 to 100 mg/kg) consistently failed to show a
20 significant rise in serum prolactin levels in female rats at any time period.

21 111. Knowing these facts at that time, it was an extreme departure from
22 ordinary standards of conduct for Anderson to represent that “all of the data”
23 regarding lorcaserin was “favorable,” when internally she knew at that time the
24 mechanistic studies were not favorable, and in fact, had failed to demonstrate an
25 increase in prolactin as required by the FDA and therefore failed to demonstrate
26 with supporting data that the Rat Study’s adverse results were not relevant to
27 humans.
28

1 112. The September 18, 2009 press release quoted Shanahan as stating the
2 following:

3 These results support lorcaserin's potential to meet the
4 need for a safe, effective and well-tolerated weight loss
5 medication. There are only two drugs that are approved
6 by the FDA for long-term treatment, and new mechanistic
and better tolerated approaches could greatly improve the
treatment of patients who are obese or significantly
overweight.

7 113. This statement, having been made by the Company's Chief Medical
8 Officer and who, along with Anderson, was responsible for collecting and
9 analyzing all preclinical/animal and clinical data, including the Rat Study data, for
10 lorcaserin's NDA, falsely represented to investors that lorcaserin's "new
11 mechanism" was safe for use in humans. But this was not true. As alleged above,
12 Shanahan knew through correspondence and meetings with the FDA, that the FDA
13 required Defendants to show that lorcaserin caused an increase in prolactin in rats
14 in order to show that the Rat Study's adverse results were not relevant to humans.
15 Shanahan also knew that by the beginning of the Class Period, Defendants'
16 mechanistic studies on rats failed to substantiate the Prolactin Hypothesis with
17 supporting data showing an increase in prolactin levels in rats, and therefore
18 Defendants had failed to show that the Rat Study was not relevant to humans. In
19 fact, Defendants' mechanistic studies showed that lorcaserin had *no effect* on serum
20 prolactin in female rats, and *reduced* prolactin in males by 50% in the rat
21 carcinogenicity study. Further, the single and multiple doses of lorcaserin (10 to
22 100 mg/kg) consistently failed to show a significant rise in serum prolactin levels in
23 female rats at any time period.

24 114. As such, it was an extreme departure from ordinary standards of
25 conduct for Shanahan to falsely represent that lorcaserin's "new mechanism" was
26 safe for use in humans.

115. Also on September 18, 2009, Lief made the following statements regarding Defendants' known "pre-clinical experience" with lorcaserin's "mechanism":

Keep in mind that the receptor, the target that lorcaserin goes after is not found in the heart basically. So the 2C receptor is largely central in the brain. And so that's very consistent, the mechanism is very consistent with the clinical as well as pre-clinical experience that we know for lorcaserin. So we're excited to be able to support all of these hypotheses regarding having a selective drug that only addresses this hypothalamic target.

116. Lief's representations about Defendants' "preclinical experience" with lorcaserin communicated to investors that Defendants' nonclinical studies of lorcaserin's mechanism supported all of their hypotheses, showed that lorcaserin safely targeted the hypothalamic part of the brain, and did not negatively affect humans. But this was not true and Lief knew it because the FDA requested data to support the Prolactin Hypothesis and Defendants did not have such supporting data. Lief's false representation was an extreme departure from ordinary standards of conduct because, at the time Lief made the statement to investors, he knew that the Rat Study's adverse results included brain cancer. Further, Lief knew that Defendants' mechanistic studies on rats failed to substantiate the Prolactin Hypothesis with supporting data showing an increase in prolactin levels in rats, and therefore Defendants had failed to show that the Rat Study's adverse results were not relevant to humans. In fact, Defendants' mechanistic studies showed that lorcaserin had *no effect* on serum prolactin in female rats, and *reduced* prolactin in males by 50% in the rat carcinogenicity study. Further, the single and multiple doses of lorcaserin (10 to 100 mg/kg) consistently failed to show a significant rise in serum prolactin levels in female rats at any time period.

117. Anderson's, Lief's and Shanahan's false representations on September 18, 2009 caused Arena's stock price to increase from \$4.39 per share at

1 the opening of trading, to close at \$5.18 per share at the close of trading, an increase
2 of approximately \$0.79 per share, or 18%.

3 118. On September 21, 2009, based on the information about lorcaserin
4 provided by Defendants on September 18, 2009, Zach's Equity Research stated that
5 lorcaserin's safety profile was "outstanding," and a research report by Summer
6 Street stated that lorcaserin's safety results was "impressive."

7 119. On November 9, 2009, Defendants caused Arena to issue a press
8 release, and caused Arena to file its quarterly report for the quarter ended
9 September 30, 2009 with the SEC on Form 10-Q, which was signed by Lief, that
10 repeated the representation that "[t]o date, long-term safety and efficacy have not
11 yet been demonstrated in clinical trials for any of our drug candidates, **except**
12 **lorcaserin.**" (Emphasis added.)

13 120. Again, Lief's representations communicated to investors that
14 Defendants had demonstrated that lorcaserin was safe for use in humans. But this
15 was not true because Defendants did not have data to support the Prolactin
16 Hypothesis. As alleged above, Lief, as a member of the Lorcaserin Team, knew,
17 through correspondence and meetings with the FDA, that the FDA required
18 Defendants to show that lorcaserin caused an increase in prolactin in rats in order to
19 show that the Rat Study's adverse results were not relevant to humans. Lief also
20 knew that by the beginning of the Class Period, Defendants' mechanistic studies on
21 rats failed to substantiate the Prolactin Hypothesis with supporting data showing an
22 increase in prolactin levels in rats, and therefore Defendants had failed to show that
23 the Rat Study was not relevant to humans. In fact, Defendants' mechanistic studies
24 showed that lorcaserin had ***no effect*** on serum prolactin in female rats, and ***reduced***
25 prolactin in males by 50% in the rat carcinogenicity study. Further, the single and
26 multiple doses of lorcaserin (10 to 100 mg/kg) consistently failed to show a
27 significant rise in serum prolactin levels in female rats at any time period.
28

121. In light of these facts that were then known to Lief, it was an extreme departure from ordinary standards of conduct for Lief to falsely represent that Defendants had demonstrated lorcaserin was safe for use in humans.

122. On a November 10, 2009 conference call with investors and research analysts, Defendants were specifically asked to identify any FDA concerns with lorcaserin. Shanahan falsely represented that “at the present time we don’t see safety signal to pursue”

123. It was an extreme departure from standards of ordinary conduct for Defendant Shanahan to represent that “at the present time we don’t see safety signal[s] to pursue”, when internally Shanahan knew at that time that Defendants’ mechanistic studies on rats did not show that lorcaserin increased prolactin in rats, and therefore Defendants failed to provide data supporting the Prolactin Hypothesis as required by the FDA. As such, Defendants had not provided the FDA with data required to show that the Rat Study’s adverse results were not relevant to humans. Shanahan’s representation communicated to investors that Defendants had checked all the boxes required for NDA approval. Again, Defendants had not checked all the boxes and Shanahan knew it.

124. On November 12, 2009, Defendants caused Arena to file a prospectus with the SEC on Form 424B3 relating to the resale, from time to time, of up to 28,000,000 shares of Arena common stock that incorporated by reference the false statements in the September 18, 2009 press release delineated above.

125. On December 22, 2009, Defendants caused Arena to issue a press release in which Shanahan falsely represented that “[b]ased on the robust data package we submitted to the FDA, lorcaserin has the potential to meet this need, offering patients the opportunity to achieve sustainable weight loss in a well-tolerated manner and improve their cardio metabolic health and quality of life.”

126. Shanahan’s representation that the “data package” was “robust” falsely represented to investors that all of the data collected by Defendants regarding

lorcaserin was favorable. But this was not true and Shanahan knew it. Shanahan knew that by the beginning of the Class Period, Defendants' mechanistic studies on rats failed to substantiate the Prolactin Hypothesis with supporting data showing an increase in prolactin levels in rats, and therefore Defendants had failed to show that the Rat Study was not relevant to humans. In fact, Defendants' mechanistic studies showed that lorcaserin had *no effect* on serum prolactin in female rats, and *reduced* prolactin in males by 50% in the rat carcinogenicity study. Further, the single and multiple doses of lorcaserin (10 to 100 mg/kg) consistently failed to show a significant rise in serum prolactin levels in female rats at any time period.

127. In light of the facts known to Shanahan at that time, it was an extreme departure from ordinary standards of conduct for Shanahan to falsely represent that the data submitted to the FDA with the lorcaserin NDA was "robust" and favorable, when internally Shanahan knew at that time of the Rat Study's adverse results and that he knew that the mechanistic studies failed to show that the Rat Study's adverse results were not relevant to humans as required by the FDA.

128. Similarly, Lief's representation on February 24, 2010, that the NDA data package, which included the Rat Study and the results of the mechanistic studies, included "excellent" safety data was materially false and misleading.

129. On March 8, 2010, Defendants caused Arena to file a prospectus supplement and accompanying prospectus pursuant to which Arena sold 8,278,432 shares of Arena common stock at a price of approximately \$2.96 per share, for a total purchase price of \$24.5 million (the "March 8 Prospectus Supplement").

130. The March 8 Prospectus Supplement incorporated by reference the false statements in the September 18, and December 22, 2009, press releases delineated above.

131. On March 12, 2010, Defendants participated in a conference call with investors and research analysts, and Lief made the following statements:

The FDA has said that there is sufficient data to review

lorcaserin on its merits. We have also had discussions and meetings around that. So while there can never be any guarantees on anything these days, we are reasonably confident, I'm reasonably confident that the FDA will review our current package as submitted in a scientific fashion.

Lorcaserin was so well tolerated, and *we don't see any safety signals that require special attention right now.*

(Emphasis added.)

132. Lief's representations that "[t]he FDA has said that there is sufficient data to review lorcaserin on its merits" and he did not "see *any* safety signals" falsely represented to investors that Defendants NDA included all required data for lorcaserin approval, but this was not true and Lief knew it.

133. As alleged above, Lief, as a member of the Lorcaserin Team, knew, through correspondence and meetings with the FDA, that the FDA required Defendants to show that lorcaserin caused an increase in prolactin in rats in order to show that the Rat Study's adverse results were not relevant to humans. Lief also knew that by the beginning of the Class Period, Defendants' mechanistic studies on rats failed to substantiate the Prolactin Hypothesis with supporting data showing an increase in prolactin levels in rats, and therefore Defendants had failed to show that the Rat Study was not relevant to humans. In fact, Defendants' mechanistic studies showed that lorcaserin had *no effect* on serum prolactin in female rats, and *reduced* prolactin in males by 50% in the rat carcinogenicity study. Further, the single and multiple doses of lorcaserin (10 to 100 mg/kg) consistently failed to show a significant rise in serum prolactin levels in female rats at any time period.

134. In light of these facts that were then known to Lief, it was an extreme departure from ordinary standards of conduct for Lief to falsely represent that Defendants had demonstrated lorcaserin was safe for use in humans.

135. On March 16, 2010, Defendants caused Arena to file the 2009 10-K. The 2009 10-K was signed by Lief and Behan, and stated, in part, the following:

Preclinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of a drug candidate, but rather to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the drug candidate's side effects at various doses and schedules. *To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our drug candidates, except lorcaserin.*

(Emphasis added.)

136. Lief's and Behan's representations communicated to investors that Defendants had "demonstrated" lorcaserin's "long-term safety" but this was not true. As alleged above, Lief and Behan, as members of the Lorcaserin Team, knew, through correspondence and meetings with the FDA, that the FDA required Defendants to show that lorcaserin caused an increase in prolactin in rats in order to show that the Rat Study's adverse results were not relevant to humans. Lief and Behan also knew that by the beginning of the Class Period, Defendants' mechanistic studies on rats failed to substantiate the Prolactin Hypothesis with supporting data showing an increase in prolactin levels in rats, and therefore Defendants had failed to show that the Rat Study was not relevant to humans. In fact, Defendants' mechanistic studies showed that lorcaserin had *no effect* on serum prolactin in female rats, and *reduced* prolactin in males by 50% in the rat carcinogenicity study. Further, the single and multiple doses of lorcaserin (10 to 100 mg/kg) consistently failed to show a significant rise in serum prolactin levels in female rats at any time period.

137. In light of these facts that were then known to Lief and Behan, it was an extreme departure from ordinary standards of conduct for Lief and Behan to represent that lorcaserin's mechanism was safe for use in humans.

138. On May 7, 2010, Defendants caused Arena to file its quarterly report for the quarter ended March 31, 2010 with the SEC on Form 10-Q. The May 7, 2010 was signed by Lief and stated repeated the false statements in the 2009 Annual Report.

1 139. Lief's representations communicated to investors that Defendants
2 "demonstrated" lorcaserin's "long-term safety" but this was not true and Lief knew
3 it because Defendants' mechanistic studies failed to show that the cancer observed
4 in the Rat Study was caused by a rat-specific mechanism.

5 140. As alleged above, Lief, as a member of the Lorcaserin Team, knew,
6 through correspondence and meetings with the FDA, that the FDA required
7 Defendants to show that lorcaserin caused an increase in prolactin in rats in order to
8 show that the Rat Study's adverse results were not relevant to humans. Lief also
9 knew that by the beginning of the Class Period, Defendants' mechanistic studies on
10 rats failed to substantiate the Prolactin Hypothesis with supporting data showing an
11 increase in prolactin levels in rats, and therefore Defendants had failed to show that
12 the Rat Study was not relevant to humans. In fact, Defendants' mechanistic studies
13 showed that lorcaserin had *no effect* on serum prolactin in female rats, and *reduced*
14 prolactin in males by 50% in the rat carcinogenicity study. Further, the single and
15 multiple doses of lorcaserin (10 to 100 mg/kg) consistently failed to show a
16 significant rise in serum prolactin levels in female rats at any time period.

17 141. In light of these facts that were then known to Lief, it was an extreme
18 departure from ordinary standards of conduct for Lief to represent that Defendants
19 had demonstrated lorcaserin was safe for use in humans.

20 142. On June 22, 2010, Defendants caused Arena to file a prospectus with
21 the SEC on Form 424B3 that incorporated by reference the false statements in the
22 2009 10-K, and the May 7, 2010 10-Q delineated above.

23 143. Also on August 3, 2010, Defendants participated a conference call
24 with investors and research analysts, and Lief made the following statements:

25 We have recently announced a number of important
26 milestones in the lorcaserin program, and we're right on
27 track with our plans Our primary objective at this
28 time is to obtain FDA approval for lorcaserin. We are
preparing for our advisory committee meeting, tentatively
scheduled for September 16, and look forward to our
October 22 PDUFA date. We have always stated that

safety is of paramount importance to the FDA, and that the right profile of efficacy, safety, and tolerability is essential for a weight-management drug

Jack Lief – *Arena Pharmaceuticals – Chairman, President, CEO*

In conclusion, we believe that lorcaserin's unique profile, safety, efficacy, and tolerability as demonstrated in our pivotal program, has the potential to advance the management of obesity. We are pleased with the recent execution of critical milestones and look forward to continuing interaction with the FDA to complete its review of the lorcaserin application.

144. Lief's representation that Defendants had "executed critical milestones" and that Defendants were preparing the FDA Advisory Committee meeting communicated to investors that Defendants submitted all required safety data for lorcaserin's NDA. Lief's representations were false and misleading because Lief knew, and failed to disclose, that Defendants' mechanistic studies failed to show an increase in prolactin as required by the FDA, and therefore, Defendants had failed to provide data to show that lorcaserin's carcinogenicity was not relevant to humans as required by the FDA. Accordingly, it was an extreme departure from ordinary standards of conduct for Lief to represent that Defendants checked all of the boxes for NDA approval, when internally he knew at that time, that the data obtained from Defendants' mechanistic studies on rats failed to satisfy the FDA's requirement that prolactin cause an increase in rats.

145. Also on August 3, 2010, Shanahan and Anderson made the following representations concerning Defendants' discussions with the FDA:

Phil Nadeau – *Cowen & Co. – Analyst*

Okay. Can you maybe give us some idea of what you think the issues could be? Or where you are focusing your preparation?

Bill Shanahan – *Arena Pharmaceuticals – SVP, Chief Medical Officer*

Well, *we're not expecting any surprises associated with the panel. Obviously we will present our view of lorcaserin*, and the FDA will present their view. I think the views will overlap substantially, and I look forward to a very positive panel. Christy, you want to—anything to add to that?

Christy Anderson – *Arena Pharmaceuticals – VP of Clinical Development*

I agree with what Jack said. Obviously, we've always said that the primary focus would be on safety, and we are well prepared to thoroughly address the safety issues, or the safety data, as well as the efficacy data with the panel.

(Emphasis added.)

146. Defendant Shanahan and Anderson's representations communicated to investors that all of the safety issues and data concerning lorcaserin had been disclosed to investors. But this was not true and Shanahan and Anderson knew it. Since the beginning of the Class Period, Shanahan and Anderson knew that Defendants' mechanistic studies failed to show an increase in prolactin as required by the FDA, and therefore, Defendants had failed to show that the Rat Study's adverse results were not relevant to humans. Accordingly, it was an extreme departure from ordinary standards of conduct for Anderson and Shanahan to falsely represent to investors that they did not expect "any surprises" at the FDA Advisory Committee meeting, when they knew internally of the Rat Study's adverse results, that the mechanistic studies on rats failed to demonstrate lorcaserin's safety, and at that time, were preparing their expert (Dr. Williams) to discuss the Rat Study's adverse results at the Advisory Committee meeting.

147. Also on August 3, 2010, Lief and Anderson made the following representations concerning lorcaserin's safety compared to other diet drugs in development:

Alan Carr – *Needham & Company – Analyst*

Question. Wanted to follow-on one of the themes from Phil. So can you tell us what lessons you all learned from the Qnexa advisory meeting, and how that might apply to lorcaserin?

Jack Lief – *Arena Pharmaceuticals – Chairman, President, CEO*

Well remember, Qnexa was a very, very different compound than lorcaserin, and we will present much of the data, as we understand it, on lorcaserin, and I don't think we're going to have any surprises. Christy, do you want to further comment on that?

1 **Christy Anderson** – *Arena Pharmaceuticals – VP of*
2 *Clinical Development*

3 I think—this is going to be a recurrent theme. As we
4 anticipated, safety was the focus of that panel, and I think
5 we can anticipate that safety will be a key focus at the
6 lorcaserin panel. We're doing everything in our power to
7 be well prepared to discuss all of the safety data with the
8 advisory panel.

9 ***

10 **Christy Anderson** – *Arena Pharmaceuticals – VP of*
11 *Clinical Development*

12 Again, we have always been very comfortable with the
13 safety profile... again, I think we are pretty comfortable
14 that we have shown a good safety and tolerability profile,
15 and we are prepared to support that at the advisory
16 committee.

17 148. Lief's and Anderson's representations that lorcaserin, unlike qnexa,
18 was "safe", falsely represented to investors that, unlike other diet drugs in
19 development that had known safety issues, the data supporting lorcaserin's NDA
20 did not show any risk to humans. But this was not true because Defendants'
21 mechanistic studies failed to show an increase in prolactin as required by the FDA,
22 and therefore, Defendants had failed to show that lorcaserin's carcinogenicity was
23 not relevant to humans. Accordingly, it was an extreme departure from ordinary
24 standards of conduct for Lief and Anderson to represent to investors that lorcaserin
25 had no safety issues and posed no risk to humans, when internally, they knew at
26 that time that Defendants had failed to submit data to the FDA that demonstrated
27 lorcaserin caused an increase in prolactin.

28 149. On August 6, 2010, Defendants caused Arena to file a prospectus
supplement pursuant to which Arena sold 8,955,244 shares of Arena common stock
at a price of approximately \$6.70 per share, for a total purchase price of
approximately \$60 million (the "August 6 Prospectus Supplement").

150. The August 6 Prospectus Supplement incorporated by reference the
false statements in the 2009 10-K and the May 7, 2010 10-Q delineated above.

1 151. On August 9, 2010, Defendants caused Arena to file its quarterly
2 report for the quarter ended June 30, 2010 with the SEC on Form 10-Q. The
3 August 9, 2010 10-Q was signed by Lief and repeated the false statements in the
4 2009 10-K and May 7, 2010 10-Q set forth above.

5 152. Lief's representations in the August 9, 2010 10-Q communicated to
6 investors that Defendants had "demonstrated" lorcaserin's "long-term safety." But
7 this was not true and Lief knew it because Defendants' mechanistic studies failed to
8 show an increase in prolactin as required by the FDA. Knowing these facts, it was
9 an extreme departure from ordinary standards of conduct for Lief to falsely
10 represent that lorcaserin's mechanism was safe for use in humans.

11 **D. Loss Causation and Economic Loss.**

12 153. During the Class Period, as detailed herein, Defendants engaged in a
13 scheme to deceive the market and a course of conduct that artificially inflated the
14 price of Arena securities and operated as a fraud or deceit on Class Period
15 purchasers of Arena's securities. Defendants achieved this by making positive
16 statements about lorcaserin's safety, data, and discussions with the FDA, while they
17 knew of material negative facts and intentionally or deliberately recklessly failed to
18 disclose them to the public.

19 154. Later, however, when Defendants' prior misrepresentations were
20 disclosed and became apparent to the market, the price of Arena's securities
21 declined precipitously as the prior artificial inflation came out of Arena's stock
22 price. As a result of their purchases of Arena securities during the Class Period,
23 Plaintiff and other members of the Class suffered economic loss, *i.e.*, damages
24 under the federal securities laws.

25 155. On September 14, 2010, the FDA briefing document was disclosed.
26 The results of the Rat Study and the FDA's interest in such results were disclosed
27 to investors, and investors learned that Defendants failed to provide data showing
28 that the Rat Study's adverse results were not relevant to humans. On September 14,

2010, the price of Arena shares declined from a close on September 13, 2010 of \$6.85 per share, to close at \$4.13 per share, a decline of \$2.72 per share or approximately 40%.

156. On September 16, 2010, trading of Arena stock was halted, pending the outcome of the Advisory Committee meeting on lorcaserin. On September 16, 2010, the Advisory Committee voted to recommend not approving lorcaserin at that time.

157. On September 17, 2010, trading in Arena shares resumed and the price of Arena's shares declined \$1.75 per share to close at \$1.99 per share, a decline of approximately 47% on heavy volume. On January 27, 2011, after the close of trading, in a report filed with the SEC on Form 8-K, Arena disclosed that the FDA required the Company to perform additional long-term studies to demonstrate lorcaserin was safe for humans:

[T]he FDA requested that we consider performing a separate 12-month study in female rats that would test whether transient prolactin elevation mediated by short-term exposure to lorcaserin can result in mammary tumors in rats

158. On January 27, 2011, Arena disclosed that Defendants learned that the FDA was interested in long-term (over 6 months) studies of lorcaserin's effects on rats. In response, on January 28, 2011, the price of Arena's common stock declined \$0.37 per share or approximately 19%, on heavy volume to close at \$1.63 per share.

E. Presumption on Reliance.

159. At all relevant times, the market for Arena's securities was an efficient market for the following reasons, among others:

(a) The Company's common stock was actively traded on the NASDAQ in a highly efficient market;

(b) As a regulated issuer, the Company filed periodic public reports with the SEC;

1 (c) The Company was covered regularly by securities analysts,
2 including, among others J.P. Morgan, Oppenheimer, Rodman & Renshaw,
3 Cowen & Co., and Canaccord;

4 (d) The Company regularly issued press releases which were carried
5 by national newswires. Each of these releases was publicly available and entered
6 the public marketplace;

7 (e) Defendants regularly participated in public conference calls with
8 investors and analysts.

9 160. As a result, the market for the Company's securities promptly digested
10 current information with respect to Arena from all publicly available sources and
11 reflected such information in the price of the Company's securities. Under these
12 circumstances, all purchasers of the Company's securities during the Class Period
13 suffered similar injury through their purchase of the securities of Arena at
14 artificially inflated prices and a presumption of reliance applies under *Basic v.*
15 *Levinson*, 485 U.S. 224 (1988).

16 161. Lead Plaintiff need not show reliance with respect to Defendants'
17 material omissions. *Affiliated Ute Citizens v. U.S.*, 406 U.S. 128 (1972).

18 **F. No Safe Harbor.**

19 162. Defendants' false and misleading statements alleged above were
20 assertions and statements of present or historical facts, and observed facts. The
21 statutory safe harbor provided for forward-looking statements under certain
22 circumstances does not apply to any of these allegedly false statements.

23 163. To the extent any of the alleged false statements could be construed as
24 forward-looking, many of these statements were not identified as "forward-looking
25 statements" when made.

26 164. To the extent any of Defendants' statements are found to be forward-
27 looking statements, there was no meaningful cautionary statements identifying
28

1 important factors that could cause actual results to differ materially from those in
2 the purportedly forward-looking statements.

3 165. Indeed, as alleged herein, Defendants' cautionary language throughout
4 the Class Period was ineffective to warn research analysts from Jefferies, J.P.
5 Morgan, Canaccord, Cowen & Co., Rodman & Renshaw, Oppenheimer, Summer
6 Street and Zach's of the undisclosed, material facts alleged herein.

7 166. Alternatively, to the extent that the statutory safe harbor does apply to
8 any forward-looking statements pleaded herein, Defendants are liable for those
9 false forward-looking statements because at the time each of those forward-looking
10 statements was made, Defendants knew that the particular forward looking
11 statement was false, and/or the forward-looking statement was authorized and/or
12 approved by an executive officer of Arena who knew that those statements were
13 false when made. Defendant had actual knowledge that by the beginning of the
14 Class Period, the FDA requested data supporting the Prolactin Hypothesis and
15 further knew that Defendants' mechanistic studies failed to produce such
16 supporting data.

17 **FIRST CLAM FOR RELIEF**
18 **For Violation of Section 10(b) of the Exchange Act**
and Rule 10b-5 Promulgated Thereunder Against Defendants

19 167. Lead Plaintiff repeats and realleges each and every allegation
20 contained above.

21 168. Defendants violated Section 10(b) of the Exchange Act and Rule 10b-
22 5 in that they:

- 23 (a) Employed devices, schemes and artifices to defraud;
24 (b) Made untrue statements of material facts or omitted to state
25 material facts necessary in order to make statements made, in light of the
26 circumstances under which they were made not misleading; or
27
28

1 (c) Engaged in acts, practices, and a course of business that operated
2 as a fraud or deceit upon Lead Plaintiff and other similarly situated investors in
3 connection with their purchases of Arena securities during the Class Period.

4 169. As alleged herein, Defendants acted with scienter in that they
5 intentionally or with deliberate recklessness made statements to investors that were
6 materially false and misleading concerning lorcaserin. Defendants knew that such
7 statements or documents would be issued or disseminated to the investing public;
8 and knowingly and substantially participated or acquiesced in the issuance or
9 dissemination of such statements or documents.

10 170. The Court's November 4, 2013 Order (ECF No. 71, at 5:14-19) found
11 that the Second Consolidated Amended Class Action Complaint's (ECF No. 59)
12 allegation gave rise to a core operations inference of knowledge about the
13 lorcaserin Rat Study for Defendants Arena, Lief, Behan, Shanahan, and Anderson,
14 and that the detailed allegations about Lief, Behan, Shanahan, and Anderson's
15 actual exposure to information gave rise to the inference that they knew about the
16 Rat Study and Arena's communications with the FDA about it.

17 171. The state of mind of the Individual Defendants, as well as other Arena
18 employees acting within the scope of their employment and on behalf of Arena,
19 and/or as Arena's agent or as agent for one or more of the Individual Defendants,
20 such as Brunswick, is imputed to Arena. As alleged above, the Individual
21 Defendants, as well as numerous other Arena employees, including Brunswick,
22 knew of the Rat Study and the FDA's concerns about the Rat Study and concerns
23 about its relevance to humans and knew that the FDA requested supporting data for
24 the Prolactin Hypothesis, and Defendants' mechanistic studies on rats failed to
25 develop such supporting data.

26 172. As set forth above in detail, Defendants, by virtue of their knowledge
27 of the Rat Study, their control over, and/or receipt and/or modification of Arena's
28 allegedly materially misleading misstatements and/or their associations with the

1 Company which made them privy to confidential proprietary information
2 concerning lorcasearin and the results of the Rat Study, and privity to meetings and
3 correspondence with the FDA participated in the fraudulent scheme alleged herein.

4 173. Defendants knew or at least with deliberate recklessness disregarded
5 the false and misleading nature of their respective statements and of the information
6 that they caused to be disseminated to the investing public. The ongoing fraudulent
7 scheme described in this complaint could not have been perpetrated over a
8 substantial period of time, as has occurred, without the knowledge and complicity
9 of personnel at the highest level of the Company, including the Individual
10 Defendants, and/or individuals with access to and/or received nonpublic material
11 information concerning the results of the Rat Study and the FDA's interest in them.

12 174. Defendants had the motive and opportunity to perpetrate the fraudulent
13 scheme and course of business described herein. The Individual Defendants were
14 the most senior officers of Arena, issued statements and press releases on behalf of
15 Arena, and each made false statements concerning lorcasearin and had the
16 opportunity to commit the fraud alleged.

17 175. Defendants were motivated to inflate the price of Arena securities in
18 order to raise approximately \$137 million for Arena from investors from the sale of
19 Arena common stock at artificially inflated prices as alleged above. As alleged
20 above, Defendants caused Arena to sell stock at suspicious times. The timing of the
21 sales was suspicious because Defendants knew of the negative material facts
22 alleged above, or acted with deliberate recklessness.

23 176. During the Class Period, Defendants disseminated or approved the
24 false statements specified above, which they knew or deliberately recklessly
25 disregarded were materially false and misleading in that they contained material
26 misrepresentations and failed to disclose material facts necessary in order to make
27 the statements made, in light of the circumstances under which they were made, not
28 misleading to investors.

177. Lead Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Arena's securities. Lead Plaintiff and the Class would not have purchased Arena securities at the prices they paid, or at all, if they had been aware that the market prices had been artificially inflated by Defendants' materially misleading statements and/or material omissions.

178. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiff and the other members of the Class suffered damages in connection with their purchases of Arena securities during the Class Period.

SECOND CLAIM FOR RELIEF
For Violation of Section 20(a) of the Exchange Act
Against the Individual Defendants

179. Lead Plaintiff repeats and realleges each and every allegation contained above.

180. The Lief, Shanahan, Behan, and Anderson each acted as controlling persons of Arena within the meaning of Section 20(a) of the Exchange Act. By virtue of their high-level positions, participation in and/or awareness of Arena's lorcaserin program, the Rat Study's results, participation in conference calls with investors and analysts and/or intimate knowledge of the statements filed by the Company with the SEC and disseminated to the investing public, and attendance at meetings with the FDA on behalf of Arena, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements concerning the development and safety of lorcaserin that Lead Plaintiff contends are materially false and misleading.

181. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, bi-monthly updates on the Rat Study to the FDA, drafts of and the final Rat Study report submitted to the FDA, press releases, public filings and other statements alleged by Lead Plaintiff to be misleading prior

1 to and/or shortly after these statements were issued and had the ability to prevent
2 the issuance of the statements or cause the statements to be corrected.

3 182. During the Class Period, Lief and Behan were members of the
4 Company's board of directors and had responsibilities to review, approve and
5 monitor fundamental financial and business strategies and major corporate actions,
6 oversee potential risks facing the Company and the Company's risk management
7 activities, select and oversee management and determine its composition and
8 oversee the establishment and maintenance of processes and conditions to maintain
9 the integrity of the Company.

10 183. The Individual Defendants had direct and supervisory involvement in
11 the day-to-day operations of the Company and the clinical and preclinical studies of
12 lorcaserin, therefore, are presumed to have had the power to control or influence the
13 materially false and misleading representations giving rise to the securities
14 violations as alleged herein, and exercised such power.

15 184. As set forth above, Arena and the Individual Defendants each violated
16 Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this
17 complaint. By virtue of their positions as well as their conduct alleged herein, the
18 Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act.

19 185. As a direct and proximate result of Defendants' wrongful conduct,
20 Lead Plaintiff and other members of the Class suffered damages in connection with
21 their purchases of the Company's securities during the Class Period.

22 **V. CLASS ACTION ALLEGATIONS**

23 186. Lead Plaintiff brings this action as a class action pursuant to Federal
24 Rules of Civil Procedure 23(a) and 23(b)(3) on behalf of a class of all persons and
25 entities who purchased the securities of Arena between May 11, 2009 through
26 January 27, 2011, inclusive (the "Class").

27 187. The members of the Class are so numerous that joinder of all members
28 is impracticable. While the exact number of Class members is unknown to Lead

1 Plaintiff at the present time and can only be ascertained through appropriate
2 discovery, Lead Plaintiff believes that there are hundreds of members of the Class
3 located throughout the United States. As of August 5, 2010, Arena had over 112
4 million shares of common stock outstanding.

5 188. Lead Plaintiff's claims are typical of the claims of the members of the
6 Class. Lead Plaintiff and all members of the Class have sustained damages because
7 of Defendants' unlawful activities alleged herein. Lead Plaintiff has retained
8 counsel competent and experienced in class and securities litigation and that intends
9 to continue to pursue this action vigorously. The interests of the Class will be fairly
10 and adequately protected by Lead Plaintiff. Lead Plaintiff has no interests which
11 are contrary to or in conflict with those of the Class that Lead Plaintiff seeks to
12 represent.

13 189. A class action is superior to all other available methods for the fair and
14 efficient adjudication of this controversy. Lead Plaintiff knows of no difficulty to
15 be encountered in the management of this action that would preclude its
16 maintenance as a class action.

17 190. Common questions of law and fact exist as to all members of the Class
18 and predominate over any questions solely affecting individual members of the
19 Class. Among the questions of law and fact common to the Class are:

- 20 (a) whether the federal securities laws were violated by Defendants'
21 acts and omissions as alleged herein;
- 22 (b) whether Defendants' misstated and/or omitted to state material
23 facts in their public statements, press releases and filings with the SEC;
- 24 (c) whether Defendants acted with the requisite state of mind;
- 25 (d) whether Defendants participated directly or indirectly in the
26 course of conduct complained of herein; and
- 27 (e) whether the members of the Class have sustained damages and
28 the proper measure of such damages.

PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiff prays for judgment as follows: declaring this action to be a proper class action; certifying the Lead Plaintiff as a Class Representative and Lead Counsel as Class Counsel; awarding damages, including interest; awarding reasonable costs, including attorneys' fees; and such equitable/injunctive relief as the Court may deem proper.

JURY DEMAND

Lead Plaintiff demands a trial by jury.

DATED: November 27, 2013 KAPLAN FOX & KILSHEIMER LLP

By: /s/ Laurence D. King
Laurence D. King

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 and the Proposed Class*

**UNITED STATES DISTRICT COURT
 SOUTHERN DISTRICT OF CALIFORNIA**

TODD SCHUENEMAN, on behalf of
 himself and all others similarly situated,

Plaintiff,

vs.

ARENA PHARMACEUTICALS, INC.,
 JACK LIEF, ROBERT E. HOFFMAN,
 DOMINIC P. BEHAN, WILLIAM R.
 SHANAHAN, and CHRISTY
 ANDERSON,

Defendants.

Case No. 3:10-cv-01959-CAB-BLM

**DECLARATION OF LAURENCE
 D. KING IN OPPOSITION TO
 DEFENDANTS' MOTION TO
 DISMISS THE SECOND
 CONSOLIDATED AMENDED
 CLASS ACTION COMPLAINT**

Judge: Hon. Cathy Ann Bencivengo
 Courtroom: 4C
 Hearing Date: Aug. 2, 2013
 Hearing Time: 2:30 p.m.

[Oral argument requested, subject to
 Court approval]

[Additional Captions on Following Pages]

WILLIAM SUTLIFF and JEAN SUTLIFF,
on behalf of themselves and all others
similarly situated,

Plaintiff,

vs.

ARENA PHARMACEUTICALS, INC.,
JACK LIEF and WILLIAM SHANAHAN,

Defendants.

Case No. 3:10-cv-01961-CAB-BLM

WILLIAM PRATT, on behalf of himself and
all others similarly situated,

Plaintiff,

vs.

ARENA PHARMACEUTICALS, INC.,
JACK LIEF, ROBERT E. HOFFMAN,
DOMINIC P. BEHAN, WILLIAM R.
SHANAHAN, and CHRISTY ANDERSON,

Defendants.

Case No. 3:10-cv-01977-CAB-BLM

CRAIG RUBENSTEIN, on behalf of himself
and all others similarly situated,

Plaintiff,

vs.

ARENA PHARMACEUTICALS, INC.,
JACK LIEF, ROBERT E. HOFFMAN,
DOMINIC P. BEHAN, WILLIAM R.
SHANAHAN, JR. and CHRISTY
ANDERSON,

Defendants.

Case No. 3:10-cv-01984-CAB-BLM

1 RODNEY VELASQUEZ, on behalf of
2 himself and all others similarly situated,

3 Plaintiff,

4 vs.
5

6 ARENA PHARMACEUTICALS, INC.,
7 JACK LIEF, ROBERT E. HOFFMAN,
8 DOMINIC P. BEHAN, WILLIAM R.
9 SHANAHAN, JR. and CHRISTY
ANDERSON,

10 Defendants.

Case No. 3:10-cv-02026-CAB-BLM

11 THONG VU, individually and on behalf of
12 all others similarly situated,

13 Plaintiff,

14 vs.
15

16 ARENA PHARMACEUTICALS, INC.,
17 JACK LIEF, ROBERT E. HOFFMAN,
18 DOMINIC P. BEHAN, WILLIAM R.
SHANAHAN, and CHRISTY ANDERSON,

19 Defendants.

Case No. 3:10-cv-2086-CAB-BLM

20 ARIC D. JACOBSON, individually and on
21 behalf of all others similarly situated,

22 Plaintiff,

23 vs.
24

25 ARENA PHARMACEUTICALS, INC.,
26 JACK LIEF, ROBERT E. HOFFMAN,
27 DOMINIC P. BEHAN, WILLIAM R.
SHANAHAN, JR., and CHRISTY
ANDERSON,

28 Defendants.

Case No. 3:10-cv-2335-CAB-BLM

1 I, Laurence D. King, declare as follows:

2 1. I am a partner with the law firm of Kaplan Fox & Kilsheimer LLP,
3 counsel for Lead Plaintiff Carl Schwartz and the Proposed Class. I have personal
4 knowledge of the following facts and, if called upon to testify, I could and would
5 testify competently thereto.

6 2. Attached hereto as Exhibit A is a true and correct copy of the redlined
7 version of the Second Consolidated Amended Class Complaint (“Complaint”) (ECF
8 No. 56), reflecting Lead Plaintiff’s amendments to the Complaint.

9 3. Attached hereto as Exhibit B is a true and correct copy of a chronology
10 of events showing when Defendants Arena Pharmaceuticals, Inc. (“Arena”), Jack
11 Lief, Robert E. Hoffman, Dominic P. Behan, William R. Shanahan, and Christy
12 Anderson (collectively, “Defendants”) learned of the adverse results observed in the
13 Rat Study and the dates of meetings and correspondence with the Federal Food &
14 Drug Administration (“FDA”) about the adverse results of the Rat Study.

15 4. Attached hereto as Exhibit C is a true and correct copy of excerpts of
16 the Pharmacology/Toxicology NDA Review and Evaluation of the lorcarserin drug
17 by the FDA, signed by Dr. Fred Alavi (with concurrence by Dr. Todd M. Bourcier)
18 on October 20, 2010.

19 5. Attached hereto as Exhibit D is a true and correct copy of the Summary
20 Review for Regulatory Action by the FDA concerning the lorcarserin drug, signed by
21 Dr. Eric Colman on October 21, 2010.

22 6. Attached hereto as Exhibit E is a true and correct copy of Prescribing
23 Information concerning BELVIQ (lorcarserin).

24 7. Attached hereto as Exhibit F is a true and correct copy of the letter
25 signed June 27, 2012 from the FDA to Arena approving Arena’s New Drug
26 Application dated December 18, 2009 for Belviq (lorcarserin).

27 8. Attached hereto as Exhibit G is a true and correct copy of Arena’s Form
28 8-K filed with U.S. Securities and Exchange Commission (“SEC”) on January 22,

2013, noting objections by the European Medicines Agency concerning approval of lorcaserin in the European Union.

9. Attached hereto as Exhibit H is a true and correct copy of Arena's Form 8-K filed with the SEC on May 2, 2013, noting Arena's withdrawal of its request for approval of lorcaserin in the European Union.

10. Attached hereto as Exhibit I is a true and correct copy of the Order filed April 11, 2010, in *In re Fannie Mae 2008 Sec. Litig.*, No. 1:08-cv-07831-PAC (S.D.N.Y.) (ECF No. 269).

11. Attached hereto as Exhibit J is a true and correct copy of excerpts of the Notice of Motion and Motion to Dismiss Consolidated Complaint for Violation of the Federal Securities Laws; Memorandum of Points and Authorities in Support, dated October 14, 2008, in *In re The PMI Group, Inc. Sec. Litig.*, No. 3:08-cv-01405-SI (N.D. Cal.) (ECF No. 28).

12. Attached hereto as Exhibit K is a true and correct copy DSI Consult Request for Nonclinical Site Inspections, dated March 3, 2010.

13. Attached hereto as Exhibit L is a true and correct copy of Arena's Form 10-Q for the quarter ended September 30, 2010, filed with the SEC on November 9, 2010.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct. Executed this 15th day of July, 2013, in San Francisco, California.

/s/ Laurence D. King
Laurence D. King

CERTIFICATE OF SERVICE

I, Laurence D. King, hereby declare that on July 15, 2013, I caused the foregoing to be filed electronically using the Court's CM/ECF system which sent notifications of the filing to counsel of record.

/s/ Laurence D. King

Laurence D. King

EXHIBIT L

ARENA PHARMACEUTICALS INC

FORM 10-Q (Quarterly Report)

Filed 11/09/10 for the Period Ending 09/30/10

Address	6154 NANCY RIDGE DRIVE SAN DIEGO, CA 92121
Telephone	858-453-7200
CIK	0001080709
Symbol	ARNA
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2010

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 000-31161

ARENA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

23-2908305
(I.R.S. Employer
Identification No.)

6166 Nancy Ridge Drive, San Diego, CA
(Address of principal executive offices)

92121
(Zip Code)

858.453.7200
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company.

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐ (Do not check if a smaller reporting company)

Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

The number of shares of common stock outstanding as of the close of business on November 5, 2010:

Class
Common Stock, \$0.0001 par value

Number of Shares Outstanding
121,411,502

Table of Contents

- Eisai may not perform as expected, including with regard to making payments under the agreement, and such agreement may not provide adequate protection or may not be effectively enforced.

Eisai and we each have the right to terminate the agreement in certain circumstances. Eisai and we could also agree to amend the terms of the agreement, and we or others, including investors and analysts, may not view the amendments as favorable. If the agreement is terminated early, we may not be able to find another company for the commercialization of lorcaserin in the United States and further development of lorcaserin on acceptable terms, if at all, and even if we elected to pursue continued commercialization or further development of lorcaserin on our own, we might not have the funds, or otherwise be able, to do so successfully.

We may enter into additional agreements for the commercialization of lorcaserin or other of our drug candidates, and may be similarly dependent on the performance of third parties with similar risk.

***We and certain of our current and former employees and directors have been named as defendants in litigation that could result in substantial costs and divert management's attention.**

Beginning September 20, 2010, a number of complaints were filed in the US District Court for the Southern District of California against us and certain of our current and former employees and directors on behalf of certain purchasers of our common stock. The complaints have been brought as purported stockholder class actions, and in general include allegations that we and certain of our current and former employees and directors violated federal securities laws by making materially false and misleading statements regarding our lorcaserin trials, thereby artificially inflating the price of our common stock. The plaintiffs are seeking unspecified monetary damages and other relief. Several derivative lawsuits also have been filed in federal and state courts.

We intend to vigorously defend these lawsuits. There is, however, no guarantee that we will be successful. Also, our insurance coverage may be insufficient, our assets may be insufficient to cover any amounts that exceed our insurance coverage, and we may have to pay damage awards or otherwise may enter into settlement arrangements in connection with such claims. Any such payments or settlement arrangements could have material adverse effects on our business, operating results or financial condition. Even if the plaintiffs' claims are not successful, this litigation could result in substantial costs and significantly and adversely impact our reputation and divert management's attention and resources, which could have a material adverse effect on our business, operating results or financial condition. In addition, such lawsuits may make it more difficult to finance our operations.

***Our stock price could decline significantly based on the results and timing of clinical trials and preclinical studies of, and decisions affecting, our most advanced drug candidates.**

The results and timing of clinical trials and preclinical studies can affect our stock price. Preclinical studies include experiments performed in test tubes, in animals, or in cells or tissues from humans or animals. These studies, which are sometimes referred to as non-clinical studies, include all drug studies except those conducted in human subjects, and may occur before or after initiation of clinical trials for a particular compound. Results of clinical trials and preclinical studies of lorcaserin or our other drug candidates may not be viewed favorably by us or third parties, including investors, analysts, current or potential collaborators, the academic and medical communities, and regulators. The same may be true of how we design the development programs of our most advanced drug candidates and regulatory decisions (including by us or regulatory authorities) affecting those development programs. Stock prices of companies in our industry have declined significantly when such results and decisions were unfavorable or perceived negatively or when a drug candidate did not otherwise meet expectations.

From time to time we have drug programs in clinical trials. In addition to successfully completing clinical trials, to conduct long-term clinical trials and gain regulatory approval to commercialize drug candidates, regulatory authorities require that all drug candidates complete short- and long-term preclinical toxicity and carcinogenicity studies. These preclinical, animal studies are required to help us and regulatory authorities assess the potential risk that drug candidates may be toxic or cause cancer in humans. The results of clinical trials and preclinical studies are uncertain and subject to different interpretations, and the design of these trials and studies (which may change significantly and be more expensive than anticipated depending on results and regulatory decisions) may also be viewed negatively by us, regulatory authorities or other third parties and adversely impact the development and opportunities for regulatory approval and commercialization of our drug candidates and those under collaborative agreements.

For example, we conducted long-term carcinogenicity preclinical studies of lorcaserin. The FDA identified in the CRL for lorcaserin issues related to such studies. We intend to provide in our response to the CRL data and other information to support our view related to such issues, but the FDA may disagree with our view or impose conditions that could delay or preclude approval of our lorcaserin NDA.

We may not be successful in advancing our programs on our projected timetable, if at all. Failure to initiate or delays in the development programs for any of our drug candidates, or unfavorable results or decisions or negative perceptions regarding any of such programs, could cause our stock price to decline significantly. This is particularly the case with respect to lorcaserin.

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 Mario M. Choi (SBN 243409)
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Robert N. Kaplan (admitted *pro hac vice*)
 Jeffrey P. Campisi (admitted *pro hac vice*)
 KAPLAN FOX & KILSHEIMER LLP
 850 Third Avenue, 14th Floor
 New York, NY 10022
 Telephone: 212-687-1980
 Facsimile: 212-687-7714

Lead Counsel for Lead Plaintiff Carl Schwartz

**UNITED STATES DISTRICT COURT
 SOUTHERN DISTRICT OF CALIFORNIA**

TODD SCHUENEMAN, on behalf of himself and
 all others similarly situated,

Plaintiff,

vs.

ARENA PHARMACEUTICALS, INC., JACK
 LIEF, ROBERT E. HOFFMAN, DOMINIC P.
 BEHAN, WILLIAM R. SHANAHAN, and
 CHRISTY ANDERSON,

Defendants.

Case No. 3:10-cv-01959-CAB

**SECOND CONSOLIDATED
 AMENDED CLASS ACTION
 COMPLAINT**

JURY TRIAL DEMANDED

[Additional Captions on Following Pages]

WILLIAM SUTLIFF and JEAN SUTLIFF, on
behalf of themselves and all others similarly
situated,

Plaintiff,

vs.

ARENA PHARMACEUTICALS, INC., JACK
LIEF and WILLIAM SHANAHAN, JR.

Defendants.

Case No. 3:10-cv-01961-CAB

WILLIAM PRATT, Individually and on Behalf of
All Others Similarly Situated,

Plaintiff,

vs.

ARENA PHARMACEUTICALS, INC., JACK
LIEF, ROBERT E. HOFFMAN, DOMINIC P.
BEHAN, WILLIAM R. SHANAHAN, JR. and
CHRISTY ANDERSON,

Defendants.

Case No. 3:10-cv-01977-CAB

CRAIG RUBENSTEIN, Individually and on
Behalf of All Others Similarly Situated,

Plaintiff,

vs.

ARENA PHARMACEUTICALS, INC., JACK
LIEF, ROBERT E. HOFFMAN, DOMINIC P.
BEHAN, WILLIAM R. SHANAHAN, JR. and
CHRISTY ANDERSON,

Defendants.

Case No. 3:10-cv-01984-CAB

RODNEY VELASQUEZ, on behalf of himself
and all others similarly situated,

Case No. 3:10-cv-02026-CAB

Plaintiff,

vs.

ARENA PHARMACEUTICALS, INC., JACK
LIEF, ROBERT E. HOFFMAN, DOMINIC P.
BEHAN, WILLIAM R. SHANAHAN, JR. and
CHRISTY ANDERSON,

Defendants.

THONG VU, individually and on behalf of all
others similarly situated,

Case No. 3:10-cv-02086-CAB

Plaintiff,

vs.

ARENA PHARMACEUTICALS, INC., JACK
LIEF, ROBERT E. HOFFMAN, DOMINIC P.
BEHAN, WILLIAM R. SHANAHAN, and
CHRISTY ANDERSON,

Defendants.

ARIC D. JACOBSON, individually and on behalf
of all others similarly situated,

Case No. 3:10-cv-02335-CAB

Plaintiff,

vs.

ARENA PHARMACEUTICALS, INC., JACK
LIEF, ROBERT E. HOFFMAN, DOMINIC P.
BEHAN, WILLIAM R. SHANAHAN, JR., and
CHRISTY ANDERSON,

Defendants.

1 Lead Plaintiff Carl Schwartz, through Lead Counsel Kaplan Fox & Kilsheimer LLP,
2 individually and on behalf of all other persons and entities similarly situated that purchased the
3 securities of Arena Pharmaceuticals, Inc. (“Arena” or the “Company”), makes the following
4 allegations, which are based upon the investigation conducted by Lead Plaintiff’s counsel, which
5 included, among other things, a review of the public statements made by defendants, Arena’s filings
6 with the United States Securities and Exchange Commission (“SEC”), transcripts of conference
7 calls with investors and research analysts and a public meeting before the FDA’s Endocrinology
8 and Metabolic Advisory Committee (“Advisory Committee”) on September 16, 2010, the Briefing
9 Document prepared by Food and Drug Administration (“FDA”) scientists for the Advisory
10 Committee meeting (the “FDA Briefing Document”), press releases, analyst reports and media
11 reports regarding Arena, and interviews with confidential informants.

12 **I. NATURE OF THE CLAIMS**

13 1. This is a securities class action brought under Sections 10(b) and 20(a) of the
14 Securities Exchange Act of 1934 (“Exchange Act”), 15 U.S.C. §§ 78j(b) and 78t(a), and the rules
15 and regulations promulgated thereunder by the SEC, including Rule 10b-5, 17 C.F.R. § 240.10b-5,
16 on behalf of purchasers of Arena securities between March 17, 2008 through January 27, 2011 (the
17 “Class Period”).

18 2. “Defendants” are the Company; Jack Lief (“Lief”), the Company’s President, Chief
19 Executive Officer and Chairman of the Company’s board of directors; Robert E. Hoffman
20 (“Hoffman”), the Company’s Chief Financial Officer; Dominic P. Behan (“Behan”), the
21 Company’s Senior Vice President and Chief Scientific Officer and a member of the Company’s
22 board of directors; William R. Shanahan (“Shanahan”), the Company’s Senior Vice President and
23 Chief Medical Officer; and Christen “Christy” Anderson (“Anderson”), the Company’s former Vice
24 President of Lorcaserin Development.

25 3. Defendants violated the Exchange Act by making untrue statements of material
26 facts, and/or omitting to state material facts necessary in order to make their statements, in light of
27

1 the circumstances under which they were made, not misleading about Arena's developmental new
2 diet drug, lorcaserin.

3 4. Arena is a small biotechnology company and during the Class Period, Defendants
4 primarily focused Arena's activities and resources on the research and development of lorcaserin.
5 The Company did not sell any drug products.

6 5. During the Class Period, Arena had a Lorcaserin Team that conducted and/or
7 supervised clinical and nonclinical tests required for approval by the FDA. According to
8 Confidential Informant 1 ("CI 1"),¹ and Confidential Informant 2 ("CI 2"),² the Lorcaserin Team
9 was led by Defendants Lief, Anderson, Shanahan and Behan, as well as other Arena senior
10 management.

11 6. As members of the Lorcaserin Team, Defendants Lief, Shanahan, Anderson and
12 Behan supervised the tests required for FDA approval of lorcaserin, including a key, long-term
13 carcinogenicity study on rats (the "Rat Study") designed to approximate a lifetime of human use,
14 and to assess risk to humans. Further, Defendants Lief, Shanahan, Anderson and Behan were privy
15 to, and knowledgeable about, the protocols and results of the Rat Study and other studies of
16 lorcaserin (*e.g.*, ¶¶ 8-15, 18), and attended meetings with the FDA at which the Rat Study and the
17 FDA's concerns about the Rat Study's results and its significance to humans were discussed. (*E.g.*,
18 ¶¶ 22, 24, 57, 85, 89.) As alleged below, Defendant Hoffman was aware of the Rat Study (*e.g.*,
19 ¶¶ 17, 27, 29, 81, 91, 94).

20 7. By 2006, Defendants were conducting advanced human studies of lorcaserin
21 (Phase 3 studies) and, at the same time, they were conducting other essential studies for lorcaserin's

22
23
24 ¹ CI 1 was a Senior Manager for Regulatory Affairs at Arena at the beginning of the Class Period
25 through 2010, who handled correspondence with the FDA and prepared meeting packages, safety
26 reports and carcinogenicity updates for the lorcaserin project.

27 ² CI 2 was a Senior Director of Drug Safety Evaluation from October 2007 through 2009. CI 2 was
28 responsible for monitoring the quality and standards used in animal studies of lorcaserin.

1 new drug application (“NDA”) to the FDA, including nonclinical carcinogenicity and toxicity
2 studies in animals, and the Rat Study to assess clinical risk to humans.

3 8. As members of the Lorcaserin Team, Defendants Shanahan and Anderson were
4 tasked as the team leaders for lorcaserin’s nonclinical and clinical studies. Shanahan and Anderson
5 were responsible for collecting and analyzing all preclinical/animal and clinical data, including the
6 Rat Study data, for lorcaserin’s NDA, which data they discussed and shared with the other members
7 of the Lorcaserin Team.

8 9. According to CI 1, the Rat Study data was collected by Bruce Ennis (“Ennis”),
9 Arena’s Associate Director and Head Toxicologist, who reported to Defendant Shanahan. Tina
10 Leakakos, Arena’s Associate Director of Drug Safety Evaluation, assisted Ennis. According to
11 CI 1, Ennis received the data from the Rat Study from outside companies that ran the nonclinical
12 trials. Ennis reported results to Shanahan who shared them with the other members of the
13 Lorcaserin Team.

14 10. According to CI 1, Mark Brunswick (“Brunswick”), Arena’s Senior Director of
15 Regulatory Affairs during the Class Period (who reported to Defendant Lief), and Terri Heyward,
16 Arena’s Regulatory Manager, were the Regulatory Project Managers for lorcaserin.

17 11. Brunswick was responsible for sending and receiving communications with the FDA
18 on behalf of Arena and senior management.

19 12. By February 2007, the results of the ongoing Rat Study indicated that lorcaserin
20 caused mammary, brain, skin and nerve-sheath tumors, including lethal, malignant mammary and
21 brain tumors. The results were unusual because the cancers were aggressive and occurred early in
22 the Rat Study. The incidents of brain cancer were a concern because lorcaserin targets the central
23 nervous system in the brain. The incidents of breast cancer were a concern because lorcaserin was
24 a drug that would be marketed to people who are overweight and therefore have a higher risk of
25 breast cancer. As members of the Lorcaserin Team, Defendants were aware of these results as they
26 occurred.

1 13. According to Confidential Informant 3 (“CI 3”),³ at a meeting in 2006 or 2007 with David
2 Unett (“Unett”), who at the time was Arena’s Senior Director, Receptor Pharmacology & Screening,
3 Unett told CI 3 that “massive tumors in breast tissues in rats” were discovered. According to CI 3, Unett
4 knew this because he had just left a meeting with the Lorcaserin Team at which the findings of the
5 ongoing Rat Study were discussed.

6 14. According to CI 3, updates on lorcaserin were discussed several times during this
7 meeting and in subsequent meetings. CI 3 and other Arena employees warned Unett that the “FDA
8 is going to look into this” (tumor findings). Based on conversations with Unett, CI 3 believes that
9 Arena executives withheld disclosing the tumor findings to the FDA “for several months, maybe
10 longer.” Further, CI 3 told Unett that the tumor findings “still have to be addressed to the FDA and
11 investors,” who were going to “take a poor view of where the data stands.” According to CI 3,
12 Unett concurred and responded that based on what he had learned at meetings with Arena
13 executives, “the last thing they (Arena executives) want to do is raise awareness about them”
14 (tumor findings).

15 15. On May 31, 2007, Defendants, through Brunswick (who reported to Lief), reported
16 the unusual Rat Study results to the FDA, but not to the public. The FDA was very concerned
17 about the Rat Study and, the FDA directed Defendants to prepare bi-monthly updates on the Rat
18 Study’s results as data became available for both mammary and brain tumors.

19 16. This direction by the FDA for bi-monthly updates was very unusual and was not part
20 of the FDA’s normal and customary process for new drug approval because interim results of
21 ongoing rat studies are not typically provided to the FDA. In particular, the FDA was concerned
22 about mammary and brain tumors that occurred during the Rat Study.

23
24
25
26 ³ CI 3 was a Senior Manager in Arena’s Pharmacology and Screening Department Arena between 2000
27 and 2009.

1 17. In mid-2007, according to Confidential Informant 4 (“CI 4”)⁴, CI 4 was told by
2 Barbara Koozer (“Koozer”), Arena’s Purchasing Director, that Defendant Hoffman stated “they are
3 trying to work on this cancer thing with the rats.” Koozer told her team and CI 4 to “cross their
4 fingers.”

5 18. According to CI 2, in October 2007, CI 2 learned through conversations with
6 Shanahan of tumor findings during the Rat Study and that Arena senior management had
7 discussions with the FDA about the Rat Study and the cancer findings. According to CI 2, the
8 findings of the ongoing Rat Study revealed unusual toxicology findings of tumors, and further that
9 Lief, Anderson and Behan were aware of the tumor findings in the Rat Study.

10 19. On September 5, and November 9, 2007, and January 9, and March 10, 2008, on
11 behalf of the Defendants, Brunswick submitted to the FDA bi-monthly updates on the ongoing Rat
12 Study.

13 20. In or around March 2008, Brunswick, on behalf of Defendants, reported results from
14 week 96 of the Rat Study to the FDA. The Rat Study results were alarming because: 1) at each
15 update from week 55 to 96, the incidence and proportion of female rats with cancerous tumors
16 (adenocarcinoma) increased at all doses; 2) a greater number of mammary-tumor-related deaths
17 occurred early in the Rat Study; 3) mammary cancer metastasized to the lungs at all doses; and
18 4) and females were found with multiple cancerous masses at all doses.

19 21. The FDA was alarmed by these results and directed Arena to meet with the FDA in
20 April 2008 to discuss the causes of mammary tumors in rats and the FDA’s concern about its
21 significance to humans.

22 22. On April 9, 2008, Defendants Shanahan, Anderson and Behan, as well as Brunswick,
23 attended a meeting with the FDA in Silver Spring, Maryland. At this meeting, the FDA was
24 surprised to learn that the Rat Study data from week 96 had changed mysteriously by week 104.
25 Specifically, Defendants Shanahan, Anderson and Behan, as well as Brunswick, informed the FDA

26
27 ⁴ CI 4 was a Purchasing Assistant from July 2006 through February 2009.

1 that the Rat Study data indicated that the number of malignant mammary tumors *decreased* and the
2 number of benign mammary tumors *increased*. The change in the Rat Study data was a significant
3 concern for the FDA and no evidence was presented on behalf of Arena to explain this change,
4 which reduced confidence in the data.

5 23. On May 16, 2008, Brunswick, on behalf of Defendants, submitted a bi-monthly
6 update to the FDA.

7 24. According to CI 2, in mid-2008, Defendants Anderson, Shanahan and Behan, and
8 Brunswick, as well as other Arena employees, met with FDA officials, including David Jacobson-
9 Kram, Chair of the FDA Executive Carcinogenicity Assessment Committee, for approximately one
10 hour at the FDA headquarters in Silver Spring, Maryland to discuss two topics – lorcaserin’s
11 clinical studies and the Rat Study.

12 25. On September 19, 2008, Brunswick, on behalf of Defendants, submitted a bi-
13 monthly update to the FDA.

14 26. In or around October 2008, according to Confidential Informant 5 (“CI 5”),⁵ CI 5
15 learned of the Rat Study and the tumor findings from conversations with Koozer.

16 27. In January 2009, CI 5 was instructed by Koozer that Lief and Hoffman gave the
17 directive to all finance departments, including purchasing, to suspend any future purchases unless
18 absolutely necessary. Based on discussions with Koozer and other Arena employees, CI 5
19 understood that management’s directive to halt purchases was directly connected to growing
20 uncertainty on whether lorcaserin would ever make it to market. For the first few months of 2009,
21 CI 5 had “nothing to do.” There was mounting concern within the Company that layoffs were
22 forthcoming.

23 28. By February 2009, the Rat Study was completed and a draft of the final Rat Study
24 report was sent to the FDA. The Rat Study found that breast tumors developed at all doses, and that
25 lorcaserin caused brain tumors as well as many other malignant tumors.

26
27 ⁵ CI 5 was a Purchasing Manager for Arena from July 2002 through April 2009.

1 29. In April 2009, CI 5 was called into Hoffman's office along with 10-12 finance staff
2 members and was informed by Hoffman that the staff members' respective positions at Arena were
3 being eliminated. Based on discussions with other Arena employees, CI 5 understood that the
4 layoffs were directly linked to management's concerns surrounding the future of lorcaserin.

5 30. On December 18, 2009, on behalf of Defendants, Brunswick submitted the
6 lorcaserin NDA to the FDA, which included the final Rat Study data. Defendants could not
7 demonstrate to the FDA that the Rat Study was irrelevant to humans. Moreover, the Rat Study data
8 that Defendants submitted with the NDA changed yet again from the data first discussed with the
9 FDA in April 2008, which further reduced confidence in the data.

10 31. Also in April 2010, Confidential Informant 6 ("CI 6"),⁶ spoke with a former
11 colleague who was working in Arena's Molecular Biology Department and who told CI 6 that there
12 was "data which found cancer in the mice" and that "they (Arena management) did not want
13 anyone else to know about it."

14 32. Defendants knew that the FDA was concerned about the results of the Rat Study and
15 its applicability to humans. Indeed, in preparation for the September 16, 2010 public meeting with
16 the FDA Advisory Committee, Arena hired an expert toxicologist to prepare slides and make a
17 presentation addressing questions from the FDA concerning the relevance of the Rat Study results
18 to humans.

19 33. Thus, by the beginning of the Class Period Defendants knew that the FDA was
20 concerned about the results of the Rat Study. They also knew that there were material and
21 unexplained changes in the mammary tumor updates which were presented to the FDA and that
22 they were unable to demonstrate to the FDA that the Rat Study was irrelevant to humans. In short,
23 they knew that the results of the Rat Study were material to the Advisory Committee and the FDA,
24 and to investors.

26 ⁶ CI 6 was a Research Associate in Arena's Molecular Biology Department at the beginning of the
27 Class Period through 2009.

1 34. These were material facts that a reasonable investor would deem important in his or
2 her decision whether to invest in Arena securities. But Defendants did not disclose these material
3 facts to investors. Instead, Defendants repeatedly falsely represented that lorcaserin had an
4 “excellent” and “remarkable” safety profile; that based on clinical and nonclinical studies and data,
5 lorcaserin’s “long-term safety” had been “demonstrated;” and that Defendants did not expect any
6 “surprises” from the FDA.

7 35. As alleged below, Defendants’ representations convinced analysts and investors that
8 lorcaserin was safe and that the Company’s application for approval by the FDA was “on track.”

9 36. On September 14, 2010, investors began to learn the truth about lorcaserin when the
10 FDA Briefing Document was released, publicly disclosing for the first time the adverse results from
11 the Rat Study and the FDA’s concerns about these results.

12 37. Analysts and investors were shocked by the disclosures of the results from the Rat
13 Study – causing a massive collapse in the price of Arena securities. On September 14, 2010, Arena
14 shares declined in price from a close on September 13, 2010 of \$6.85 per share, to close at \$4.13
15 per share, a decline of \$2.72 per share or approximately 40% on heavy volume. On September 15,
16 2010, trading in Arena common stock was halted.

17 38. On September 16, 2010, a strong majority of the Advisory Committee (9 of 14
18 members) voted to not recommend approval of lorcaserin, in material part, because of concerns
19 raised by the results of the Rat Study.

20 39. On September 17, 2010, trading in Arena shares resumed and the price of Arena’s
21 shares declined \$1.75 per share to close at \$1.99 per share, a decline of approximately 47% on heavy
22 volume.

23 40. On October 23, 2010 the FDA sent Arena a “complete response letter” (“CRL”) that
24 informed Defendants that lorcaserin was not approvable and requested, among other things, the following
25 information from Arena relating to the Rat Study: 1) a recount of the mammary tumors analyzed in the
26 Rat Study updates to the FDA; and 2) further information concerning the relevance of the results to
27 humans.

41. Even after the results from the Rat Study were disclosed and the FDA declined to approve Arena's NDA for lorcaserin, Defendants continued to mislead investors by failing to disclose additional material facts. On December 15, 2010, Defendants Lief, Shanahan, Anderson, and Behan, as well as Brunswick and other Arena senior management, met with the FDA. At this meeting, the FDA expressed its view that short-term studies of rats (duration of 6 months or less), would be insufficient to demonstrate that lorcaserin's tumor-causing effects were rat specific.

42. On December 22, 2010, on a conference call with investors Defendant Lief falsely represented that any further studies concerning applicability of the Rat Study to humans would be "short in duration."

43. On January 27, 2011, the end of the Class Period, Arena disclosed that the FDA recommended long-term studies of at least 12-months in duration to demonstrate that lorcaserin's mechanism was rat-specific.

44. Again, investors were shocked. On January 28, 2011, the price of Arena's common stock closed at \$1.63 per share, a decline of \$0.37 per share or approximately 19% from the closing price on January 27, 2011, on heavy volume.

II. JURISDICTION AND VENUE

45. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act.

46. Venue is proper in this District pursuant to Section 27 of the Exchange Act and 28 U.S.C. §§ 1391(b) and (c). Substantial acts in furtherance of the wrongs alleged and/or their effects have occurred within this District and Arena maintains its headquarters in San Diego, California.

47. In connection with the facts and omissions alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

III. THE PARTIES

48. Lead Plaintiff purchased Arena securities as detailed in the certification previously filed with the Court and was damaged thereby.

49. Defendant Arena is incorporated in Delaware and has executive offices in San Diego, California. The Company's common stock trades on the NASDAQ under the symbol "ARNA." Arena purports to be a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing drugs for cardiovascular, central nervous system, inflammatory and metabolic diseases. During the Class Period, the Company did not sell any products.

50. During the Class Period, Arena, a small company, focused on the development of lorcaserin. Arena's 2009 annual report filed with the SEC on March 16, 2010 on Form 10-K (the "2009 10-K") stated that "we are focusing our activities and resources on our lorcaserin program." According to the 2009 10-K, approximately 95% and 86% of Arena's total external clinical and preclinical study fees and expenses related to lorcaserin in 2009 and 2008, respectively.

51. Defendant Lief was, at all relevant times, the Company's President and Chief Executive Officer, and Chairman of the Company's board of directors. Lief is a co-founder of the Company. During the Class Period, Lief made false statements in the Company's quarterly and annual reports filed with the SEC, in certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX Certifications") that were filed with the SEC, and in conference calls with investors and research analysts.

52. Defendant Hoffman was, at all relevant times, the Company's Vice President, Finance and Chief Financial Officer. During the Class Period, Hoffman made false statements in the Company's quarterly reports and in SOX Certifications that were filed with the SEC. Hoffman left Arena in February 2011 and later in 2011 returned to the Company as CFO.

53. Defendant Behan was, at all relevant times, the Company's Senior Vice President and Chief Scientific Officer and a member of the Company's board of directors. Behan is a co-founder of the Company. During the Class Period, Behan made false statements in the Company's

1 annual reports filed with the SEC and made false statements in conference calls with investors and
2 research analysts.

3 54. Defendant Shanahan was, at all relevant times, the Company's Senior Vice President
4 and Chief Medical Officer. During the Class Period, Shanahan made false statements in conference
5 calls with investors and research analysts.

6 55. Defendant Anderson was the Company's Vice President of Lorcaserin Development
7 during the Class Period and left Arena after the Class Period. During the Class Period, Anderson
8 made false statements in conference calls with investors and research analysts.

9 56. Defendants Lief, Shanahan, Behan, Anderson and Hoffman are referred to herein as
10 the "Individual Defendants." The Individual Defendants, because of their positions with the
11 Company, possessed the power and authority to control the contents of Arena's press releases and
12 presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*,
13 the market. Each Individual Defendant was provided with copies of the Company's press releases
14 and filings with the SEC alleged herein to be misleading prior to or shortly after their issuance and
15 had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of
16 their positions and access to material, non-public information available to them but not to the
17 public, each of the Individual Defendants knew that the adverse material facts specified herein had
18 not been disclosed to and were being concealed from the public and that the positive representations
19 which were being made were materially false and misleading at that time.

20 57. Defendants Lief, Shanahan, Anderson and Behan attended meetings with the FDA
21 concerning lorcasein, including meetings at which the Rat Study and the FDA's concerns about its
22 findings were discussed.

23 58. During the Class Period, each of the Individual Defendants knew of the Rat Study
24 results, received and/or had access to data concerning lorcasein, including the results of the Rat
25 Study, and made false statements about lorcasein's safety.

59. During the Class Period, none of the Individual Defendants purchased Arena common stock on the open market and Lief, Shanahan, Behan and Hoffman were subject to at least one “lock-up” agreement that prevented them from selling shares of Arena common stock.

60. During the Class Period, Defendants caused Arena to sell stock at artificially inflated prices, raising over \$150 million for Arena. The sales were suspicious as they occurred after or around the same time as Defendants learned of material negative facts, and/or were timed to occur just before a partial disclosure of their wrongful conduct that caused Arena common stock to decline. For example, on August 6, 2010, Defendants caused Arena to sell approximately 8.9 million shares at approximately \$6.70 per share for proceeds of approximately \$60 million. This sale was suspicious because it occurred after Defendants learned about all of the material negative facts alleged above concerning the Rat Study, and just weeks before Defendants’ meeting with the Advisory Committee. As alleged above, the disclosures on September 14 and 17, 2010 caused Arena’s stock to decline to \$1.99 per share at the close of trading on September 17, 2010.

IV. BACKGROUND AND BASIS OF DEFENDANTS’ LIABILITY

A. Background on Arena’s Development of Lorcaserin.

1. Arena’s Animal (Non or Pre-Clinical) and Human (Clinical) Studies of Lorcaserin.

61. Lorcaserin is intended for weight management, including weight loss and maintenance of weight loss. Lorcaserin is described by Arena as “a novel single agent that represents the first in a new class of selective serotonin 2C receptor agonists. The serotonin 2C receptor is located in areas of the brain involved in the control of appetite and metabolism, such as the hypothalamus. Stimulation of this receptor is strongly associated with feeding behavior and satiety.” Because lorcaserin’s mechanism affected the central nervous system in the brain, any signal of brain tumors would be a red flag of a safety risk.

62. Arena has been developing lorcaserin since at least 2003. To market lorcaserin, Arena needs approval from the FDA. Approval by the FDA of a new drug requires a new drug

1 sponsor to submit data demonstrating the drug's safety and efficacy based on nonclinical animal
2 studies and clinical trials on humans. Human clinical trials are referred to as phases 1, 2, and 3.
3 Phase 1 trials are mainly aimed at determining if the metabolic and pharmacologic actions of the
4 drug in humans are safe enough to proceed to Phase 2 studies. Phase 2 studies are controlled
5 clinical studies that involve a limited population infected with the disease the drug proposes to treat.
6 Phase 3 studies usually involve many more people than Phase 2 studies and are intended to gather
7 additional information on the drug's efficacy and safety that will be used in evaluating its overall
8 risks and benefits. Nonclinical animal studies include long-term studies on animals of a drug's
9 toxicity and carcinogenicity.

10 63. Between 2006 and 2009, Arena concurrently conducted nonclinical animal studies,
11 (including the Rat Study) and human studies, including two "pivotal" Phase 3 trials - BLOOM
12 (Behavioral modification and Lorcaserin for Overweight and Obesity Management) and
13 BLOSSOM (Behavioral modification and Lorcaserin Second Study for Obesity Management) - all
14 of which were intended to be submitted with the lorcaserin NDA.

15 64. BLOOM started in September 2006 and was completed in February 2009.
16 BLOSSOM was conducted between January 2008 and July 2009.

17 **2. *Lorcaserin's Safety Was Critical to the FDA and Investors.***

18 65. As with all new drugs, a drug sponsor must demonstrate the drug's safety. Safety
19 with respect to diet drugs was highly important because prior FDA-approved diet drugs, including
20 Fen-Phen, were removed from the market because of serious adverse side effects after it was shown
21 that they cause heart-valve disease (valvulopathy).

22 66. Fen-Phen, like lorcaserin, was a "serotonin agonist", and affects the brain and central
23 nervous system in similar ways. As such, it was important for Arena to demonstrate that lorcaserin
24 did not cause negative side effects. Indeed, in February 2008, just before the beginning of the Class
25 Period, Defendant Lief acknowledged that focus was on "safety, safety, safety, safety ... and then
26 safety."

67. Further, lorcaserin's safety profile was of paramount importance to investors. Vivus and Orexigen, competitors of Arena, were developing competing weight-loss drugs (qnexa and contrave, respectively) and certain clinical studies for these drugs showed potential adverse side effects, like birth defects and cardiovascular risks.

68. Accordingly, Defendants represented that lorcaserin was different from the drugs being developed by Vivus and Orexigen because, according to Defendants, lorcaserin was purportedly *both* safe and effective.

3. The Individual Defendants knew of the Rat Study results, and received and/or had access to data concerning lorcaserin, including the results of the Rat Study.

69. As noted above, Arena was required to conduct a long-term study of potential carcinogenesis relating to lorcaserin, including the Rat Study. Carcinogenicity studies, like the Rat Study, are highly relevant to humans because they are designed to approximate results of lifetime use of a drug in humans and to detect tumor risks in humans.

70. When safety margins are absent or uncertain in a carcinogenicity study, it is critical that a drug sponsor demonstrate that the drug's mechanism or tumorigenic mode of action is not relevant to humans.

71. Pursuant to FDA protocols, during a carcinogenicity study, rats are observed on a daily basis for signs of departure from normal activity, morbidity and mortality. If tumors develop, the time of onset, location, dimensions, appearance and progression are recorded.

B. Defendants' Fraudulent Conduct.

1. Arena's Rat Study Reveals to Defendants Alarming Findings.

72. By February 2007, Defendants learned that the Rat Study showed lorcaserin caused tumors in rats, including malignant mammary (breast) tumors in both male and female rats, malignant astrocytoma (brain cancer), squamous carcinomas of the subcutis (skin cancer), malignant schwannomas (cancer of connective tissue surrounding nerves or nerve sheath tissue), liver and thyroid.

1 73. According to CI 3, at a meeting with Unett, Unett told CI 3 that “massive tumors in breast
2 tissues in rats” were discovered. According to CI 3, Unett knew this because he had just left a meeting
3 with the Lorcaserin Team that included Defendant Behan at which the findings of the ongoing Rat Study
4 were discussed.

5 74. According to CI 3, updates on lorcaserin were discussed several times during this
6 meeting and in subsequent meetings. CI 3 and other team members warned Unett that the “FDA is
7 going to look into this” (cancer findings). Based on conversations with Unett, CI 3 believes that
8 Arena executives withheld disclosing the cancer findings to the FDA “for several months, maybe
9 longer.” Further, CI 3 told Unett that even if the findings were not relevant to humans, “it still has
10 to be addressed to the FDA and investors,” who were going to “take a poor view of where the data
11 stands.” According to CI 3, Unett concurred and responded that based on what he had learned at
12 meetings with Arena executives, “the last thing they (Arena executives) want to do is raise
13 awareness about them” (cancer findings).

14 **2. Defendants Inform the FDA of Lorcaserin’s Risks and the FDA**
15 **Directs Defendants to Provide Bi-Monthly Updates on the Results of**
16 **the Rat Study.**

17 75. On May 31, 2007, Defendants submitted a safety report informing the FDA of
18 increased mortality of female rats due to breast cancers and tumors (mammary adenocarcinoma and
19 fibroadenoma) at all doses of lorcaserin by week 55 of the ongoing Rat Study. Additionally,
20 Defendants described a higher incidence of brain cancer (astrocytoma).

21 76. Mammary tumors were of particular concern to the FDA because potential lorcaserin
22 users – overweight and obese women – were a group that was already at high risk for breast cancer.
23 Brain tumors were a concern because lorcaserin’s mechanism affects the central nervous system in
24 the brain.

25 77. The high incidence of mortality and palpable tumors in female rats observed during
26 the course of the Rat Study, as well as the incidents of brain cancer, prompted the FDA to direct
27 that Defendants provide bi-monthly updates to the FDA regarding the incidence of observed tumors
28 in the Rat Study, including survival and tumor incidence.

78. The cancer observed in the Rat Study was unusual because cancer occurred very early in the Rat Study and the cancers observed were aggressive. As Defendant Lief later admitted, Arena's bi-monthly updates to the FDA were highly unusual and not part of the normal process with the FDA.

79. Defendants' bi-monthly updates to the FDA were unusual because interim results of rat studies are not typically provided to the FDA. The bi-monthly updates were reviewed by the FDA and the findings were periodically discussed with the FDA's Executive Carcinogenicity Assessment Committee (eCAC). The FDA considered the Rat Study's findings relevant to humans. According to CI 1, at least 10 carcinogenicity updates were sent by Defendants to the FDA.

80. The FDA's request for bi-monthly updates put the Defendants on notice and was a red flag that the FDA had concerns about the findings of breast, brain and other tumors in the Rat Study and that they were relevant to humans.

81. In mid-2007, CI 4 was told by Koozer that Defendant Hoffman stated "they are trying to work on this cancer thing with the rats." Koozer told her team and CI 4 to "cross their fingers."

82. In October 2007, CI 2 learned through conversations with Shanahan of tumor findings during the Rat Study and that Arena senior management had discussions with the FDA about the Rat Study. According to CI 2, the findings of the ongoing Rat Study revealed unusual toxicology findings of tumors.

3. *The Ongoing Rat Study Results Reveal Increases in Tumors and Cancer.*

83. By March 2008, week 96 of the Rat Study had been reached. The number of deaths and the incidence of malignant and benign mammary tumors *increased* at all doses of lorcaserin in each bi-monthly update. This was reported to the FDA by Defendants. The increase in cancer found in the ongoing Rat Study concerned the FDA and the FDA directed that Defendants meet with the FDA.

1 84. As alleged above, by the beginning of the Class Period (March 17, 2008), each of the
2 Individual Defendants knew about the Rat Study's negative findings and that the FDA was
3 concerned that the results were relevant to humans.

4 85. On April 9, 2008, Defendants Shanahan, Behan and Anderson, as well as Brunswick,
5 met with the FDA to discuss the tumor findings in rats and the potential safety implications for the
6 ongoing clinical studies and the Rat Study's relevance to humans.

7 86. At that meeting, Defendants informed the FDA that the week 96 data previously
8 reported to the FDA had changed to show a *decline* in the total number of malignant mammary
9 tumors and an *increase* in benign mammary tumors. The sudden shift was highly unusual, and was
10 imbalanced, which reduced confidence in the reliability of the data.

11 87. At the April 2008 meeting, Defendants did not provide data to the FDA to explain
12 the mysterious and sudden shift in favor of lorcaserin.

13 88. The FDA conditionally permitted Defendants to continue clinical studies because
14 incidents of tumors and tumor risk would be monitored in clinical studies and Defendants did not
15 have certain data from the Rat Study at that time. The FDA requested a draft report of the Rat Study
16 as soon it was available.

17 89. According to CI 2, in mid-2008, Defendants Anderson, Shanahan and Behan, and
18 Brunswick as well as other Arena employees, met with FDA officials at the FDA headquarters in
19 Silver Spring, Maryland to discuss the lorcaserin NDA at which one of two topics on the agenda
20 was the ongoing Rat Study.

21 90. In or around October 2008, according to CI 5, CI 5 learned of the Rat Study and its
22 negative findings from conversations with Koozer.

23 91. In January 2009, CI 5 was instructed by Koozer that Lief and Hoffman gave the
24 directive to all finance departments, including purchasing, to suspend any future purchases unless
25 absolutely necessary. Based on discussions with Koozer and other Arena employees, CI 5 believed
26 that management's directive to halt purchases was directly connected to growing uncertainty on
27 whether lorcaserin would ever make it to market.

1 92. For the first few months on 2009, CI 5 had “nothing to do.” There was mounting
2 concern within the Company that layoffs were forthcoming.

3 93. On February 3, 2009, with the Rat Study completed, Brunswick, on behalf of
4 Defendants, submitted a draft of the final Rat Study to the FDA. The Rat Study found mammary
5 tumors occurred at all doses, and that lorcaserin causes brain and other cancers.

6 94. In April 2009, CI 5 was called into Hoffman’s office along with 10-12 finance staff
7 and was informed by Hoffman that the staff members’ respective positions at Arena were being
8 eliminated. Based on discussions with other Arena employees, CI 5 believed that the layoffs were
9 directly linked to management’s concerns surrounding the future of lorcaserin.

10 95. Around the same time, while knowing of the Rat Study and its relevance to humans
11 and the FDA’s concerns about them, or at least ignoring all of these risks with deliberate
12 recklessness, Defendants caused Arena to sell millions of dollars in Arena common stock at
13 artificially inflated prices. On April 14, 2009, Defendants caused Arena to sell approximately
14 5.7 million Arena shares at an artificially inflated price (\$2.61 per share) for proceeds of
15 \$15 million. On July 8, 2009, Defendants caused Arena to sell 12.5 million Arena shares at an
16 artificially inflated price (\$4.17 per share) for proceeds of approximately \$ 52.1 million.

17 96. On August 9, 2009, Defendants Shanahan, Anderson, and Behan, and Brunswick
18 conducted a pre-NDA meeting with the FDA to discuss lorcaserin.

19 97. On a November 10, 2009 conference call with investors and research analysts,
20 Defendants were specifically asked to identify any FDA concerns with lorcaserin.

21 98. Despite knowing of the negative results of the Rat Study, and that the FDA was
22 concerned about the results and their applicability to humans, Defendant Shanahan lied to investors,
23 stating “at the present time we don’t see safety signal[s] to pursue. . . .” Again, Defendants failed to
24 disclose the negative results of the Rat Study, and that the FDA was concerned about the results and
25 their applicability to humans.

26 99. On December 18, 2009, Brunswick, on behalf of Arena, submitted the NDA for
27 lorcaserin. The NDA included the final Rat Study data.

1 100. The final Rat Study data that Brunswick submitted on behalf of Defendants was
2 *further* revised from the data that Defendants reported to the FDA in April 2008 to show an increase
3 in benign tumors and a decrease in malignant tumors, and there were gross errors in the pathology
4 reports. Rat tissue samples that contained tumors were identified as normal, which reduced
5 confidence in the data.

6 101. Defendants did not submit data that demonstrated that the results of the Rat Study
7 were irrelevant to humans. No safety margin was identified for the mammary tumors and the safety
8 margin for brain tumors was uncertain. The final Rat Study data that Defendants submitted to the
9 FDA showed that tumors in female rats occurred at *all* doses and increased multiple tumor types in
10 male rats, and that tumors occurred early and were very aggressive, leading to premature deaths.
11 Defendants had no plausible explanation for these results.

12 **4. Defendants Mislead Investors Prior to the September 16, 2010 Advisory**
13 **Committee Meeting.**

14 102. After Defendants filed the lorcaserin NDA, investors repeatedly asked Defendants
15 about the status of the NDA application and about any FDA concerns with lorcaserin. Despite
16 knowing of the material, negative results of the Rat Study, that the FDA was concerned about the
17 results and their applicability to humans, and that the final Rat Study update materially changed
18 from prior updates, Defendants lied to investors by failing to disclose these material facts.

19 103. On March 8, 2010, while knowing of the Rat Study and its relevance to humans and
20 the FDA's concerns about such, or at least ignoring all of these risks with deliberate recklessness,
21 Defendants caused Arena to sell approximately 8.3 million Arena shares at an artificially inflated
22 price (\$2.96 per share) for proceeds of approximately \$24.5 million.

23 104. In April 2010, CI 6 spoke with a former colleague who was working in Arena's
24 Molecular Biology Department and was told that there was "data which found cancer in the mice"
25 and that "they (Arena management) did not want anyone else to know about it."
26
27
28

1 105. Defendants’ repeated lies concerning lorcaserin’s safety misled investors in Arena
2 stock, including sophisticated research analysts. On May 7, 2010, a Cowen & Co. analyst observed
3 that lorcaserin’s “**Modest Efficacy Plus Clean Safety Carves Out Niche**”.

4 106. On June 2, 2010, Arena disclosed that it had been notified that the FDA Advisory
5 Committee would meet publicly on September 16, 2010 to consider whether to recommend
6 lorcaserin’s approval to the FDA.

7 107. Defendant Lief represented that “[w]e are focused on obtaining the FDA’s approval
8 of lorcaserin, and have been preparing for this anticipated advisory committee meeting,” but again
9 failed to disclose the material, negative results of the Rat Study and the FDA’s concerns about these
10 results.

11 108. Defendants knew that the Rat Study and its relevance to humans and the FDA’s
12 concerns about the Rat Study were issues for the Advisory Committee. Notably, Arena retained
13 Dr. Gary Williams (“Dr. Williams”), a New York Medical College Pathologist with a focus on the
14 mechanisms of carcinogenesis and the metabolic and genetic effects of chemical carcinogenesis, to
15 present a slide presentation to the Advisory Committee, a fact indicating that Defendants knew that
16 the results of the Rat Study were materially important to the FDA and would be important to the
17 Advisory Committee’s and FDA’s consideration of Arena’s NDA for lorcaserin.

18 109. On June 2, 2010, an Oppenheimer analyst stated “we do not see negative read-
19 through for the lorcaserin NDA ... we believe lorcaserin’s clean safety profile in trials to date,
20 including minimal cardiovascular side effects, should sway the [Advisory Committee] panel to
21 recommend approval. . . .”

22 110. Defendants knew that the FDA continued to have concerns about the mysterious
23 changes to the Rat Study results. At the request of the FDA’s Division of Metabolism and
24 Endocrinology Products, on June 7 through 11, 2010, the FDA’s Division of Scientific Inspections
25 inspected Arena and a facility where nonclinical studies for the Rat Study were conducted. The
26 inspections concerned, in part, the change in tumor classification in the Rat Study and the quality

1 and integrity of the data compiled in the Rat Study. In June 2010, a Form 483 was issued to Arena
2 regarding the inspection.

3 111. As late as August 3, 2010, Defendant Shanahan represented in a conference call with
4 investors and research analysts that he did not expect any “surprises” at the September 16 FDA
5 Advisory Committee meeting. But, internally, Defendants knew about the negative results of the
6 Rat Study and the FDA’s concern about those results. Indeed, Defendants were preparing for the
7 September 16, 2010 Advisory Committee meeting by preparing slides and statements to address the
8 negative results of the Rat Study.

9 112. On August 5, 2010, while knowing of the Rat Study and its relevance to humans and
10 the FDA’s concerns about such, and knowing that Defendants and their expert Dr. Williams were
11 preparing to give a presentation concerning the Rat Study, or at least ignoring these risks with
12 deliberate recklessness, Defendants caused Arena to sell 9 million shares of Arena common stock at
13 an artificially inflated price (\$6.70 per share) for proceeds of \$60 million.

14 113. As late as August 2010, based on Defendants’ false representations, analysts
15 continued to believe that lorcaserin was safe: “lorcaserin appears relatively well positioned with two
16 years of controlled safety data, no clear adverse safety signal, and a robust clinical trial design” (J.P.
17 Morgan); “We believe that lorcaserin’s profile is fundamentally approvable.” (Jefferies); and “We
18 expect Additional Upside on a Positive Lorcaserin AdCom Mtg. . . . The company reported that no
19 new issues have emerged ahead of the 9/16 FDA AdCom meeting for lorcaserin. . . . **Safety is**
20 **lorcaserin’s defining characteristic, in our view.**” (Oppenheimer) (emphasis added).

21 **5. The Truth about Lorcaserin Begins to be Revealed.**

22 114. On September 14, 2010, the FDA Briefing Document and the negative results from
23 the Rat Study and the FDA’s concern about the results were publicly disclosed for the first time,
24 causing Arena’s stock price to decline.

25 115. On September 14, 2010, the price of Arena shares declined from a close on
26 September 13, 2010 of \$6.85 per share, to close at \$4.13 per share, a decline of \$2.72 per share or
27 approximately 40% on heavy volume.

116. Investors and analysts, without exception, were shocked and surprised:

- September 14, 2010 J.P. Morgan *ALERT*: “**The biggest surprise is a preclinical cancer signal.** We (and investors we’ve spoken with this morning) were caught off guard by the question relating to lorcaserin-related tumors in rats. In the FDA’s question alone, the agency specifically notes that the neoplasms involve breast, brain, peripheral nerve, skin, and subcutis. . . .” (emphasis in original);
- September 14, 2010 Cowen Analyst Report: “Quick Take: Rat Carcinogenicity Data A Surprise In Briefing Docs The documents were disappointing in that they showed a major disagreement between Arena and the FDA on the interpretation of preclinical rat carcinogenicity findings that had not previously been disclosed. We believe the fact that the FDA believes that lorcaserin increases the risk for malignant breast tumors in rats reduces the likelihood that lorcaserin will receive a positive panel recommendation on Thursday. . . .”;
- September 14, 2010 Jefferies Analyst Report: “The biggest surprise in the briefing documents is the finding of preclinical cancers”;
- September 14, 2010 Oppenheimer Analyst Report – “**We see the FDA’s rejection of ARNA’s explanation of pre-clinical cancers in rats as a significant concern**” (emphasis in original);
- September 15, 2010 Canaccord Analyst Report: “**Cancer risk in the briefing document was unforeseen; presents another challenge for lorcaserin, especially since it is a new chemical entity**” (emphasis added); and
- September 15, 2010 Summer Street Analyst Report: “Yesterday **we were completely blindsided by preclinical carcinogenicity data from the two year lorcaserin animal study.** . . . Most importantly, we do not believe Arena will be able to produce preclinical data and/or design a post-approval trial/registry to rule out a breast cancer risk” (emphasis added).

117. On September 16, 2010, the Advisory Committee met and heard statements from FDA scientist Dr. Fred Alavi, who authored a report on the Rat Study that was part of the FDA Briefing Document, and Dr. Williams, on behalf of Arena, who gave a presentation concerning the Rat Study.

118. After hearing statements and presentations from Arena, FDA scientists, and others, the Advisory Committee voted 9-5 against recommending approval of lorcaserin, in material part, because of safety concerns raised by the Rat Study and their relevance to humans.

119. On September 17, 2010, Lief and Shanahan participated in a conference call with investors and research analysts to discuss the Advisory Committee meeting and Lief made the following admissions:

Karen Jay - JPMorgan - Analyst

I had a question about the pre-clinical cancer signals. I was wondering when -- I guess you're aware of them pretty early and the cancer, you had potentially underestimated the FDA's concern on that topic.

Jack Lief - Arena Pharmaceuticals Inc. - President & CEO

Well, what we can say, as we stated in our presentation yesterday, is that *when we learned of the data, we promptly discussed it with the FDA.*

* * *

Bill Tanner - Lazard Capital Markets – Analyst

And just -- and I don't know if you were there, I'm sure you would have been debriefed. How much of an in depth discussion was it? How much of it was back and forth? You may not wish to comment on it, but was there any kind of inkling, any kind of thought that perhaps the FDA reviewers would have been in agreement? Or are they just cursorily looking at your data, making a cursory decision to proceed without any real hard analytical processes being done?

Jack Lief - Arena Pharmaceuticals Inc. - President & CEO

Yes, you know we can't provide more details on that at this time. But I appreciate your question.

(Emphasis added).

6. The FDA Rejects Arena's NDA.

120. On October 23, 2010, Arena disclosed that it received the CRL from the FDA that indicated that the FDA completed its review of the NDA and the FDA could not approve Arena's NDA "in its present form." The CRL, according to Arena, outlined the reasons for the FDA's decision, including the following:

The non-clinical issues identified by the FDA included diagnostic *uncertainty in the classification of mammary masses in female rats, unresolved exposure-response*

1 *relationship for lorcaserin-emergent mammary adenocarcinoma, and unidentified*
 2 *mode of action and unclear safety margin for lorcaserin-emergent brain*
 3 *astrocytoma.*

4 (Emphasis added).

5 121. Further, according to Defendants, the FDA requested that Defendants provide the
 6 following evidence to address the FDA’s concern that the Rat Study was relevant to humans –
 7 concerns that the Defendants knew about by the beginning of the Class Period: (1) provide a valid
 8 explanation for the mysterious reclassification of tumors between week 96 and week 104 of the Rat
 9 Study (“provide a detailed accounting of all slides prepared from female rats that contributed to
 10 mammary tumor incidence data in each update to the FDA and to the final study report; in
 11 consultation with the FDA, identify an independent pathologist or group of pathologists to re-
 12 adjudicate all mammary and lung tissues (neoplastic and nonneoplastic lesions) from all female
 13 rats”); and (2) show that the Rat Study is not relevant to humans (“demonstrate that the apparent
 14 increase in aggressiveness of adenocarcinoma in rats administered lorcaserin is reasonably
 15 irrelevant to human risk assessment,” and “provide additional data/information regarding the
 16 distribution of lorcaserin to the central nervous system in animals and human subjects that would
 17 clarify or provide a better estimate of astrocytoma exposure margins”).

18 122. The FDA further stated in the CRL that “in the event evidence cannot be provided to
 19 alleviate concern regarding clinical [human] relevance of the tumor findings in rats, additional
 20 clinical studies may be required to obtain a more robust assessment of lorcaserin’s benefit-risk
 21 profile.” (Alteration added).

22 123. On October 25, 2010, Lief, Hoffman, Shanahan and Behan conducted a conference
 23 call with investors and research analysts concerning the CRL and Lief made the following
 24 statements:

25 **Bill Tanner - Lazard Capital Markets – Analyst**

26 Can you help us understand a little bit the first sentence on the fourth paragraph
 27 about detailed accounting of slides prepared? Is there a snafu here, or what's the gist
 28 of that? ... It says, provide a detailed accounting of all slides prepared from female

1 rats [contribute] to [mammary] tumor incidence, and each update to FDA in the final
2 report. Is there an accounting issue with the slides or with the data?

3 **Jack Lief** - Arena Pharmaceuticals - President & CEO

4 As the FDA indicated in their briefing document, what they were concerned about
5 were the changes between the initial readings by a single veterinary pathologist as
6 part of the normal process, and then the final peer-reviewed, adjudicated diagnoses
7 for each of these slides. *We, at the FDA's request, got into an out-of-process type of*
8 *procedure whereby we updated, every two months, the Agency with the results...*
9 some of these diagnoses changed from when the final peer review process with -- I
10 believe that included three veterinary pathologists reviewed the slides and came to a
11 consensus view on them. So that's how that changed. Normally, the only data
12 submitted to the Agency would be the final peer reviewed data. . . .

13 [Question:] I was wondering if the panel of three vet pathologists that you used to
14 review the mammary tumors at the end of the study were also retained to go back
15 and review the earlier slides. Did they indeed come up with different diagnoses than
16 the earlier reports?

17 **Jack Lief** - Arena Pharmaceuticals - President & CEO

18 *The process was that we had a single pathologist make the initial reads as the*
19 *study was ongoing. At the request of the FDA we provided these data every two*
20 *months as the study was unfolding. And then the normal process is you never*
21 *submit those data. Everyone gets together and makes a final reading on these*
22 *tissues, and then that's what gets accounted for in the study report. So it's just the*
23 *change from an initial reading from one pathologist. And so that's the process.*

24 **Steve Byrne** - Banc of America – Analyst

25 Okay, and just an overall question about the rat study. *Almost half of the female rats*
26 *in the control study had mammary tumors, and that just seems to be outside the*
27 *historical range. Do you have any hypotheses as to why there was such prevalence*
28 *of rat tumors in the females?*

Jack Lief - Arena Pharmaceuticals - President & CEO

Yes, we don't. It was slightly -- I believe the upper range on the lab was around 40%,
and we were, I think, around 43% or 44% in the control group. So outside the range,
very high FDN. But no, *we don't have an explanation for that.* . . .

Jim Birchenough - Barclays Capital – Analyst

I just wanted to follow up on the pre-clinical data and the request by FDA for the
slides. How difficult is it to distinguish between adenocarcinoma and fibroid

adenoma? *And I ask the question because, between week 96 and week 104 it seemed like there were several animals that were reclassified, or at least that was the question that FDA raised in their briefing documents.* And I just wanted confirmation that in animals that were reclassified as fibroadenoma from adeno, they had no evidence of lung metastases. And then I have a follow-up.

Jack Lief - *Arena Pharmaceuticals - President & CEO*

We'll have to review all those data, but we have the data, and we will review it. . . .

(Emphasis added).

7. Defendants Mislead Investors Concerning the “End of Review” Meeting with the FDA.

124. On December 15, 2010, Defendants Lief, Shanahan, Behan, and Anderson, as well as Brunswick and other Arena senior management, met with the FDA in Silver Spring, Maryland. At this meeting the FDA expressed its view that short-term studies were insufficient to demonstrate that lorcaserin’s tumor-causing mechanism was specific to rats, indicating that studies of at least 6 months or longer would be required.

125. On December 22, 2010, Arena issued a press release disclosing that Defendants completed the “end-of-review” meeting with the FDA for lorcaserin that stated, in part, the following:

Based on guidance we have received from the agency, we are executing several activities and expect to resubmit the lorcaserin NDA by the end of 2011. . . . The end-of-review meeting with the FDA included a discussion of the FDA's position on issues identified in the CRL and Arena's plan to respond.

126. Also on December 22, 2010, Defendants conducted a conference call with investors and research analysts to discuss the “end-of-review” meeting with the FDA, and Lief and Anderson made the following statements:

Christy Anderson - *Arena Pharmaceuticals, Inc. - VP of Lorcaserin Development*

The FDA has asked that we demonstrate the mechanism by which lorcaserin causes mammary tumors in rats and that this mechanism is reasonably irrelevant to human risk. . . . To address this issue, we have initiated nonclinical studies to provide the requested evidence to the agency.

1 **Carol Werther** - *Summer Street Research* - Analyst
2 So the duration of the trial is pretty short then?

3 **Jack Lief** - *Arena Pharmaceuticals, Inc.* - President and CEO
4 Yes.

5 127. On January 27, 2011, after the close of trading, in a report filed with the SEC on
6 Form 8-K, Arena disclosed that the FDA required the Company to perform additional long-term
7 studies to demonstrate lorcaserin was safe for humans:

8 [T]he FDA requested that we consider performing a separate 12-month study in
9 female rats that would test whether transient prolactin elevation mediated by
10 short-term exposure to lorcaserin can result in mammary tumors in rats. . . .

11 128. On January 28, 2011, Arena shares declined from a closing price on January 27,
12 2011 of \$2 per share, to close at \$1.63 per share, a decline of \$0.37 per share or approximately 19%,
13 on heavier than usual volume.

14 **D. Defendants' Materially False and Misleading Statements and Material Omissions.**

15 129. Defendants' statements were untrue statements of material facts and/or omitted to
16 state material facts necessary in order to make their statements in light of the circumstances under
17 which they were made, not misleading, because Defendants intentionally, or with deliberate
18 recklessness, failed to disclose the following to investors:

19 (i) that by February 2007, Defendants Lief, Shanahan, Behan and Anderson
20 learned that the findings of the Rat Study included mammary and brain tumors (§§ 12, 72);

21 (ii) that on May 31, 2007, Defendants alerted the FDA of the adverse findings
22 from the Rat Study and the FDA instructed that Arena provide updates every two months to the
23 FDA on the Rat Study's breast and brain tumors results, an unusual request for interim results that
24 is not part of the normal FDA process for development of new drugs (§§ 15, 16, 75-79);

25 (iii) that starting in May 2007, Arena provided bi-monthly updates to the FDA on
26 the Rat Study and in September 2007 Defendants began sending formal bi-monthly updates to the
27 FDA (§§ 15, 19, 23, 25, 77);

(iv) that in March 2008, Defendants sent the Rat Study’s results from week 96 that revealed tumors increased at all doses. The FDA was alarmed by these findings because the results of the Rat Study between weeks 55 and 96 showed an increase in tumors at all doses. The FDA directed Defendants to meet with the FDA in April 2008 to discuss the Rat Study and its relevance to humans (§§ 20-22, 83);

(v) that on April 9, 2008, Defendants Shanahan, Anderson and Behan met with the FDA to discuss the Rat Study and its relevance to humans and Defendants told the FDA that the week 104 data from the Rat Study changed. Specifically, the number of benign mammary tumors *increased* and the number of malignant tumors *decreased*, which reduced confidence in the Rat Study data. Defendants did not provide any documentation to explain the mysterious and sudden shift (§§ 22, 86, 87); and

(vi) that in mid-2008, Defendants Shanahan, Anderson, Behan, as well as Brunswick met with the FDA and discussed the ongoing Rat Study results (§§ 24, 89);

(vii) that on February 3, 2009, the Rat Study was completed and a draft of the report was sent to the FDA. By early 2009, Defendants Lief and Hoffman, aware of the Rat Study, began to implement budget cuts, such as the termination of employment of Arena employees, due to the uncertainty of lorcaserin’s NDA (§§ 28-29, 91-94);

(viii) that in December 2009, at the time Defendants submitted lorcaserin’s NDA along with the final Rat Study, Defendants were not able to demonstrate to the FDA that the Rat Study results were irrelevant to humans, and could not explain the tumor reclassification between the week 96 data and the week 104 data of the Rat Study (§§ 30, 99-101); and

(ix) that at the “end-of-review” meeting on December 15, 2010 with the FDA as part of a resubmission of lorcaserin’s NDA, Defendants learned that the FDA was interested in additional long-term (longer than 6 months) studies of lorcaserin’s effects on rats. (§§ 41-42, 124-28).

130. The Class Period begins on March 17, 2008 when Defendants caused Arena to issue a press release that represented that lorcaserin passed a key safety test demonstrating lorcaserin’s cardiovascular safety:

Arena Pharmaceuticals' Lorcaserin for Obesity Passes Major Safety Milestone

- Month-12 Independent Echocardiographic Data Safety Monitoring Board Review Strengthens Lorcaserin's Emerging Cardiovascular Safety Profile -

SAN DIEGO, March 17 /PRNewswire-FirstCall/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) announced today that following a planned review by an independent Echocardiographic Data Safety Monitoring Board (EDSMB) it is continuing BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management), a pivotal trial evaluating the efficacy and safety of lorcaserin hydrochloride for the treatment of obesity. . . . This critical milestone assessing month-12 echocardiographic data strongly supports lorcaserin's cardiovascular safety profile. We believe that this exposure duration, even under a conservative interpretation of the literature, would have been sufficient to observe a fenfluramine [Fen-Phen] like effect on heart valves if present.

131. The representation that Defendants collected data that “strongly supports” lorcaserin’s safety profile was false and misleading because Defendants knew of the material facts in ¶ 129(i)-(iii) and intentionally or with deliberate recklessness failed to disclose them to investors.

132. On May 12, 2008, Defendants caused Arena to file its quarterly report with the SEC on Form 10-Q for the period ended March 31, 2008. The May 12, 2008 10-Q was signed by Lief and Hoffman, and stated, in part, the following:

In addition to successfully completing clinical trials, in order to conduct long-term clinical trials and gain regulatory approval to commercialize drug candidates, regulatory authorities require that all drug candidates complete short- and long-term preclinical toxicity and carcinogenicity studies. These studies in animals are required to help determine the potential risk that drug candidates may be toxic or cause cancer in humans. The preclinical assessment of carcinogenic potential includes short-term in vitro and in vivo studies to look for chromosomal damage. Short-term carcinogenicity and toxicity studies have been completed for all of our clinical-stage programs. To date, we have only completed long-term preclinical toxicity studies for lorcaserin, and we have not completed carcinogenicity studies for lorcaserin or any of our other clinical-stage programs. . . .

133. Lief and Hoffman’s representations that Defendants “completed long-term preclinical toxicity studies for lorcaserin,” that “short-term carcinogenicity and toxicity studies have been completed” and that the carcinogenicity studies were ongoing were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(v) and intentionally or with deliberate recklessness failed to disclose them to investors.

1 134. The May 12, 2008 10-Q included SOX Certifications signed by Lief and Hoffman
2 that represented that they each reviewed the 10-Q and they each represented that it “does not
3 contain any untrue statement of a material fact or omit to state a material fact necessary to make the
4 statements made, in light of the circumstances under which such statements were made, not
5 misleading with respect to the period covered by this report. . . .”

6 135. Lief’s and Hoffman’s SOX Certifications were false and misleading because
7 Defendants knew of the material facts in ¶¶ 129(i)-(v) and intentionally or with deliberate
8 recklessness failed to disclose them to investors in the May 12, 2008 10-Q.

9 136. On August 11, 2008, Defendants caused Arena to file its quarterly report with the
10 SEC on Form 10-Q for the period ended June 30, 2008. The August 11, 2008 10-Q was signed by
11 Lief and Hoffman and, stated, in part, the following:

12 In addition to successfully completing clinical trials, in order to conduct long-term
13 clinical trials and gain regulatory approval to commercialize drug candidates,
14 regulatory authorities require that all drug candidates complete short- and long-
15 term preclinical toxicity and carcinogenicity studies. These studies in animals are
16 required to help determine the potential risk that drug candidates may be toxic or
17 cause cancer in humans. The preclinical assessment of carcinogenic potential
includes short-term in vitro and in vivo studies to look for chromosomal damage.
Short-term carcinogenicity and toxicity studies have been completed for all of our
clinical-stage programs. To date, we have only completed long-term preclinical
toxicity studies for lorcaserin, and we have not completed carcinogenicity studies
for lorcaserin or any of our other clinical-stage programs. . . .

18 Our most advanced drug candidates, including lorcaserin ... have not completed
19 all preclinical studies ... for efficacy and safety that are required for FDA
approval.

20 137. Lief and Hoffman’s representations that Defendants “completed long-term
21 preclinical toxicity studies for lorcaserin,” that “short-term carcinogenicity and toxicity studies have
22 been completed” and that carcinogenicity studies for lorcaserin were ongoing were false and
23 misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vi) and intentionally or with
24 deliberate recklessness failed to disclose them to investors.

25 138. The August 11, 2008 10-Q included SOX Certifications signed by Lief and Hoffman
26 similar to the SOX Certifications in the May 12, 2008 10-Q alleged above in ¶ 134.

139. Lief’s and Hoffman’s SOX Certifications were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vi) and intentionally or with deliberate recklessness failed to disclose them to investors in the August 11, 2008 10-Q.

140. On November 7, 2008, Defendants caused Arena to file its quarterly report with the SEC on Form 10-Q for the period ended September 30, 2008. The 10-Q was signed by Lief and Hoffman and, stated, in part, the following:

In addition to successfully completing clinical trials, in order to conduct long-term clinical trials and gain regulatory approval to commercialize drug candidates, regulatory authorities require that all drug candidates complete short- and long-term preclinical toxicity and carcinogenicity studies. These studies in animals are required to help determine the potential risk that drug candidates may be toxic or cause cancer in humans. The preclinical assessment of carcinogenic potential includes short-term in vitro and in vivo studies to look for chromosomal damage. Short-term carcinogenicity and toxicity studies have been completed for all of our clinical-stage programs. To date, we have only completed long-term preclinical toxicity studies for lorcaserin, and we have not completed carcinogenicity studies for lorcaserin or any of our other clinical-stage programs. . . .

Our most advanced drug candidates, including lorcaserin ... have not completed all preclinical studies ... for efficacy and safety that are required for FDA approval.

141. Lief and Hoffman’s representation that Defendants “completed long-term preclinical toxicity studies for lorcaserin,” that “short-term carcinogenicity and toxicity studies have been completed” and that the carcinogenicity studies for lorcaserin were ongoing were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vi) and intentionally or with deliberate recklessness failed to disclose them to investors.

142. The November 7, 2008 10-Q included SOX Certifications signed by Lief and Hoffman similar to the SOX Certifications in the May 12, 2008 10-Q alleged above in ¶ 134.

143. Lief’s and Hoffman’s SOX Certifications were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vi) and intentionally or with deliberate recklessness failed to disclose them to investors in the November 7, 2008 10-Q.

144. On March 12, 2009, Hoffman, Lief, Behan and Shanahan participated in a conference call with investors and research analysts, and Lief made the following statements:

1 **Phil Nadeau - Cowen & Co. - Analyst**

2 Good evening, thanks for taking my question. Jack, my first one is to you, in your
3 prepared remarks you made the comment that you folks are getting increasingly
4 confident on lorcaserin's potential based on the blinded data that you're saying. I was
5 wondering if you could elaborate on that comment, what in particular is giving you
6 confiden[ce] and maybe even more importantly, what have you really learned since
7 the R&D day, if anything, that has made your confidence increase?

8 **Jack Lief - Arena Pharmaceuticals, Inc. - President, CEO**

9 Well, the confidence is not just based on the blinded data, of course, the confidence
10 is based on the Phase II data, the Phase I data, the preclinical studies that was done,
11 all the animal studies that have been completed, as well as how the studies are
12 recruiting, have recruited, the retention in those studies, and that sort of thing. So
13 since the December date, of course, we've finished the BLOOM study, and so that
14 gives us a lot more confidence that we're unlikely to find some surprises that we're
15 not already aware of. Keep in mind the data is still blinded, so I don't know who's on
16 drug and who's on placebo, so we might be surprised when we unblind the data. But
17 it looks like we're seeing such things that we absolutely would expect to see.

18 145. Lief's representations were false and misleading because Defendants knew of the
19 material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose
20 them to investors.

21 146. Also on March 12, 2009, Defendant Shanahan represented that "[a]nimal studies"
22 provided "a lot of visibility on our safety associated with lorcaserin."

23 147. Defendant Shanahan's representations were false and misleading because
24 Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate
25 recklessness failed to disclose them to investors.

26 148. On March 16, 2009, Defendants caused Arena to file its annual report for the year
27 ended December 31, 2008 with the SEC on Form 10-K ("2008 10-K"). The 2008 10-K was signed
28 by Lief, Hoffman and Behan and stated, in part, the following:

Based on preclinical studies and clinical trial data to date, we believe that lorcaserin
is unlikely to cause serotonin-mediated valvulopathy or other cardiovascular side
effects.

1 Preclinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed
2 to test the efficacy of a drug candidate, but rather to test safety, to study
3 pharmacokinetics and pharmacodynamics, and to understand the drug candidate's
4 side effects at various doses and schedules. To date, long-term safety and efficacy
5 have not yet been demonstrated in clinical trials for any of our drug candidates. . . .

6 ***

7 In addition to successfully completing clinical trials, to conduct long-term clinical
8 trials and gain regulatory approval to commercialize drug candidates, regulatory
9 authorities require that all drug candidates complete short- and long-term preclinical
10 toxicity and carcinogenicity studies. These preclinical, animal studies are required to
11 help us and regulatory authorities assess the potential risk that drug candidates may
12 be toxic or cause cancer in humans.

13 ***

14 Our most advanced drug candidates, including lorcaserin, have not completed all
15 preclinical studies ... for efficacy and safety that are required for FDA approval.

16 149. Lief, Hoffman and Behan's representation that "[b]ased on preclinical studies and
17 clinical trial data to date, we believe that lorcaserin is unlikely to cause serotonin-mediated
18 valvulopathy or other cardiovascular side effects," and representations that "preclinical, animal
19 studies are required to help us and regulatory authorities assess the potential risk that drug
20 candidates may be toxic or cause cancer in humans" were false and misleading because Defendants
21 knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed
22 to disclose them to investors.

23 150. The 2008 10-K included SOX Certifications signed by Lief and Hoffman similar to
24 the certifications in the May 12, 2008 10-Q as alleged above in ¶ 134.

25 151. Lief's and Hoffman's SOX Certifications were false and misleading because
26 Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate
27 recklessness failed to disclose them to investors in the 2008 10-K.

28 152. On March 23, 2009, Defendants caused Arena to file a prospectus with the SEC on
Form 424B2 (the "March 23 Prospectus"). The March 23 Prospectus related to a registration
statement on Form S-3 that Arena filed with the SEC, using a "shelf" registration process and stated

1 that Arena “from time to time [will] offer to sell up to 25,000,000 shares of our common stock at
2 prices and on terms described in one or more supplements to this prospectus.” The March 23
3 Prospectus incorporated by reference the false statements in the 2008 10-K delineated above in
4 ¶¶ 148, 150.

5 153. On March 30, 2009, Defendants caused Arena to issue a press release that stated, in
6 part, the following:

7 Arena Pharmaceuticals Announces Positive Lorcaserin Pivotal Phase 3 Obesity Trial
8 Results: Meets All Primary Efficacy and Safety Endpoints

9 **Lorcaserin Very Well Tolerated Throughout Two-Year Study...**

10 **Safety and Tolerability Profile**

11 Lorcaserin was generally very well tolerated. The most frequent adverse events
12 reported in Year 1 and their rates for lorcaserin and placebo patients, respectively,
13 were as follows: headache (18.0% vs. 11.0%), upper respiratory tract infection
14 (14.8% vs. 11.9%), nasopharyngitis (13.4% vs. 12.0%), sinusitis (7.2% vs. 8.2%)
15 and nausea (7.5% vs. 5.4%). The most frequent adverse events reported in Year 2
16 and their rates for lorcaserin and placebo patients, respectively, were as follows:
17 upper respiratory tract infection (14.5% vs. 16.1%), nasopharyngitis (16.4% vs.
18 12.6%), sinusitis (8.6% vs. 6.9%), arthralgia (6.6% vs. 6.2%) and influenza (6.6% vs.
19 6.0%). In patients crossing over from lorcaserin to placebo after Year 1, the rates of
20 these Year 2 adverse events were: 11.0%, 13.8%, 10.6%, 6.0% and 4.9%,
21 respectively.

22 Adverse events of depression, anxiety and suicidal ideation were infrequent and
23 reported at a similar rate in each treatment group, and no seizures were reported.
24 Serious adverse events occurred with similar frequency in each group throughout the
25 trial without apparent relationship to lorcaserin. One death occurred during the trial,
26 which was a patient in the placebo arm.

27 154. Defendants’ representation that lorcaserin was “very well tolerated” based on data
28 collected throughout a two-year study was false and misleading because Defendants knew of the
material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose
them to investors.

155. Also on March 30, 2009, Lief, Shanahan, Behan and Anderson participated in a
conference call with investors and research analysts, and Defendant Shanahan made the following
statements:

[B]ased on earlier data and Lorcaserin-selected mechanism, the topline data has not
indicated any significant safety concerns....

1 I believe the BLOSSOM data will support our findings to date and allow us to
2 submit a robust database to the FDA for its evaluation....

3 ***

4 We primarily look at safety and that's what -- again, we're getting support for the
5 excellent safety profile of the drug.

6 156. Shanahan's representations concerning lorcaserin's mechanism was safe for use in
7 humans, that "topline data has not indicated any significant safety concerns," and that Defendants
8 were getting support for lorcaserin's "excellent safety profile" were false and misleading because
9 Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate
10 recklessness failed to disclose them to investors.

11 157. Also on March 30, 2009, Defendant Lief made the following representation in
12 response to an analyst's question:

13 **Alan Carr - Needham & Company - Analyst**

14 [C]an you tell me a bit more about what you think the FDA is looking for in the year
two data? . . .

15 **Jack Lief - Arena Pharmaceuticals - President and CEO**

16 We also know that there is no increase in any heart valve disease and we're not aware
17 of any excess in other areas as well. So we are really thrilled that we have such an
effective as well as safe compound. . . .

18 ***

19 We don't believe that there's any numerical disadvantage in any of these important
20 risk factors. And as you will see when the full data set is presented, our drug will be
very safe, well-tolerated.

21 I think there's a lot of information in the press release. I think over the two-year
22 period of time, as I said, more people lose more weight in a safer fashion on
Lorcaserin. The heart valves, there is a slight increase in placebo versus drug.

23 So clearly there is no signal there. . . . And so I'm really happy that we have such a
24 safe drug without the CNS or cardiovascular side effects that have plagued other
drugs potentially in the past.

25 158. Defendant Lief's answer to research analyst Alan Carr's question "[c]an you tell me
26 what you think the FDA is looking for in the year two data?" was materially false and misleading
27

1 because Lief failed to disclose the material facts in ¶¶ 129(i)-(vii) and intentionally or with
2 deliberate recklessness failed to disclose them to investors. Further, Lief's representations that the
3 "full data set" showed lorcaserin was "very safe", and that lorcaserin was a safe drug without CNS,
4 or central nervous system, side effects, were false and misleading because Defendants knew of
5 ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

6 159. On April 14, 2009, Defendants caused Arena to file a Form 424B5 with the SEC (the
7 "April 14 Prospectus Supplement"). The April 14 Prospectus Supplement related to Arena's
8 offering 5,745,591 shares of Arena common stock to Azimuth Opportunity Ltd. ("Azimuth")
9 pursuant to a Common Stock Purchase Agreement, dated March 23, 2009, between Arena and
10 Azimuth, at a price of approximately \$2.61 per share, for a total purchase price for the shares of
11 \$15.0 million. The April 14 Prospectus Supplement incorporated by reference the false statements
12 in the 2008 10-K and the March 30, 2009 press release delineated above in ¶¶ 148, 150, 153.

13 160. On May 11, 2009, Defendants caused Arena to issue a press release in which it
14 disclosed its financial results for the quarter ended March 31, 2009. The press release stated, in part,
15 the following:

16 Treatment with lorcaserin was generally very well tolerated. Lorcaserin treatment for
17 up to two years was not associated with evidence of heart valve damage; rates for the
18 development of echocardiographic FDA-defined valvulopathy were similar to
19 placebo throughout the study.

20 161. Defendants' representation that lorcaserin was "well tolerated" and that the two-year
21 data showed that lorcaserin was safe were false and misleading because Defendants knew of the
22 material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose
23 them to investors.

24 162. On May 11, 2009, Defendants caused Arena to file its quarterly report with the SEC
25 on Form 10-Q for the period ended March 31, 2009. The 10-Q was signed by Lief and Hoffman and
26 stated, in part, the following:

27 Preclinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed
28 to test the efficacy of a drug candidate, but rather to test safety, to study
pharmacokinetics and pharmacodynamics, and to understand the drug candidate's
side effects at various doses and schedules. To date, long-term safety and efficacy

have not yet been demonstrated in clinical trials for any of our drug candidates, except lorcaserin.

In addition to successfully completing clinical trials, to conduct long-term clinical trials and gain regulatory approval to commercialize drug candidates, regulatory authorities require that all drug candidates complete short- and long-term preclinical toxicity and carcinogenicity studies. These preclinical, animal studies are required to help us and regulatory authorities assess the potential risk that drug candidates may be toxic or cause cancer in humans.

Our most advanced drug candidates, including lorcaserin, have not completed all preclinical studies ... for efficacy and safety that are required for FDA approval.

163. Lief and Hoffman's representations that "long-term safety and efficacy" had been demonstrated in clinical trials of lorcaserin and that preclinical, animal studies were ongoing were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

164. The May 11, 2009 10-Q included SOX Certifications signed by Lief and Hoffman similar to certifications in the May 12, 2008 10-Q alleged above in ¶ 134.

165. Lief's and Hoffman's SOX Certifications were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

166. Also, on May 11, 2009, Defendants participated in a conference call with investors and research analysts, and Lief made the following statements:

Based on results from the BLOOM trial meeting the FDA's efficacy criteria, and coupled with a strong tolerability profile, that includes no signal of FDA Valvulopathy at any time point over the two-year treatment period, we believe that lorcaserin is approvable for weight management, both here in the US, and eventually in Europe as well

First, patients on lorcaserin in the BLOOM trial generally tolerated the drug very well. The only adverse event that exceeded placebo by 5% or greater was headache. We know from BLOOM and previous trials, that headaches associated with lorcaserin are typically mild and transient. We think that this tolerability profile will provide physicians with the confidence to use lorcaserin as a first line therapy for the majority of their patients...

1 167. Lief's representations that lorcaserin was safe and had a strong tolerability profile
2 were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vii) and
3 intentionally or with deliberate recklessness failed to disclose them to investors.

4 168. On June 6, 2009, Defendants caused Arena to issue a press release that stated, in
5 part, that as "[p]reviously announced BLOOM data demonstrated that lorcaserin ... was very well
6 tolerated. . . ."

7 169. Defendants' representation was false and misleading because Defendants knew of
8 the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to
9 disclose them to investors.

10 170. On July 8, 2009, Arena issued 12,500,000 shares of its common stock at a public
11 offering price of \$4.17 per share pursuant to a prospectus supplement and registration statement
12 filed with the SEC on Form 424B5 on July 8, 2009 (the "July 8 Prospectus Supplement"). The
13 common stock offering was made pursuant to a shelf registration statement Arena filed with the
14 SEC on November 25, 2008, which became effective on December 3, 2008 (File No. 333-155660)
15 and was signed by Lief, Hoffman and Behan. The July 8 Prospectus Supplement incorporated by
16 reference the false statements in the 2008 10-K, the May 11, 2009 10-Q and the March 30, 2009
17 press release delineated above in ¶¶ 148, 150, 153, 162, 164.

18 171. On August 3, 2009, Defendants caused Arena to issue a press release in which Lief
19 stated, in part, the following:

20 Based on its emerging efficacy, safety and tolerability profile, lorcaserin has the
21 potential to be an important new treatment option for patients needing to better
manage their weight and improve their overall health.

22 172. Lief's representation that lorcaserin had an emerging "safety and tolerability profile"
23 was false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vii) and
24 intentionally or with deliberate recklessness failed to disclose them to investors.

25 173. On August 3, 2009, Defendants participated in a conference call with investors and
26 research analysts, and Lief made the following statement:

1 We believe that Lorcaserin's complete efficacy, safety and tolerability profile will
2 position the drug candidate as an ideal new option to help manage excess body
3 weight and its associated risks. . . . This compelling safety and efficacy profile will
differentiate Lorcaserin from currently-available therapies and others in late-stage
development.

4 174. Lief's representations that lorcaserin's safety profile was "complete" and
5 "compelling," and that lorcaserin's safety profile differentiated it from drugs being developed by its
6 competitors (Orexigen and Vivus), were false and misleading because Defendants knew of the
7 material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose
8 them to investors.

9 175. Also on August 3, 2009, Defendant Anderson made the following representations:

10 **Alan Carr - Needham & Company - Analyst**

11 Are there any other gating studies, preclinical or clinical, that are still needed at the
FDA? Is the -- that last abuse potential trial, is that the last of them?

12 **Anderson:**

13 The (inaudible) study pretty much finished up that package that we are planning to
14 submit to the FDA as our initial NDA, so we will have no additional studies that
we'll be submitting in the initial NDA once we complete that study report.

15 176. Defendant Anderson's representations regarding the completed clinical and
16 preclinical studies were false and misleading because Defendants knew of the material facts in
17 ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

18 177. On August 3, 2009, Defendants caused Arena to file a registration statement on Form
19 S-3 with the SEC for the sale of up to 28 million shares of Arena common stock that was signed by
20 Lief, Hoffman and Behan that incorporated by reference the false statements in the 2008 10-K, the
21 May 11, 2009 10-Q and the March 30, 2009 press release delineated above in ¶¶ 148, 150, 153, 162,
22 164.

23 178. On August 7, 2009, Defendants caused Arena to file its quarterly report with the
24 SEC on Form 10-Q for the period ended June 30, 2009. The 10-Q was signed by Lief and Hoffman,
25 and stated, in part, the following:

26 Lorcaserin was very well tolerated, did not result in increased risk of depression and
27 was not associated with development of cardiac valvular insufficiency.

1 ***

2 In addition to successfully completing clinical trials, to conduct long-term clinical
3 trials and gain regulatory approval to commercialize drug candidates, regulatory
4 authorities require that all drug candidates complete short- and long-term preclinical
5 toxicity and carcinogenicity studies. These preclinical, animal studies are required to
6 help us and regulatory authorities assess the potential risk that drug candidates may
7 be toxic or cause cancer in humans.

8 ***

9 In addition to successfully completing clinical trials, to conduct long-term clinical
10 trials and gain regulatory approval to commercialize drug candidates, regulatory
11 authorities require that all drug candidates complete short- and long-term preclinical
12 toxicity and carcinogenicity studies. These preclinical, animal studies are required to
13 help us and regulatory authorities assess the potential risk that drug candidates may
14 be toxic or cause cancer in humans.

15 ***

16 Preclinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed
17 to test the efficacy of a drug candidate, but rather to test safety, to study
18 pharmacokinetics and pharmacodynamics, and to understand the drug candidate's
19 side effects at various doses and schedules. To date, long-term safety and efficacy
20 have not yet been demonstrated in clinical trials for any of our drug candidates,
21 except lorcaserin.

22 179. Lief and Hoffman's representation that the "long-term safety and efficacy" of
23 lorcaserin was demonstrated was false and misleading because by August 7, 2009, Defendants'
24 preclinical studies, including the Rat Study, on lorcaserin were completed, and Defendants knew of
25 the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to
26 disclose them to investors.

27 180. The August 7, 2009 10-Q included SOX Certifications signed by Lief and Hoffman
28 similar to certifications in the May 12, 2008 10-Q alleged above in ¶ 134.

181. Lief's and Hoffman's SOX Certifications were false and misleading because
Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate
recklessness failed to disclose them to investors in the August 7, 2009 10-Q.

182. On September 18, 2009, Defendants caused Arena to issue a press release that stated,
in part the following, and quoted Defendant Lief:

Lorcaserin was very well tolerated and was not associated with depression or
suicidal ideation. The integrated echocardiographic data set from BLOSSOM and

1 BLOOM rules out a risk of valvulopathy in lorcaserin patients according to criteria
2 requested by the FDA. Treatment with lorcaserin also resulted in significant
3 improvements as compared to placebo in multiple secondary endpoints associated
4 with cardiovascular risk. . . . "History has taught us that the marriage of efficacy and
5 safety is of critical importance in treating patients. Neither is sufficient without the
6 other. With its excellent safety and tolerability profile, we expect lorcaserin to
7 change the way primary care doctors treat the broad cross-section of overweight and
8 obese patients with pharmacotherapy," said Jack Lief, Arena's President and Chief
9 Executive Officer.

10 183. Lief's representation that lorcaserin had an "excellent safety profile" was false and
11 misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or
12 with deliberate recklessness failed to disclose them to investors.

13 184. The September 18, 2009 press release quoted Shanahan as stating the following:

14 These results support lorcaserin's potential to meet the need for a safe, effective and
15 well-tolerated weight loss medication. There are only two drugs that are approved by
16 the FDA for long-term treatment, and new mechanistic and better tolerated
17 approaches could greatly improve the treatment of patients who are obese or
18 significantly overweight.

19 185. Shanahan's representation that lorcaserin's "mechanism" was safe and well-tolerated
20 was false and misleading because Shanahan knew of the material facts in ¶¶ 129(i)-(vii) and
21 intentionally or with deliberate recklessness failed to disclose them to investors.

22 186. On September 18, 2009, Lief, Behan, Shanahan and Anderson participated in a
23 conference call with investors and research analysts, and Lief, Behan and Anderson made the
24 following statements regarding lorcaserin's safety:

25 **Jack Lief** - *Arena Pharmaceuticals, Inc. - President, CEO*

26 We showed that lorcaserin has an excellent safety and tolerability profile....

27 **Christy Anderson** - *Arena Pharmaceuticals, Inc. - VP Clinical Development*

28 Lorcaserin met all of BLOSSOM's primary efficacy and safety endpoints and helped
patients achieve significant weight loss with a remarkable tolerability and safety
profile. . . . We are pleased to deliver a single agent that achieves rapid and clinically
meaningful efficacy concomitant with remarkable safety and tolerability....
Lorcaserin is further differentiated from approved drugs for weight management and
those in development [qnexa and contrive] by its excellent safety and tolerability
profile.

Dominic Behan - Arena Pharmaceuticals, Inc. - CSO

We have shown that it is possible to engineer an efficacious weight management drug candidate with an excellent safety and tolerability profile.... Safety and tolerability are the foundation for compliance in the broad population of obese and overweight patients.

Jack Lief - Arena Pharmaceuticals, Inc. - President, CEO

As we've seen, lorcaserin side effects are not really meaningfully different than placebo, but patients lose twice as much weight on lorcaserin as on placebo. So we think that it's a compelling story, this marriage of efficacy, safety and tolerability.

Dominic Behan - Arena Pharmaceuticals, Inc. - CSO

[T]hat's the true unmet need in the real world which is the marriage, as Jack said, between the efficacy and the tolerability and the safety. I mean, you can't have one without the other in order to address this issue in the broad diverse obese population. It's very important that you have all of those attributes in your drug. And we have clearly shown that lorcaserin's profile meets that unmet need in the real world.

Jack Lief - Arena Pharmaceuticals, Inc. - President, CEO

[b]ecause we've tested our drug for two years I think most physicians will be comfortable with long-term use of our compound.

Jack Lief - Arena Pharmaceuticals, Inc. - President, CEO

it's a very effective drug, very safe. . . .

Dominic Behan - Arena Pharmaceuticals, Inc. - CSO

In order to have an effective viable commercial drug applicable to the broad diverse population, this marriage that Jack talked about of efficacy, tolerability and safety is absolutely critical, absolutely critical. And we have captured that profile very nicely with lorcaserin.

187. Lief, Anderson and Behan's representations that lorcaserin was safe and had an "excellent safety and tolerability profile," and that lorcaserin's safety profile differentiated it from other weight-loss drugs in development by Arena's competitors, were false and misleading because they knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

188. Also on September 18, 2009, Lief, Anderson and Behan made the following statements regarding lorcaserin's "mechanism":

Jack Lief - Arena Pharmaceuticals, Inc. - President, CEO

[lorcaserin] is a game changer in the weight management area. . . . If you look at drugs to treat hypertension, physicians have numerous choices of mechanisms to use. In weight management there are only two and the side affects actually limit the usefulness of these drugs. So I think physicians really need another choice, another mechanism, a new mechanism.

Christy Anderson - Arena Pharmaceuticals, Inc. - VP Clinical Development

Again, you've got to let us save some of the thunder here for our scientific meeting that's upcoming. I'll just reiterate that we did rule out the risk of valvulopathy the way we agreed to with the FDA. And I think this just supports both our hypothesis for the mechanism of the drug and supports the safety of the drug....

Jack Lief - Arena Pharmaceuticals, Inc. - President, CEO

Keep in mind that the receptor, the target that lorcaserin goes after is not found in the heart basically. So the 2C receptor is largely central in the brain. And so that's very consistent, the mechanism is very consistent with the clinical as well as pre-clinical experience that we know for lorcaserin. So we're excited to be able to support all of these hypotheses regarding having a selective drug that only addresses this hypothalamic target.

189. Lief and Behan's representations regarding lorcaserin's "mechanism" and Defendants' "pre-clinical experience" with lorcaserin were false and misleading because they knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

190. Also on September 18, 2009, Behan and Anderson made the following statements regarding the data concerning lorcaserin's safety:

Dominic Behan - Arena Pharmaceuticals, Inc. - CSO

As you can see from the data, we believe that lorcaserin is a game changer.

Christy Anderson - Arena Pharmaceuticals, Inc. - VP Clinical Development

You know, we've, I think, put together pretty much all of the data that we now need for this NDA. We have favorable results on everything that we've compiled so far.

191. Behan and Anderson's representations regarding the data collected for the lorcaserin NDA were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

1 192. On October 12, 2009, Defendants caused Arena to file a press release in which
2 Shanahan is quoted as stating the following:

3 "The positive results from our Phase 3 pivotal program highlight lorcaserin's
4 potential to provide physicians with a treatment option that combines three important
5 attributes - efficacy, safety and tolerability - critical to broad applicability in the
6 majority of their patients to help manage weight and improve cardiometabolic
7 health," stated William R. Shanahan, M.D., Arena's Vice President and Chief
8 Medical Officer.

9 193. Shanahan's representations concerning lorcaserin's safety were false and misleading
10 because Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate
11 recklessness failed to disclose them to investors.

12 194. On October 27, 2009, Defendants caused Arena to issue a press release in which Lief
13 and Shanahan are quoted as making the following statements:

14 William R. Shanahan, M.D., Arena's Vice President and Chief Medical Officer,
15 stated, "Based on lorcaserin's safety and efficacy profile, we expect primary care
16 physicians to find lorcaserin an attractive first-line therapy for weight
17 management...."

18 ***

19 "Our team at Arena has worked diligently to discover and develop a novel treatment
20 for weight management that delivers the combination of efficacy, safety and
21 tolerability. . . ," said Jack Lief, Arena's President and Chief Executive Officer....

22 195. Lief and Shanahan's representations that lorcaserin was safe were false and
23 misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or
24 with deliberate recklessness failed to disclose them to investors.

25 196. On October 30, 2009, Defendants caused Arena to file a report with the SEC on
26 Form 8-K that stated, in part, that lorcaserin was "very well tolerated."

27 197. This statement was false and misleading because Defendants knew of the material
28 facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to
investors.

 198. On November 9, 2009, Defendants caused Arena to issue a press release, and caused
Arena to file its quarterly report for the quarter ended September 30, 2009 with the SEC on Form
10-Q, which signed by Lief and Hoffman, that stated, in part, the following:

1 Lorcaserin was very well tolerated and no excess depression or suicidal ideation was
2 observed with lorcase rin treatment. The incidence of new FDA-defined valvulopathy
3 from the integrated echocardiographic data set from BLOSSOM and BLOOM did
4 not differ from placebo.

5 199. These representations that lorcase rin was safe were false and misleading because
6 Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate
7 recklessness failed to disclose them to investors.

8 200. Also, Lief and Hoffman made the following representations in the November 9, 2009
9 10-Q:

10 Preclinical studies include experiments performed in test tubes, in animals, or in cells
11 or tissues from humans or animals. These studies include all drug studies except
12 those conducted in human subjects, and may occur before or after initiation of
13 clinical trials for a particular compound. . . .

14 In addition to successfully completing clinical trials, to conduct long-term clinical
15 trials and gain regulatory approval to commercialize drug candidates, regulatory
16 authorities require that all drug candidates complete short- and long-term preclinical
17 toxicity and carcinogenicity studies. These preclinical, animal studies are required to
18 help us and regulatory authorities assess the potential risk that drug candidates may
19 be toxic or cause cancer in humans.

20 ***

21 Preclinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed
22 to test the efficacy of a drug candidate, but rather to test safety, to study
23 pharmacokinetics and pharmacodynamics, and to understand the drug candidate's
24 side effects at various doses and schedules. To date, long-term safety and efficacy
25 have not yet been demonstrated in clinical trials for any of our drug candidates,
26 except lorcase rin.

27 201. Lief and Hoffman's representations that Defendants demonstrated lorcase rin's "long-
28 term safety" were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-
(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

202. The November 9, 2009 10-Q included SOX Certifications signed by Lief and
Hoffman similar to certifications in the May 12, 2008 10-Q as alleged above in ¶ 134.

203. Lief's and Hoffman's SOX Certifications were false and misleading because
Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate
recklessness failed to disclose them to investors in the November 9, 2009 10-Q.

204. On November 10, 2009, Defendants conducted a conference call with investors and research analysts, and Lief made the following statements concerning the data collected concerning lorcaserin:

Jack Lief - Arena Pharmaceuticals - Chairman, CEO, President

Let me begin by telling you that our Lorcaserin program remains on track... I am pleased to report at this time we have all of the data in hand that will be included in the new drug application that we are planning to submit to the FDA next month.

Two-year data support Lorcaserin's long-term safety profile.

205. Also on November 10, 2009, Lief and Anderson made the following statements concerning lorcaserin's safety:

Christen Anderson - Arena Pharmaceuticals - VP, Clinical Development

Lorcaserin's overall profile of medically meaningful efficacy combined with excellent safety and tolerability was received with support and enthusiasm from the physicians in attendance at Obesity 2009. . . .

Jack Lief - Arena Pharmaceuticals - Chairman, CEO, President

Lorcaserin has a unique competitive profile and is differentiated from currently approved treatments for weight management and those in development by a number of important characteristics. Lorcaserin has the right combination of meaningful efficacy with a safety profile that is similar to placebo and avoids increased blood pressure and heart rate, depression, suicidal ideation and cardiac toxicity. Lorcaserin has demonstrated an outstanding tolerability profile reflected by the low incidence of withdrawals due to adverse events.

206. Also on November 10, 2009, Shanahan made the following statements concerning Defendants' meeting with the FDA concerning the lorcaserin NDA and lorcaserin's safety:

[A]t the present time we don't see safety signal to pursue, so we are going to down evaluate our data, file the NDA and then have discussions with the FDA after that.

207. The representations alleged in ¶¶ 204-06 were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

208. On November 12, 2009, Defendants caused Arena to file a prospectus with the SEC on Form 424B3 relating to the resale, from time to time, of up to 28,000,000 shares of Arena common stock by Deerfield Management Company, L.P. (and affiliated entities) that incorporated by reference the false statements in the 2008 10-K, the May 11, August 7 and November 9, 2009

1 10-Qs, and the March 30, September 18 and October 27, 2009 press releases delineated above in
2 ¶¶ 148, 150, 153, 162, 164, 178, 180, 182, 184, 194, 198, 200, 202.

3 209. On December 22, 2009, Defendants caused Arena to issue a press release that stated,
4 in part, the following:

5 William R. Shanahan, M.D., Arena's Vice President and Chief Medical Officer,
6 stated, "... Based on the robust data package we submitted to the FDA, lorcaserin
7 has the potential to meet this need, offering patients the opportunity to achieve
sustainable weight loss in a well-tolerated manner and improve their cardiometabolic
health and quality of life. . . ."

8 The pivotal Phase 3 clinical trial program, BLOOM (Behavioral modification and
9 Lorcaserin for Overweight and Obesity Management) and BLOSSOM (Behavioral
modification and Lorcaserin Second Study for Obesity Management), evaluated
10 nearly 7,200 patients treated for up to two years and showed that lorcaserin
consistently produced significant weight loss with excellent safety and tolerability.

11 210. Shanahan's representations that a "robust data package" showed lorcaserin produced
12 weight loss with "excellent safety and tolerability" were false and misleading because Defendants
13 knew of the material facts in ¶¶ 129(i)-(viii) and intentionally or with deliberate recklessness failed
14 to disclose them to investors.

15 211. On February 24, 2010, Defendants caused Arena to issue a press release that quoted
16 Defendant Lief as stating the following:

17 "The FDA's acceptance of the lorcaserin NDA is a significant milestone towards our
18 goal of providing physicians and their patients with a new mechanistic approach to
achieve sustainable weight loss in a well-tolerated manner," said Jack Lief, Arena's
19 President and Chief Executive Officer. "We look forward to working with the FDA
to facilitate a thoughtful and efficient review of the lorcaserin NDA."

20 The NDA is based on a data package from lorcaserin's development program that
21 includes 18 clinical trials totaling 8,576 patients. The pivotal Phase 3 clinical trial
program, BLOOM (Behavioral modification and Lorcaserin for Overweight and
22 Obesity Management) and BLOSSOM (Behavioral modification and Lorcaserin
Second Study for Obesity Management), evaluated nearly 7,200 patients treated for
23 up to two years. In both trials, lorcaserin produced statistically significant weight
loss with excellent safety and tolerability.

24 212. Lief's representations that based on the "data package" submitted with the NDA,
25 which included the negative Rat Study results, lorcaserin's mechanism was safe, were false and
26 misleading because Defendants knew of the material facts in ¶¶ 129(i)-(viii) and intentionally or
27 with deliberate recklessness failed to disclose them to investors.

213. On February 26, 2010, Defendants caused Arena to issue a press release that stated, in part, the following:

Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) announced today that the US Food and Drug Administration (FDA) has assigned a Prescription Drug User Fee Act (PDUFA) date of October 22, 2010, for the review of the lorcaserin New Drug Application (NDA). The acceptance of the lorcaserin NDA filing confirms that the application is sufficiently complete to permit a substantive review, and the PDUFA date is the goal date for the FDA to complete its review of the NDA...

Jack Lief, Arena's President and Chief Executive Officer, stated, "With an October PDUFA date for the lorcaserin NDA, we are another step closer to our goal of improving the treatment of obesity. We believe that lorcaserin, if approved, will be well positioned as first-line therapy to help patients achieve sustainable weight loss in a well-tolerated manner."

214. Lief's representation that lorcaserin was "well-tolerated" was false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(viii) and intentionally or with deliberate recklessness failed to disclose them to investors.

215. On March 8, 2010, Defendants caused Arena to file a prospectus supplement and accompanying prospectus pursuant to which Arena offered 8,278,432 shares of Arena common stock to Azimuth, pursuant to a Common Stock Purchase Agreement, dated March 23, 2009, between Arena and Azimuth, at a price of approximately \$2.96 per share, for a total purchase price of \$24.5 million (the "March 8 Prospectus Supplement").

216. The March 8 Prospectus Supplement incorporated by reference the false statements in the 2008 10-K, the May 11, August 7, and November 9, 2009 10-Qs and the March 30, September 18, October 27, and December 22, 2009, February 24, and February 26, 2010 press releases delineated above in ¶¶ 148, 150, 153, 162, 164, 178, 180, 182, 184, 194, 198, 200, 202, 209, 211, 213.

217. On March 12, 2010, Defendants caused Arena to issue a press release that quoted Defendant Lief as stating the following:

"We are pleased with the timely execution and significant progress made in our lorcaserin program," stated Jack Lief, Arena's President and Chief Executive Officer. "As we continue efforts to reach a commercial agreement for lorcaserin, we are building a strong foundation for a successful launch upon potential approval."

219. On March 12, 2010, Defendants participated in a conference call with investors and research analysts, and Lief made the following statements:

A couple of weeks ago we announced that the FDA accepted our NDA for filing and assigned October 22 as the PDUFA date. We are pleased to be on track as we move through an exciting year for Arena.

Lorcaserin holds significant potential to re-energize and expand the weight management category based on its unique combination of safety, efficacy and tolerability.

The FDA has said that there is sufficient data to review lorcaserin on its merits. We have also had discussions and meetings around that. So while there can never be any guarantees on anything these days, we are reasonably confident, I'm reasonably confident that the FDA will review our current package as submitted in a scientific fashion.

Lorcaserin was so well tolerated, and we don't see any safety signals that require special attention right now.

220. Lief’s representations that lorcaserin was safe, that he was “confident” in the data submitted to the FDA, and that Defendants did not “see any safety signals” were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(viii) and intentionally or with deliberate recklessness failed to disclose them to investors.

221. Also on March 12, 2010, Lief made the following statements concerning Defendants' discussions with the FDA:

Thomas Wei - Jefferies - Analyst

I had a question actually on the regulatory process so far for lorcaserin. Can you share with us any of the questions or issues that were raised in the 74-day letter from the FDA that you must have just gotten from them?

Jack Lief - *Arena Pharmaceuticals - Chairman, CEO & President*

Well, we typically do not go into the details of FDA correspondence. Having said that, we are confident that we have the ability to work with the FDA in the future during their review of the NDA, and I think we will be able to satisfy if there are any questions that they might have in the future.

222. Lief's representations concerning Arena's correspondence with the FDA, and that he was "confident" that Defendants would be able to satisfy any questions were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(viii) and intentionally or with deliberate recklessness failed to disclose them to investors.

223. Also on March 12, 2010, Behan made the following statements concerning Defendants' preparation for the FDA Advisory Committee meeting:

Terence Flynn - *Lazard Capital Markets - Analyst*

Okay and just a follow-up question. There has been a lot of focus obviously on a potential panel. I'm just wondering what you guys are doing to prepare for that and how you potentially plan to frame the discussion around the risk benefit of the drug at that potential panel if it does occur?

Dominic Behan

Well, again, [while] we have not got any specific data or communication regarding if a panel will occur, we are assuming one will, and we are preparing intensely for it. So this is quite a process. There's [sic] thousands of slides that will need to be prepared, that will be needed to be appropriately brought up to address questions almost instantaneously. So we have a team focused on that process.

(Alteration added).

224. Behan's representations were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(viii) and intentionally or with deliberate recklessness failed to disclose them to investors.

225. On March 16, 2010, Defendants caused Arena to file the 2009 10-K. The 2009 10-K was signed by Lief, Hoffman and Behan, and stated, in part, the following:

Lorcaserin was very well tolerated, did not result in increased risk of depression or suicidal ideation and was not associated with the development of cardiac valvular insufficiency.

Safety and Tolerability Profile

Treatment with lorcaserin was very well tolerated, resulting in very few adverse events with greater frequency than the placebo group.

Preclinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of a drug candidate, but rather to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the drug candidate's side effects at various doses and schedules. To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our drug candidates, except lorcaserin.

226. Lief, Behan and Hoffman's representation that lorcaserin was safe, and that Defendants demonstrated lorcaserin's "long-term safety" were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(viii) and intentionally or with deliberate recklessness failed to disclose them to investors.

227. The 2009 10-K included SOX Certifications signed by Lief and Hoffman similar to certifications in the May 12, 2008 10-Q as alleged above in ¶ 134.

228. Lief's and Hoffman's SOX Certifications were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(viii) and intentionally or with deliberate recklessness failed to disclose them to investors in the 2009 10-K.

229. On May 7, 2010, Defendants caused Arena to file its quarterly report for the quarter ended March 31, 2010 with the SEC on Form 10-Q. The May 7, 2010 was signed by Lief and Hoffman and stated, in part, the following:

Preclinical studies include experiments performed in test tubes, in animals, or in cells or tissues from humans or animals. These studies include all drug studies except those conducted in human subjects, and may occur before or after initiation of clinical trials for a particular compound. . . .

In addition to successfully completing clinical trials, to conduct long-term clinical trials and gain regulatory approval to commercialize drug candidates, regulatory authorities require that all drug candidates complete short- and long-term preclinical toxicity and carcinogenicity studies. These preclinical, animal studies are required to help us and regulatory authorities assess the potential risk that drug candidates may be toxic or cause cancer in humans.

1 Preclinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed
2 to test the efficacy of a drug candidate, but rather to test safety, to study
3 pharmacokinetics and pharmacodynamics, and to understand the drug candidate's
4 side effects at various doses and schedules. To date, long-term safety and efficacy
5 have not yet been demonstrated in clinical trials for any of our drug candidates,
6 except lorcaserin.

7 230. Lief and Hoffman's representation that Defendants demonstrated lorcaserin's "long-
8 term safety" was false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-
9 (viii) and intentionally or with deliberate recklessness failed to disclose them to investors.

10 231. The May 7, 2010 10-Q included SOX Certifications signed by Lief and Hoffman
11 similar to certifications in the May 12, 2008 10-Q as alleged above in ¶ 134.

12 232. Lief's and Hoffman's SOX Certifications were false and misleading because
13 Defendants knew of the material facts in ¶¶ 129(i)-(viii) and intentionally or with deliberate
14 recklessness failed to disclose them to investors in the May 7, 2010 10-Q.

15 233. On June 2, 2010, Defendants caused Arena to issue a press release that quoted
16 Defendant Lief as stating the following:

17 "We are focused on obtaining the FDA's approval of lorcaserin, and have been
18 preparing for this anticipated advisory committee meeting," said Jack Lief, Arena's
19 President and Chief Executive Officer. "With its unique combination of safety,
20 tolerability and efficacy, we believe that lorcaserin, if approved, has the potential to
21 serve as first-line therapy to help patients achieve sustainable weight loss in a well-
22 tolerated manner."

23 234. Lief's representation that lorcaserin was safe was false and misleading because
24 Defendants knew of the material facts in ¶¶ 129(i)-(viii) and intentionally or with deliberate
25 recklessness failed to disclose them.

26 235. On June 22, 2010, Defendants caused Arena to file a prospectus with the SEC on
27 Form 424B3 that incorporated by reference the false statements in the 2009 10-K, the May 7, 2010
28 10-Q and the February 26, 2010 press release delineated above in ¶¶ 213, 225, 227, 229, 231.

236. On July 14, 2010, Arena issued a press release that stated, in part, that "[a]mong the
most frequent adverse events reported with lorcaserin were headache (18.0% vs. 11.0%, lorcaserin
vs. placebo); dizziness (8.2% vs. 3.8%); and nausea (7.5% vs. 5.4%). The rates of serious adverse

events were similar in both treatment groups. The rates of depression and the incidence of anxiety and suicidal thoughts were low in both treatment groups. Lorcaserin caused no significant increase compared to placebo in the incidence of new cardiac valvulopathy.”

237. Defendants’ representation that lorcaserin was safe, was false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(viii) and intentionally or with deliberate recklessness failed to disclose them to investors.

238. Also on August 3, 2010, Defendants participated a conference call with investors and research analysts, and Lief made the following statements:

Jack Lief - Arena Pharmaceuticals - Chairman, President, CEO

We have recently announced a number of important milestones in the lorcaserin program, and we're right on track with our plans. . . . Our primary objective at this time is to obtain FDA approval for lorcaserin. We are preparing for our advisory committee meeting, tentatively scheduled for September 16, and look forward to our October 22 PDUFA date. We have always stated that safety is of paramount importance to the FDA, and that the right profile of efficacy, safety, and tolerability is essential for a weight-management drug. . . .

Jack Lief - Arena Pharmaceuticals - Chairman, President, CEO

In conclusion, we believe that lorcaserin's unique profile, safety, efficacy, and tolerability as demonstrated in our pivotal program, has the potential to advance the management of obesity. We are pleased with the recent execution of critical milestones and look forward to continuing interaction with the FDA to complete its review of the lorcaserin application.

239. Lief’s representation that lorcaserin was safe and that Defendants “always stated that safety is of paramount importance to the FDA” were false and misleading because Lief knew of the material facts in ¶¶ 129(i)-(viii) and intentionally or with deliberate recklessness failed to disclose them.

240. Also on August 3, 2010, Shanahan, Lief and Anderson made the following representations concerning Defendants discussions with the FDA:

Phil Nadeau - Cowen & Co. - Analyst

Okay. Can you maybe give us some idea of what you think the issues could be? Or where you are focusing your preparation?

Bill Shanahan - Arena Pharmaceuticals - SVP, Chief Medical Officer

Well, we're not expecting any surprises associated with the panel. Obviously we will present our view of lorcaserin, and the FDA will present their view. I think the views

1 will overlap substantially, and I look forward to a very positive panel. Christy, you
2 want to -- anything to add to that?

3 **Christy Anderson** - *Arena Pharmaceuticals - VP of Clinical Development*

4 I agree with what Jack said. Obviously, we've always said that the primary focus
5 would be on safety, and we are well prepared to thoroughly address the safety issues,
6 or the safety data, as well as the efficacy data with the panel.

7 ***

8 **Alan Carr** - *Needham & Company - Analyst*

9 Question. Wanted to follow-on one of the themes from Phil. So can you tell us what
10 lessons you all learned from the Qnexa advisory meeting, and how that might apply
11 to lorcaserin?

12 **Jack Lief** - *Arena Pharmaceuticals - Chairman, President, CEO*

13 Well remember, Qnexa was a very, very different compound than lorcaserin, and we
14 will present much of the data, as we understand it, on lorcaserin, and I don't think
15 we're going to have any surprises. Christy, do you want to further comment on that?

16 **Christy Anderson** - *Arena Pharmaceuticals - VP of Clinical Development*

17 I think -- this is going to be a recurrent theme. As we anticipated, safety was the
18 focus of that panel, and I think we can anticipate that safety will be a key focus at the
19 lorcaserin panel. We're doing everything in our power to be well prepared to discuss
20 all of the safety data with the advisory panel.

21 ***

22 **Christy Anderson** - *Arena Pharmaceuticals - VP of Clinical Development*

23 Again, we have always been very comfortable with the safety profile... again, I think
24 we are pretty comfortable that we have shown a good safety and tolerability profile,
25 and we are prepared to support that at the advisory committee.

26 241. Shanahan, Lief and Anderson's representations that lorcaserin, unlike Qnexa, was
27 "safe," that "[w]e're doing everything in our power to be well prepared to discuss all of the safety
28 data with the advisory panel," and representations about the issues the FDA and Defendants would
discuss at the Advisory Committee meeting were false and misleading because Defendants knew of
the material facts in ¶¶ 129(i)-(viii) and intentionally or with deliberate recklessness failed to
disclose them to investors.

242. On August 6, 2010, Arena issued a press release that stated, in part, the following:

FDA Confirms September 16th Advisory Committee Meeting to Review Lorcaserin
for Obesity and Weight Management. . . .

"Our primary objective at this time is to obtain FDA approval of lorcaserin," said
Jack Lief, Arena's President and Chief Executive Officer. "We have been preparing

1 for this anticipated Advisory Committee meeting, and look forward to reviewing
2 lorcaserin's profile with the panel members. . . ."

3 243. Lief's representations were false and misleading because he knew of the material
4 facts in ¶¶ 129(i)-(viii) and intentionally or with deliberate recklessness failed to disclose them.

5 244. On August 6, 2010, Defendants caused Arena to file a prospectus supplement
6 pursuant to which Arena offered 8,955,244 shares of Arena common stock at a price of
7 approximately \$6.70 per share, for a total purchase price of approximately \$60 million (the
8 "August 6 Prospectus Supplement").

9 245. The August 6 Prospectus Supplement incorporated by reference the false statements
10 in the 2009 10-K and the May 7, 2010 10-Q delineated above in ¶¶ 225, 227, 229, 231.

11 246. On August 9, 2010, Defendants caused Arena to file its quarterly report for the
12 quarter ended June 30, 2010 with the SEC on Form 10-Q. The August 9, 2010 10-Q was signed by
13 Lief and Hoffman and stated, in part, the following:

14 An NDA must be supported by extensive clinical and preclinical data, as well as
15 extensive information regarding chemistry, manufacturing and controls to
16 demonstrate the safety and effectiveness of the drug candidate. . . . We submitted our
17 NDA for lorcaserin in December 2009, and the FDA has assigned an October 22,
18 2010 PDUFA date for their review of our NDA

19 ***

20 Preclinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed
21 to test the efficacy of a drug candidate, but rather to test safety, to study
22 pharmacokinetics and pharmacodynamics, and to understand the drug candidate's
23 side effects at various doses and schedules. To date, long-term safety and efficacy
24 have not yet been demonstrated in clinical trials for any of our drug candidates,
25 except lorcaserin.

26 247. Lief and Hoffman's representations that Defendants had demonstrated lorcaserin's
27 "long-term safety" were false and misleading because Defendants knew of the material facts in
28 ¶¶ 129(i)-(viii) and intentionally or with deliberate recklessness failed to disclose them to investors.

29 248. The August 9, 2010 10-Q included SOX Certifications signed by Lief and Hoffman
30 similar to certifications in the May 12, 2008 10-Q as alleged above in ¶ 134.

1 249. Lief's and Hoffman's SOX Certifications were false and misleading because
2 Defendants knew of the material facts in ¶¶ 129(i)-(viii) and intentionally or with deliberate
3 recklessness failed to disclose them to investors in the August 9, 2010 10-Q.

4 On December 22, 2010, Arena issued a press release disclosing that Defendants
5 completed the "end-of-review" meeting with the FDA for lorcaserin that stated, in
part, the following:

6 Based on guidance we have received from the agency, we are executing several
7 activities and expect to resubmit the lorcaserin NDA by the end of 2011. . . . The
8 end-of-review meeting with the FDA included a discussion of the FDA's position
on issues identified in the CRL and Arena's plan to respond.

9 250. Also on December 22, 2010, Defendants conducted a conference call with investors
10 and research analysts to discuss the "end-of-review" meeting with the FDA, and Lief and Anderson
11 made the following statements:

12 **Christy Anderson** - *Arena Pharmaceuticals, Inc. - VP of Lorcaserin Development*

13 Thanks, Jack. I will first summarize each of the three nonclinical topics that Jack
14 mentioned. . . .

15 The second nonclinical issue was an unresolved exposure response relationship for
16 lorcaserin emergent mammary adenocarcinoma. The FDA has asked that we
17 demonstrate the mechanism by which lorcaserin causes mammary tumors in rats and
that this mechanism is reasonably irrelevant to human risk. . . . To address this issue,
we have initiated nonclinical studies to provide the requested evidence to the agency.

18 ***

19 **Carol Werther** - *Summer Street Research - Analyst*

So the duration of the trial is pretty short then?

20 **Jack Lief** - *Arena Pharmaceuticals, Inc. - President and CEO*

21 Yes.

22 ***

23 **Jack Lief** - *Arena Pharmaceuticals, Inc. - President and CEO*

24 And the agency has been very helpful in approving our protocols for the
25 readjudication and that sort of thing. So this is all pretty clear for us.

26 251. These statements were false and misleading because Defendants knew of the
27 material facts in ¶ 129(ix) and intentionally or with deliberate recklessness failed to disclose them to
investors.

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263. To the extent any of Defendants' statements are found to be forward-looking statements, there was no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

264. Indeed, as alleged herein, Defendants' cautionary language throughout the Class Period was ineffective to warn research analysts from Jefferies, J.P. Morgan, Canaccord, Cowen & Co., Rodman & Renshaw, Oppenheimer, Summer Street and Zach's of the undisclosed, material facts alleged herein.

265. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, Defendants knew that the particular forward looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Arena who knew that those statements were false when made.

FIRST CLAIM FOR RELIEF UNDER THE EXCHANGE ACT
For Violation of Section 10(b) of the Exchange Act
and Rule 10b-5 Promulgated Thereunder Against Defendants

266. Lead Plaintiff repeats and realleges each and every allegation contained above.

267. Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 in that they:

(a) employed devices, schemes and artifices to defraud;

(b) made untrue statements of material facts or omitted to state material facts necessary in order to make statements made, in light of the circumstances under which they were made not misleading; or

(c) engaged in acts, practices, and a course of business that operated as a fraud or deceit upon Lead Plaintiff and other similarly situated investors in connection with their purchases of Arena securities during the Class Period.

268. As alleged herein, Defendants acted with scienter in that they intentionally or with deliberate recklessness made statements to investors that were materially false and misleading

1 concerning lorcasearin. Defendants knew that such statements or documents would be issued or
2 disseminated to the investing public; and knowingly and substantially participated or acquiesced in
3 the issuance or dissemination of such statements or documents.

4 269. The state of mind of the Individual Defendants, as well as other Arena employees
5 acting within the scope of their employment and on behalf of Arena, and/or as Arena's agent or as
6 agent for one or more of the Individual Defendants, such as Brunswick, is imputed to Arena. As
7 alleged above, the Individual Defendants, as well as numerous other Arena employees, including
8 Brunswick, knew of the Rat Study and the FDA's concerns about the Rat Study and concerns about
9 its relevance to humans.

10 270. As set forth above in detail, Defendants, by virtue of their knowledge of the Rat
11 Study, their control over, and/or receipt and/or modification of Arena's allegedly materially
12 misleading misstatements and/or their associations with the Company which made them privy to
13 confidential proprietary information concerning lorcasearin and the results of the Rat Study,
14 participated in the fraudulent scheme alleged herein.

15 271. Defendants knew or at least with deliberate recklessness disregarded the false and
16 misleading nature of their respective statements and of the information that they caused to be
17 disseminated to the investing public. The ongoing fraudulent scheme described in this complaint
18 could not have been perpetrated over a substantial period of time, as has occurred, without the
19 knowledge and complicity of personnel at the highest level of the Company, including the
20 Individual Defendants, and/or individuals with access to and/or received nonpublic material
21 information concerning the results of the Rat Study and the FDA's interest in them.

22 272. Defendants had the motive and opportunity to perpetrate the fraudulent scheme and
23 course of business described herein. The Individual Defendants were the most senior officers of
24 Arena, issued statements and press releases on behalf of Arena, and each made false statements
25 concerning lorcasearin and had the opportunity to commit the fraud alleged.

26 273. Defendants were motivated to inflate the price of Arena securities in order to raise
27 over \$150 million for Arena from investors from the sale of Arena common stock at artificially

1 inflated prices as alleged above. As alleged above, Defendants caused Arena to sell stock at
2 suspicious times. The timing of the sales was suspicious because Defendants knew of the negative
3 material facts alleged above, or acted with deliberate recklessness.

4 274. During the Class Period, Defendants disseminated or approved the false statements
5 specified above, which they knew or deliberately and recklessly disregarded as materially false and
6 misleading in that they contained material misrepresentations and failed to disclose material facts
7 necessary in order to make the statements made, in light of the circumstances under which they
8 were made, not misleading to investors.

9 275. Lead Plaintiff and the Class have suffered damages in that, in reliance on the
10 integrity of the market, they paid artificially inflated prices for Arena's securities. Lead Plaintiff and
11 the Class would not have purchased Arena securities at the prices they paid, nor at all, if they had
12 been aware that the market prices had been artificially inflated by Defendants' materially
13 misleading statements and/or material omissions.

14 276. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiff and
15 the other members of the Class suffered damages in connection with their purchases of Arena
16 securities during the Class Period.

17 **SECOND CLAIM FOR RELIEF UNDER THE EXCHANGE ACT**

18 **For Violation of Section 20(a) of the Exchange Act** 19 **Against the Individual Defendants**

20 277. Lead Plaintiff repeats and realleges each and every allegation contained above.

21 278. Individual Defendants Lief, Shanahan, Behan, Hoffman and Anderson each acted as
22 controlling persons of Arena within the meaning of Section 20(a) of the Exchange Act. By virtue of
23 their high-level positions, participation in and/or awareness of Arena's lorcaserin program, the Rat
24 Study's results, participation in conference calls with investors and analysts and/or intimate
25 knowledge of the statements filed by the Company with the SEC and disseminated to the investing
26 public, and attendance at meetings with the FDA on behalf of Arena, the Individual Defendants had
27

1 the power to influence and control and did influence and control, directly or indirectly, the decision-
2 making of the Company, including the content and dissemination of the various statements
3 concerning the development and safety of lorcaserin that Lead Plaintiff contends are materially false
4 and misleading.

5 279. The Individual Defendants were provided with or had unlimited access to copies of
6 the Company's reports, bi-monthly updates on the Rat Study to the FDA, drafts of, and the final Rat
7 Study report submitted to the FDA, press releases, public filings and other statements alleged by
8 Lead Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the
9 ability to prevent the issuance of the statements or cause the statements to be corrected.

10 280. During the Class Period, Lief and Behan were members of the Company's board of
11 directors and had responsibilities to review, approve and monitor fundamental financial and
12 business strategies and major corporate actions, oversee potential risks facing the Company and the
13 Company's risk management activities, select and oversee management and determine its
14 composition and oversee the establishment and maintenance of processes and conditions to
15 maintain the integrity of the Company.

16 281. The Individual Defendants had direct and supervisory involvement in the day-to-day
17 operations of the Company and the clinical and preclinical studies of lorcaserin, and therefore, are
18 presumed to have had the power to control or influence the materially false and misleading
19 representations giving rise to the securities violations as alleged herein, and exercised such power.

20 282. As set forth above, Arena and the Individual Defendants each violated Section 10(b)
21 and Rule 10b-5 by their acts and omissions as alleged in this complaint. By virtue of their positions
22 as well as their conduct alleged herein, the Individual Defendants are liable pursuant to
23 Section 20(a) of the Exchange Act.

24 283. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiff and
25 other members of the Class suffered damages in connection with their purchases of the Company's
26 securities during the Class Period.

1 **IV. CLASS ACTION ALLEGATIONS**

2 284. Lead Plaintiff brings this action as a class action pursuant to Federal Rules of Civil
3 Procedure 23(a) and 23(b)(3) on behalf of a class of all persons and entities who purchased the
4 securities of Arena between March 17, 2008 and January 27, 2011, inclusive (the “Class”).

5 285. The members of the Class are so numerous that joinder of all members is
6 impracticable. While the exact number of Class members is unknown to Lead Plaintiff at the
7 present time and can only be ascertained through appropriate discovery, Lead Plaintiff believes that
8 there are hundreds of members of the Class located throughout the United States. As of August 5,
9 2010, Arena had over 112 million shares of common stock outstanding.

10 286. Lead Plaintiff’s claims are typical of the claims of the members of the Class. Lead
11 Plaintiff and all members of the Class have sustained damages because of Defendants’ unlawful
12 activities alleged herein. Lead Plaintiff has retained counsel competent and experienced in class and
13 securities litigation and intends to pursue this action vigorously. The interests of the Class will be
14 fairly and adequately protected by Lead Plaintiff. Lead Plaintiff has no interests which are contrary
15 to or in conflict with those of the Class that Lead Plaintiff seeks to represent.

16 287. A class action is superior to all other available methods for the fair and efficient
17 adjudication of this controversy. Lead Plaintiff knows of no difficulty to be encountered in the
18 management of this action that would preclude its maintenance as a class action.

19 288. Common questions of law and fact exist as to all members of the Class and
20 predominate over any questions solely affecting individual members of the Class. Among the
21 questions of law and fact common to the Class are:

22 (a) whether the federal securities laws were violated by Defendants’ acts and
23 omissions as alleged herein;

24 (b) whether Defendants’ misstated and/or omitted to state material facts in their
25 public statements, press releases and filings with the SEC;

26 (c) whether Defendants acted with the requisite state of mind;

(d) whether Defendants participated directly or indirectly in the course of conduct complained of herein; and

(e) whether the members of the Class have sustained damages and the proper measure of such damages.

PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiff prays for judgment as follows: declaring this action to be a proper class action; certifying the Lead Plaintiff as a Class Representative and Lead Counsel as Class Counsel; awarding damages, including interest; awarding reasonable costs, including attorneys' fees; and such equitable/injunctive relief as the Court may deem proper.

JURY DEMAND

Lead Plaintiff demands a trial by jury.

DATED: May 13, 2013

KAPLAN FOX & KILSHEIMER LLP

By: /s/ Laurence D. King

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CERTIFICATE OF SERVICE

I, Laurence D. King, hereby declare that on May 13, 2013, I caused the foregoing to be filed electronically using the Court’s CM/ECF system which sent notifications of the filing to counsel of record.

/s/ Laurence D. King
Laurence D. King

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Attorneys for Defendants Arena Pharmaceuticals, Inc., Jack Lief,
 Robert E. Hoffman, Dominic P. Behan, William R. Shanahan, Jr.,
 and Christy Anderson

UNITED STATES DISTRICT COURT
 SOUTHERN DISTRICT OF CALIFORNIA

TODD SCHUENEMAN, on behalf of himself
 and all others similarly situation,

Plaintiff,

v.

ARENA PHARMACEUTICALS, INC.,
 JACK LIEF, ROBERT E. HOFFMAN,
 DOMINIC P. BEHAN, WILLIAM R.
 SHANAHAN, and CHRISTY ANDERSON,

Defendants.

Case No. 10-CV-1959-BTM (BLM)

**REQUEST FOR JUDICIAL NOTICE IN
 SUPPORT OF MOTION TO DISMISS
 CONSOLIDATED AMENDED CLASS
 ACTION COMPLAINT**

Hearing Date: March 30, 2012
 Hearing Time: 11:00 a.m.
 Courtroom: 15, 5th Floor
 Judge: Hon. Barry T. Moskowitz

**[Per Chambers, no oral argument unless
 requested by the Court]**

WILLIAM SUTLIFF and JEAN SUTLIFF,
 on behalf of themselves and all others
 similarly situation,

Plaintiffs,

v.

ARENA PHARMACEUTICALS, INC.,
 JACK LIEF, and WILLIAM SHANAHAN,
 JR.

Defendants.

Case No. 10-CV-1961-BTM (BLM)

WILLIAM PRATT, Individually and on
Behalf of All Others Similarly Situated,

Plaintiff,

v.

ARENA PHARMACEUTICALS, INC.,
JACK LIEF, ROBERT E. HOFFMAN,
DOMINIC P. BEHAN, WILLIAM R.
SHANAHAN, JR. and CHRISTY
ANDERSON

Defendants.

Case No. 10-CV-1977-BTM (BLM)

CRAIG RUBENSTEIN, Individually and on
Behalf of All Others Similarly Situated,

Plaintiff,

v.

ARENA PHARMACEUTICALS, INC.,
JACK LIEF, ROBERT E. HOFFMAN,
DOMINIC P. BEHAN, WILLIAM R.
SHANAHAN, JR. and CHRISTY
ANDERSON

Defendants.

Case No. 10-CV-1984-BTM (BLM)

RODNEY VELASQUEZ, on behalf of
himself and all others similarly situated,

Plaintiff,

v.

ARENA PHARMACEUTICALS, INC.,
JACK LIEF, ROBERT E. HOFFMAN,
DOMINIC P. BEHAN, WILLIAM R.
SHANAHAN, JR. and CHRISTY
ANDERSON

Defendants.

Case No. 10-CV-2026 BTM (BLM)

THONG VU, Individually and on behalf of all
others similarly situated

Plaintiff,

v.

ARENA PHARMACEUTICALS, INC.,
JACK LIEF, ROBERT E. HOFFMAN,
DOMINIC P. BEHAN, WILLIAM R.
SHANAHAN, and CHRISTY ANDERSON

Defendants.

Case No. 10-CV-2086-BTM (BLM)

ARIC D. JACOBSON, individually and on
behalf of all others similarly situated,

Plaintiff,

v.

ARENA PHARMACEUTICALS, INC.,
JACK LIEF, ROBERT E. HOFFMAN,
DOMINIC P. BEHAN, WILLIAM R.
SHANAHAN, JR. and CHRISTY
ANDERSON,

Defendants.

Case No. 10-cv-2335-BTM (BLM)

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that defendants Arena Pharmaceuticals, Inc. (“Arena”), Jack Lief, Robert Hoffman, Dominic Behan, William Shanahan, Jr., and Christy Anderson (collectively “defendants”) request that the Court take judicial notice of the following documents pursuant to Federal Rule of Evidence 201 and related authority.

- Exhibit A¹ Arena Fiscal Year (“FY”) 2008 Form 10-K, filed with the Securities and Exchange Commission (“SEC”) on March 16, 2009 (excerpted).
- Exhibit B U.S. Food and Drug Administration (“FDA”) Manual of Policies and Procedures, Center for Drug Evaluation and Research, section 6010.5.
- Exhibit C Arena FY2009 Form 10-K, filed with the SEC on March 16, 2010 (excerpted).
- Exhibit D Arena Press Release dated December 22, 2009.
- Exhibit E Arena Press Release dated March 17, 2008.
- Exhibit F Arena Press Release dated March 12, 2009.
- Exhibit G Arena Press Release dated March 30, 2009.
- Exhibit H Transcript of an Arena Conference Call on May 11, 2009 (excerpted).
- Exhibit I Arena Press Release dated September 18, 2009.
- Exhibit J Transcript of an Arena Conference Call on September 18, 2009 (excerpted).
- Exhibit K Arena Press Release dated October 12, 2009.
- Exhibit L Arena Press Release dated November 9, 2009.
- Exhibit M Transcript of an Arena Conference Call on November 10, 2009 (excerpted).
- Exhibit N Arena Press Release dated February 24, 2010.
- Exhibit O Arena Press Release dated February 26, 2010.
- Exhibit P FDA Briefing Document for September 16, 2010 FDA Advisory Committee Meeting re: lorcaserin, available at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/ucm225628.htm> (last visited December 19, 2011) (excerpted).

¹ All exhibit references correspond to the exhibits attached to the Declaration of Ryan E. Blair in Support of Defendants’ Motion to Dismiss Consolidated Amended Class Action Complaint (“Blair Decl.”).

- 1 Exhibit Q Screenshot of webpage on FDA Website containing Arena and FDA
2 Briefing Documents, available at
3 <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/ucm225628.htm>
4 (last visited December 19, 2011).
- 5 Exhibit R Arena Briefing Document for September 16, 2010 FDA Advisory
6 Committee Meeting re: lorcaserin, available at
7 <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/ucm225628.htm>
8 (last visited December 19, 2011) (excerpted).
- 9 Exhibit S Transcript of September 16, 2010 FDA Advisory Committee Meeting re:
10 lorcaserin (excerpted).
- 11 Exhibit T FDA Guidance for Industry: S1C(R2) Dose Selection for Carcinogenicity
12 Studies.
- 13 Exhibit U Transcript of an Arena Conference Call on December 22, 2010 (excerpted).
- 14 Exhibit V Arena Form 8-K and accompanying Exhibit 99.1, filed with the SEC on
15 August 9, 2011.
- 16 Exhibit W² FDA drug labels for Caduet, Geodon, Kuvan, Lexapro, Lunesta, Protonix,
17 Vytarin, and Xopenex HFA (all excerpted and all available at
18 <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>); Pfizer,
19 Inc. Form 8-K and accompanying Exhibit 99.1, filed with the SEC on
20 January 22, 2003; Pfizer, Inc. Form 10-Q for the quarter ended June 30,
21 2000, filed with the SEC on August 15, 2000 (excerpted); BioMarin
22 Pharmaceutical Inc. FY2006 Form 10-K, filed with the SEC on February
23 28, 2007 (excerpted); Forest Laboratories, Inc. FY2002 Form 10-K, filed
24 with the SEC on June 27, 2003 (excerpted); Sepracor, Inc. FY2002 Form
25 10-K, filed with the SEC on March 31, 2003 (excerpted); American Home
26 Products Corp. FY1998 Form 10-K, filed with the SEC on March 29, 1999
27 (excerpted); Schering-Plough Corp. Form 8-K and accompanying Exhibit
28 99.1, filed with the SEC on July 21, 2004; Merck & Co. Inc. Form 8-K and
accompanying Exhibit 99.1, filed with the SEC on March 15, 2004;
Sepracor, Inc. Form 10-Q for the quarter ended September 30, 2004, filed
with the SEC on November 9, 2004 (excerpted).
- Exhibit X Arena Form DEF14A, filed with the SEC on April 24, 2008 (excerpted);
Arena Form DEF14A, filed with the SEC on April 27, 2011 (excerpted).
- Exhibit Y *Kovtun v. Vivus, Inc.*, Case No. 10-cv-4957-PJH (N.D. Cal. Oct. 13, 2011).
- Exhibit Z Transcript of an Arena Conference Call on March 30, 2009.
- Exhibit AA Arena Press Release dated May 11, 2009.
- Exhibit AB Arena Press Release dated June 6, 2009.

² Defendants have also attached to **Exhibits W** and **X** charts summarizing the exhibits' contents. Defendants do not seek judicial notice of the charts, and include them for the Court's convenience only.

- 1 Exhibit AC Arena Form 10-Q for the period ending June 30, 2009, filed with the SEC
on August 7, 2009 (excerpted).
- 2 Exhibit AD Arena Press Release dated October 27, 2009.
- 3 Exhibit AE Arena Form 8-K, filed with the SEC on October 30, 2009.
- 4 Exhibit AF Arena Form 10-Q for the period ending September 30, 2009, filed with the
5 SEC on November 9, 2009 (excerpted).
- 6 Exhibit AG Arena Press Release dated July 14, 2010.
- 7 Exhibit AH Arena Form 8-K, filed with the SEC on January 27, 2011.
- 8 Exhibit AI Transcript of an Arena Conference Call on August 3, 2009.
- 9 Exhibit AJ Arena Press Release dated August 3, 2009.
- 10 Exhibit AK Arena Press Release dated March 12, 2010.
- 11 Exhibit AL Arena Press Release dated August 6, 2010.
- 12 Exhibit AM Transcript of an Arena Conference Call on March 12, 2009.
- 13 Exhibit AN Transcript of an Arena Conference Call on March 12, 2010.
- 14 Exhibit AO Transcript of an Arena Conference Call on August 3, 2010.
- 15 Exhibit AP Arena Form 10-Q for the period ending March 31, 2008, filed with the
16 SEC on May 12, 2008 (excerpted).
- 17 Exhibit AQ Arena Form 10-Q for the period ending June 30, 2008, filed with the SEC
on August 11, 2008 (excerpted).
- 18 Exhibit AR Arena Form 10-Q for the period ending September 30, 2008, filed with the
19 SEC on November 7, 2008 (excerpted).
- 20 Exhibit AS Arena Form 10-Q for the period ending March 31, 2009, filed with the
SEC on May 11, 2009 (excerpted).
- 21 Exhibit AT Arena Form 10-Q for the period ending March 31, 2010, filed with the
22 SEC on May 7, 2010 (excerpted).
- 23 Exhibit AU Arena Form 10-Q for the period ending June 30, 2010, filed with the SEC
on August 9, 2010 (excerpted).
- 24 Exhibit AV Arena Press Release dated June 2, 2010.
- 25 Exhibit AW Arena Press Release dated December 22, 2010.

26 **I. GENERAL STANDARDS.**

27 Under the Federal Rules of Evidence, a court can judicially notice any fact that is “not
28 subject to reasonable dispute in that it is either (1) generally known within the territorial

jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned.” Fed. R. Evid. 201(b). “Facts subject to judicial notice may be considered in ruling on a motion to dismiss.” *Patel v. Parnes*, 253 F.R.D. 531, 545 (C.D. Cal. 2008) (citing *Mullis v. U.S. Bankr. Ct., Dist. of Nev.*, 828 F.2d 1385, 1388 (9th Cir. 1987)). And, the Court *must* take judicial notice if “requested by a party and supplied with the necessary information.” Fed. R. Evid. 201(d).

II. JUDICIAL NOTICE OF DOCUMENTS REFERENCED IN THE CAC IS PROPER.

Under the “incorporation by reference” doctrine, a court may consider, in ruling on a Rule 12(b)(6) motion, “documents whose contents are alleged in a complaint and whose authenticity no party questions, but which are not physically attached to the pleading[.]” *Patel*, 253 F.R.D. at 545 (quoting *In re Stac Elecs. Sec. Litig.*, 89 F.3d 1399, 1405, n.4 (9th Cir. 1996)). This doctrine also includes documents that are “necessary to plaintiffs’ allegations, even if not explicitly referenced in the complaint.” *Wietschner v. Monterey Pasta Co.*, 294 F. Supp. 2d 1102, 1109 (N.D. Cal. 2003) (taking judicial notice of SEC filings because “they are clearly, if indirectly, referenced in the Complaint as integral to the . . . allegations made in the Complaint”).

Here, **Exhibits A-P, S, U, and Z-AW** contain excerpts from public documents that are referenced and quoted extensively in plaintiff’s Consolidated Amended Class Action Complaint (“CAC”) and, therefore, are explicitly incorporated by reference into the CAC and are properly subject to judicial notice. (See CAC ¶¶ 18, 54, 70, 71, 78, 84, 86, 89, 92, 95, 97, 99, 103, 105, 107, 108, 110, 113, 115, 118, 123, 126, 128, 130, 132, 134, 136, 138, 141, 144, 146, 148, 152, 154, 156, 159, 162, 169, 173, and 176-177.) Accordingly, **Exhibits A-P, S, U, and Z-AW** are properly subject to judicial notice under the incorporation by reference doctrine.

III. JUDICIAL NOTICE OF PUBLIC FILINGS WITH THE SEC IS PROPER.

Courts are also specifically authorized to take judicial notice of documents filed with the SEC. See, e.g., *Metzler Inv. GMBH v. Corinthian Colls., Inc.*, 540 F.3d 1049, 1064 n.7 (9th Cir. 2008) (affirming district court’s judicial notice of SEC filings as “proper”); *Dreiling v. Am. Exp. Co.*, 458 F.3d 942, 946 n.2 (9th Cir. 2006) (noting courts may consider “any matter subject to judicial notice, such as SEC filings” in ruling on Rule 12(b)(6) motion to dismiss); *In re Rackable*

1 *Sys., Inc. Sec. Litig.*, 2010 WL 3447857, at *3 (N.D. Cal. Aug. 27, 2010) (“The Court grants
 2 Defendants’ request for judicial notice of Exhibits 1 through 23 of the request because SEC
 3 filings may be judicially noticed.”) (citation omitted). Courts may take notice of relevant SEC
 4 filings even when those filings are not mentioned in the underlying complaint. *See Glenbrook*
 5 *Capital Ltd. P’ship v. Kuo*, 525 F. Supp. 2d 1130, 1137 (N.D. Cal. 2007); *Plevy v. Haggarty*, 38
 6 F. Supp. 2d 816, 821 (C.D. Cal. 1998).

7 Here, in addition to being properly noticeable under the incorporation by reference
 8 doctrine (*see* Section II., above), **Exhibits A, C, V, X, AC, AE-AF, AH, and AP-AU** are
 9 excerpts from certain of Arena’s public filings with the SEC between 2008 and 2011. The
 10 documents in **Exhibit W** consist, in part, of excerpts from other companies’ SEC filings. These
 11 documents are “capable of accurate and ready determination” and their “accuracy cannot
 12 reasonably be questioned.” Fed. R. Evid. 201(b). Therefore, the Court should take judicial notice
 13 of **Exhibits A, C, V, W-X, AC, AE-AF, AH, and AP-AU**.

14 **IV. JUDICIAL NOTICE OF PUBLICLY AVAILABLE INFORMATION IS PROPER.**

15 Courts may take judicial notice of “information that was publicly available to reasonable
 16 investors at the time the defendant made statements plaintiffs alleged were fraudulent.” *See In re*
 17 *The First Union Corp. Sec. Litig.*, 128 F. Supp. 2d 871, 883 (W.D.N.C. 2001); *In re FAC Realty*
 18 *Sec. Litig.* (“*FAC Realty*”), 990 F. Supp. 416, 420 (E.D.N.C. 1997). In addition to being
 19 judicially noticeable under the incorporation by reference doctrine, or as documents filed with the
 20 SEC, **Exhibits A-AW** are press releases, transcripts of conference calls, official FDA documents,
 21 SEC filings, and other documents widely available to reasonable investors during the relevant
 22 time period. Judicial notice of these documents is proper. *See FAC Realty*, 990 F. Supp. at 420
 23 (taking judicial notice of press releases); *Wenger v. Lumisys, Inc.*, 2 F. Supp. 2d 1231, 1243 (N.D.
 24 Cal. 1998) (taking judicial notice of a conference call transcript “for the purpose of alerting the
 25 court to [defendant’s] safe harbor warning”).

V. JUDICIAL NOTICE OF OFFICIAL FDA DOCUMENTS, DOCUMENTS ON THE FDA'S WEBSITE, AND OTHER PUBLIC RECORDS IS PROPER.

Courts may take judicial notice of public records and other government documents. *See L'Garde, Inc. v. Raytheon Space & Airborne Sys.*, 2011 U.S. Dist. LEXIS 82125, at *6-7 (C.D. Cal. July 26, 2011) (“[J]ust as public records and government documents are generally considered not to be subject to reasonable dispute, so too does this include public records and government documents available from reliable sources on the Internet.”). FDA documents and other documents available on the FDA’s website and records of official FDA proceedings are therefore proper subjects of judicial notice. *See, e.g., Hansen Beverage Co. v. Innovation Ventures, LLC*, 2009 U.S. Dist. LEXIS 127605, at *7 (S.D. Cal. Dec. 23, 2009) (Gonzalez, J.) (taking judicial notice of FDA materials from the FDA website because “[i]nformation on government agency websites has often been treated as properly subject to judicial notice”); *Meeker v. Belridge Water Storage Dist.*, 2006 U.S. Dist. LEXIS 91775, at *27-28 (E.D. Cal. Oct. 18, 2006) (minutes from district’s board meeting are public records subject to judicial notice); *In re Nuvelo, Inc.*, 668 F. Supp. 2d 1217, 1220 (N.D. Cal. 2009) (“Courts hearing securities fraud cases routinely take judicial notice of documents with unquestioned authenticity that demonstrate the information available to the market during the class period.”).

Exhibits B is an official FDA Manual available to the public. **Exhibit T** is guidance issued by the FDA to the pharmaceutical industry and available to the public. As official FDA documents, **Exhibits B** and **T** are proper subjects of judicial notice. *See Hansen Beverage Co.*, 2009 U.S. Dist. LEXIS 127605, at *7; *In re XenoPort, Inc. Sec. Litig.*, 2011 U.S. Dist. LEXIS 142523, at *7 (N.D. Cal. Dec. 12, 2011) (holding that FDA guidance is a type of information that may be considered on a motion to dismiss); *Peviani v. Hostess Brands, Inc.*, 750 F. Supp. 2d 1111, 1116 (C.D. Cal. 2010) (the FDA Food Labeling Guide is a judicially noticeable document). **Exhibits P** (FDA’s Briefing Document) and **R** (Arena’s Briefing Document) were both available on an FDA website (a screenshot of which is attached as **Exhibit Q**) during the class period and were therefore available to reasonable investors. Judicial notice of **Exhibits P, Q, and R** is proper. *See In re Nuvelo, Inc.*, 668 F. Supp. at 1220; *Constr. Laborers Pension Trust of Greater*

1 *St. Louis v. Neurocrine Biosciences, Inc.*, 2008 U.S. Dist. LEXIS 73020, at *18 (S.D. Cal. Sept.
 2 23, 2008) (Gonzalez, J.) (taking judicial notice of an FDA document because “[d]ocuments
 3 publically available to a reasonable investor during the class period are an appropriate subject of
 4 judicial notice”). **Exhibit S** is a copy of the transcript from the September 16, 2010 FDA
 5 Advisory Committee meeting for lorcaserin and, as such, is the record of an official government
 6 proceeding subject to judicial notice. *See Meeker*, 2006 U.S. Dist. LEXIS 91775, at *27-28.
 7 **Exhibit W** consists, in part, of drug labels for FDA-approved drugs which are available on an
 8 FDA website. (*See* <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm> (last visited
 9 December 19, 2011).) As documents publicly available on a government website, the drug labels
 10 in **Exhibit W** are properly subject to judicial notice. *See Daniels-Hall v. Nat’l Educ. Ass’n.*, 629
 11 F.3d 992, 998-99 (9th Cir. 2010) (finding that it is appropriate to take judicial notice of
 12 information on a school district’s website where it was made publicly available by a government
 13 entity). Finally, **Exhibit Y** is an official public court record that is properly subject to judicial
 14 notice. *See DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212, 1218 (S.D. Cal. 2001) (Whelan,
 15 J.) (unpublished district court orders in unrelated actions are public documents properly subject to
 16 judicial notice). Therefore, the Court should take judicial notice of **Exhibits B, P-T, W, and Y**.

17 **VI. CONCLUSION.**

18 All of the documents for which defendants seek judicial notice (**Exhibits A through AW**)
 19 are capable of immediate and accurate determination by resort to easily accessible sources of
 20 indisputable accuracy. Fed. R. Evid. 201. For this and all the reasons stated above, defendants
 21 respectfully ask that the Court take judicial notice of the requested documents.

22 ///

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26 ///

27 ///

28

1 Dated: December 30, 2011

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KOJI F. FUKUMURA (189719)
MARY KATHRYN KELLEY (170259)
RYAN E. BLAIR (246724)

/s/ Ryan E. Blair

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 Robert E. Hoffman, Dominic P. Behan, William R. Shanahan, Jr.,
 and Christy Anderson

UNITED STATES DISTRICT COURT
 SOUTHERN DISTRICT OF CALIFORNIA

TODD SCHUENEMAN, on behalf of himself
 and all others similarly situation,

Plaintiff,

v.

ARENA PHARMACEUTICALS, INC.,
 JACK LIEF, ROBERT E. HOFFMAN,
 DOMINIC P. BEHAN, WILLIAM R.
 SHANAHAN, and CHRISTY ANDERSON,

Defendants.

Case No. 10-CV-1959-BTM (BLM)

**DECLARATION OF RYAN E. BLAIR IN
 SUPPORT OF MOTION TO DISMISS
 CONSOLIDATED AMENDED CLASS
 ACTION COMPLAINT**

Hearing Date: March 30, 2012
 Hearing Time: 11:00 a.m.
 Courtroom: 15, 5th Floor
 Judge: Hon. Barry T. Moskowitz

**[Per Chambers, no oral argument unless
 requested by the Court]**

WILLIAM SUTLIFF and JEAN SUTLIFF,
 on behalf of themselves and all others
 similarly situation,

Plaintiffs,

v.

ARENA PHARMACEUTICALS, INC.,
 JACK LIEF, and WILLIAM SHANAHAN,
 JR.

Defendants.

Case No. 10-CV-1961-BTM (BLM)

1 WILLIAM PRATT, Individually and on
2 Behalf of All Others Similarly Situated,

3 Plaintiff,

4 v.

5 ARENA PHARMACEUTICALS, INC.,
6 JACK LIEF, ROBERT E. HOFFMAN,
7 DOMINIC P. BEHAN, WILLIAM R.
8 SHANAHAN, JR. and CHRISTY
9 ANDERSON

10 Defendants.

Case No. 10-CV-1977-BTM (BLM)

11 CRAIG RUBENSTEIN, Individually and on
12 Behalf of All Others Similarly Situated,

13 Plaintiff,

14 v.

15 ARENA PHARMACEUTICALS, INC.,
16 JACK LIEF, ROBERT E. HOFFMAN,
17 DOMINIC P. BEHAN, WILLIAM R.
18 SHANAHAN, JR. and CHRISTY
19 ANDERSON

20 Defendants.

Case No. 10-CV-1984-BTM (BLM)

21 RODNEY VELASQUEZ, on behalf of
22 himself and all others similarly situated,

23 Plaintiff,

24 v.

25 ARENA PHARMACEUTICALS, INC.,
26 JACK LIEF, ROBERT E. HOFFMAN,
27 DOMINIC P. BEHAN, WILLIAM R.
28 SHANAHAN, JR. and CHRISTY
ANDERSON

Defendants.

Case No. 10-CV-2026 BTM (BLM)

1 THONG VU, Individually and on behalf of all
2 others similarly situated

3 Plaintiff,

4 v.

5 ARENA PHARMACEUTICALS, INC.,
6 JACK LIEF, ROBERT E. HOFFMAN,
7 DOMINIC P. BEHAN, WILLIAM R.
8 SHANAHAN, and CHRISTY ANDERSON

9 Defendants.

Case No. 10-CV-2086-BTM (BLM)

10 ARIC D. JACOBSON, individually and on
11 behalf of all others similarly situated,

12 Plaintiff,

13 v.

14 ARENA PHARMACEUTICALS, INC.,
15 JACK LIEF, ROBERT E. HOFFMAN,
16 DOMINIC P. BEHAN, WILLIAM R.
17 SHANAHAN, JR. and CHRISTY
18 ANDERSON,

19 Defendants.

Case No. 10-cv-2335-BTM (BLM)

1 I, Ryan E. Blair, declare as follows:

2 1. I am an attorney with the law firm of Cooley LLP, counsel for defendants Arena
3 Pharmaceuticals, Inc. (“Arena”), Jack Lief, Robert E. Hoffman, Dominic P. Behan, William R.
4 Shanahan, Jr., and Christy Anderson. I have personal knowledge of the following facts and, if
5 called upon to testify, I could and would testify competently thereto.

6 2. Attached hereto as Exhibit A is a true and correct copy of excerpts of Arena’s
7 Fiscal Year (“FY”) 2008 Form 10-K (without exhibits), filed with the Securities and Exchange
8 Commission (“SEC”) on March 16, 2009.

9 3. Attached hereto as Exhibit B is a true and correct copy of the U.S. Food and Drug
10 Administration’s (“FDA”) Manual of Policies and Procedures, Center for Drug Evaluation and
11 Research, section 6010.5.

12 4. Attached hereto as Exhibit C is a true and correct copy of excerpts of Arena’s
13 FY2009 Form 10-K (without exhibits), filed with the SEC on March 16, 2010.

14 5. Attached hereto as Exhibit D is a true and correct copy of Arena’s press release
15 dated December 22, 2009.

16 6. Attached hereto as Exhibit E is a true and correct copy of Arena’s press release
17 dated March 17, 2008.

18 7. Attached hereto as Exhibit F is a true and correct copy of Arena’s press release
19 dated March 12, 2009.

20 8. Attached hereto as Exhibit G is a true and correct copy of Arena’s press release
21 dated March 30, 2009.

22 9. Attached hereto as Exhibit H is a true and correct copy of excerpts of Arena’s
23 conference call transcript dated May 11, 2009.

24 10. Attached hereto as Exhibit I is a true and correct copy of Arena’s press release
25 dated September 18, 2009.

26 11. Attached hereto as Exhibit J is a true and correct copy of excerpts of Arena’s
27 conference call transcript dated September 18, 2009.

28

12. Attached hereto as Exhibit K is a true and correct copy of Arena's press release dated October 12, 2009.

13. Attached hereto as Exhibit L is a true and correct copy of Arena's press release dated November 9, 2009.

14. Attached hereto as Exhibit M is a true and correct copy of excerpts of Arena's conference call transcript dated November 10, 2009.

15. Attached hereto as Exhibit N is a true and correct copy of Arena's press release dated February 24, 2010.

16. Attached hereto as Exhibit O is a true and correct copy of Arena's press release dated February 26, 2010.

17. Attached hereto as Exhibit P is a true and correct copy of excerpts of the FDA's Briefing Document for the FDA Advisory Committee meeting on September 16, 2010 regarding lorcaserin, also available at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/ucm225628.htm> (last visited December 19, 2011).

18. Attached hereto as Exhibit Q is a true and correct copy of a screenshot of a webpage on the FDA's website containing Arena's and the FDA's Briefing Documents for the FDA Advisory Committee meeting on September 16, 2010 regarding lorcaserin, also available at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/ucm225628.htm> (last visited December 19, 2011).

19. Attached hereto as Exhibit R is a true and correct copy of excerpts of Arena's Briefing Document for the FDA Advisory Committee meeting on September 16, 2010 regarding lorcaserin, also available at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/ucm225628.htm> (last visited December 19, 2011).

20. Attached hereto as Exhibit S is a true and correct copy of excerpts of the transcript of the FDA Advisory Committee meeting on September 16, 2010.

21. Attached hereto as Exhibit T is a true and correct copy of the FDA's Guidance for Industry: S1C(R2) Dose Selection for Carcinogenicity Studies.

22. Attached hereto as Exhibit U is a true and correct copy of excerpts of Arena's conference call transcript dated December 22, 2010.

23. Attached hereto as Exhibit V is a true and correct copy of Arena's Form 8-K and accompanying Exhibit 99.1, filed with the SEC on August 9, 2011.

24. Attached hereto as Exhibit W is a true and correct copy of, and excerpts from, drug labels for the FDA-approved drugs Caduet, Geodon, Kuvan, Lexapro, Lunesta, Protonix, Vytorin, and Xopenex HFA, and documents filed with the SEC by Pfizer, Inc., BioMarin Pharmaceuticals, Inc., Forest Laboratories, inc., Sepracor, Inc., American Home Products Corp., Schering-Plough Corp., and Merck & Co., Inc. (the makers of the aforementioned drugs). For the convenience of the Court, this exhibit also includes a chart summarizing relevant portions of the attached documents.

25. Attached hereto as Exhibit X is a true and correct copy of excerpts of Arena's Form DEF14A, filed with the SEC on April 24, 2008, and Arena's Form DEF14A, filed with the SEC on April 27, 2011. For the convenience of the Court, this exhibit also includes a chart summarizing the information contained in the attached documents.

26. Attached hereto as Exhibit Y is a true and correct copy of an order issued by the United States District Court, Northern District of California, in the action styled *Kovtun v. Vivus, Inc.*, Case No. 10-cv-4957-PJH (N.D. Cal. Oct. 13, 2011).

27. Attached hereto as Exhibit Z is a true and correct copy of excerpts of Arena's conference call transcript dated March 30, 2009.

28. Attached hereto as Exhibit AA is a true and correct copy of Arena's press release dated May 11, 2009.

29. Attached hereto as Exhibit AB is a true and correct copy of Arena's press release dated June 6, 2009.

30. Attached hereto as Exhibit AC is a true and correct copy of excerpts of Arena's Form 10-Q for the period ending June 30, 2009 (without exhibits), filed with the SEC on

1 August 7, 2009.

2 31. Attached hereto as Exhibit AD is a true and correct copy of Arena's press release
3 dated October 27, 2009.

4 32. Attached hereto as Exhibit AE is a true and correct copy of Arena's Form 8-K,
5 filed with the SEC on October 30, 2009.

6 33. Attached hereto as Exhibit AF is a true and correct copy of excerpts of Arena's
7 Form 10-Q for the period ending September 30, 2009 (without exhibits), filed with the SEC on
8 November 9, 2009.

9 34. Attached hereto as Exhibit AG is a true and correct copy of Arena's press release
10 dated July 14, 2010.

11 35. Attached hereto as Exhibit AH is a true and correct copy of Arena's Form 8-K,
12 filed with the SEC on January 27, 2011.

13 36. Attached hereto as Exhibit AI is a true and correct copy of excerpts of Arena's
14 conference call transcript dated August 3, 2009.

15 37. Attached hereto as Exhibit AJ is a true and correct copy of Arena's press release
16 dated August 3, 2009.

17 38. Attached hereto as Exhibit AK is a true and correct copy of Arena's press release
18 dated March 12, 2010.

19 39. Attached hereto as Exhibit AL is a true and correct copy of Arena's press release
20 dated August 6, 2010.

21 40. Attached hereto as Exhibit AM is a true and correct copy of excerpts of Arena's
22 conference call transcript dated March 12, 2009.

23 41. Attached hereto as Exhibit AN is a true and correct copy of excerpts of Arena's
24 conference call transcript dated March 12, 2010.

25 42. Attached hereto as Exhibit AO is a true and correct copy of excerpts of Arena's
26 conference call transcript dated August 3, 2010.

27 43. Attached hereto as Exhibit AP is a true and correct copy of excerpts of Arena's
28 Form 10-Q for the period ending March 31, 2008 (without exhibits), filed with the SEC on

1 May 12, 2008.

2 44. Attached hereto as Exhibit AQ is a true and correct copy of excerpts of Arena's
3 Form 10-Q for the period ending June 30, 2008 (without exhibits), filed with the SEC on August
4 11, 2008.

5 45. Attached hereto as Exhibit AR is a true and correct copy of excerpts of Arena's
6 Form 10-Q for the period ending September 30, 2008 (without exhibits), filed with the SEC on
7 November 7, 2008.

8 46. Attached hereto as Exhibit AS is a true and correct copy of excerpts of Arena's
9 Form 10-Q for the period ending March 31, 2009 (without exhibits), filed with the SEC on May
10 11, 2009.

11 47. Attached hereto as Exhibit AT is a true and correct copy of excerpts of Arena's
12 Form 10-Q for the period ending March 31, 2010 (without exhibits), filed with the SEC on
13 May 7, 2010.

14 48. Attached hereto as Exhibit AU is a true and correct copy of excerpts of Arena's
15 Form 10-Q for the period ending June 30, 2010 (without exhibits), filed with the SEC on August
16 9, 2010.

17 49. Attached hereto as Exhibit AV is a true and correct copy of Arena's press release
18 dated June 2, 2010.

19 50. Attached hereto as Exhibit AW is a true and correct copy of Arena's press release
20 dated December 22, 2010.

21 I declare under penalty of perjury under the laws of the United States that the foregoing is
22 true and correct. Executed this 30th day of December, 2011 at San Diego, California.

23
24 /s/ Ryan E. Blair
25 Ryan E. Blair
26
27
28

EXHIBIT A

Table of Contents

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2008

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____
COMMISSION FILE NUMBER 000-31161

ARENA PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

23-2908305
(I.R.S. Employer
Identification No.)

6166 Nancy Ridge Drive, San Diego, CA
(Address of principal executive offices)

92121
(Zip Code)

858.453.7200
(Registrant's telephone number, including area code)
Securities registered pursuant to 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, \$0.0001 par value	NASDAQ Global Market
Preferred Stock Purchase Rights	NASDAQ Global Market

Securities registered pursuant to 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐ (Do not check if a smaller reporting company)

Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately \$377.5 million as of June 30, 2008, based on the last sale price of the registrant's common stock as reported on the NASDAQ Global Market on such date. For purposes of this calculation, shares of the registrant's common stock held by directors and executive officers have been excluded. This number is provided only for purposes of this Annual Report on Form 10-K and does not represent an admission that any particular person or entity is an affiliate of the registrant.

As of March 13, 2009, there were 74,194,462 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required by Part III of this Annual Report on Form 10-K is incorporated by reference from the registrant's definitive proxy statement for the annual meeting of stockholders to be held in June 2009, which will be filed with the Securities and Exchange Commission within 120 days after the close of the registrant's fiscal year ended December 31, 2008.

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In addition to internal programs, we have partnerships with pharmaceutical companies, including Merck and Ortho-McNeil-Janssen. Our Merck partnership is focused on niacin receptor agonists as treatments for atherosclerosis and other disorders. In February 2009, we announced that Merck initiated a Phase 2 clinical trial of a second generation oral niacin receptor agonist under our partnership. Our Ortho-McNeil-Janssen partnership is focused on receptor agonists of an orphan GPCR, known as GPR119, as treatments for diabetes and other disorders. In December 2008, we announced that Ortho-McNeil-Janssen initiated a first-in-human Phase 1 clinical trial of APD597, a novel, oral drug candidate discovered by Arena.

We intend to commercialize our drug candidates with partners or independently. We have not received regulatory approval for marketing or selling any drugs. We have also not generated commercial revenues from selling any drugs, other than in connection with manufacturing drugs for Siegfried Ltd, or Siegfried. We were incorporated in 1997.

Our Research and Development Programs

We have built a broad pipeline of drug candidates that target large and attractive market opportunities in several therapeutic areas. The following table summarizes our current independent and partnered development programs and selected research programs:

Development Program (Indication)	Development Status	Commercial Rights
Lorcaserin (obesity)	Phase 3	Arena
APD791 (arterial thrombosis)	Phase 1	Arena
Niacin receptor agonist (atherosclerosis and other related conditions)	Phase 2	Merck
APD597 (type 2 diabetes)	Phase 1	Ortho-McNeil-Janssen
APD916 (narcolepsy and cataplexy)	Preclinical	Arena
APD811 (pulmonary arterial hypertension)	Preclinical	Arena
Research Program		
Cardiovascular	Research	Arena
Central nervous system	Research	Arena
Inflammatory diseases	Research	Arena
Metabolic diseases	Research	Arena

Note: The above table does not list all of our research programs.

Due to the current global economic challenges and our financial condition, we have decided to focus our near-term research and development efforts on lorcaserin, preclinical activities sufficient to support an IND filing for our most promising research programs, and on earlier-stage research programs. Since preclinical research and development is significantly less resource intensive than clinical development, this will help us conserve resources and focus on the completion of the lorcaserin clinical trials and the preparation and submission of our planned filing of an NDA for lorcaserin by the end of 2009. Consistent with this approach, we have temporarily suspended further clinical development of APD791 and delayed the IND filing for APD916. We will reevaluate this approach in light of changes in our financial condition and the global economic environment. We do not expect this approach to impact the progress of our partnered programs because our partners are controlling and funding the development of these programs.

Clinical Development Programs

Lorcaserin

We are investigating lorcaserin in a Phase 3 pivotal trial program for the treatment of obesity. The US Department of Health and Human Services states that approximately one third of US adults were obese in 2005-2006. Studies have shown that a modest weight loss of 5% to 10% of body weight from baseline can result

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in meaningful improvements in cardiovascular risk factors (e.g., lipids, blood pressure and blood glucose) and a significant reduction in the incidence of type 2 diabetes. Pharmaceutical treatment options for obesity are currently limited.

Mechanism of Action. Lorcaserin is a novel and selective serotonin 2C receptor agonist. The serotonin 2C receptor is a GPCR located in the brain, including the hypothalamus, which is an area of the brain involved in the control of appetite and metabolism. Stimulation of this receptor is strongly associated with feeding behavior and satiety. We conducted preclinical studies examining the activity and serotonin receptor subtype specificity of lorcaserin. In these studies, lorcaserin demonstrated a high affinity and selectivity for the serotonin 2C receptor, with approximately 15-fold and 100-fold selectivity *in vitro* over the human serotonin 2A and serotonin 2B receptors, respectively, and no pharmacologic activity at other serotonin receptors except at concentrations greatly exceeding the expected therapeutic range.

Based on preclinical studies and clinical trial data to date, we believe that lorcaserin is unlikely to cause serotonin-mediated valvulopathy or other cardiovascular side effects. This belief is supported by the independent Echocardiographic Data Safety Monitoring Board, or ESMB, reviews of unblinded echocardiographic data that were performed after patients completed 6 and 12 months of dosing in the BLOOM trial. The ESMB reviews confirmed that differences, if any, in the rates of FDA-defined valvulopathy in patients treated with lorcaserin and in the control group did not meet the ESMB's predetermined stopping criteria. Our belief is also supported by data from our 4- and 12-week clinical trials, in which no apparent effects of the drug were seen on heart valves or pulmonary arterial pressure, and by long-term (6-12 month) toxicity studies at high doses in animals. However, the longer-term, ongoing clinical trials of lorcaserin will be needed to confirm these results. This is a major and continuing focus of our Phase 3 clinical trial program.

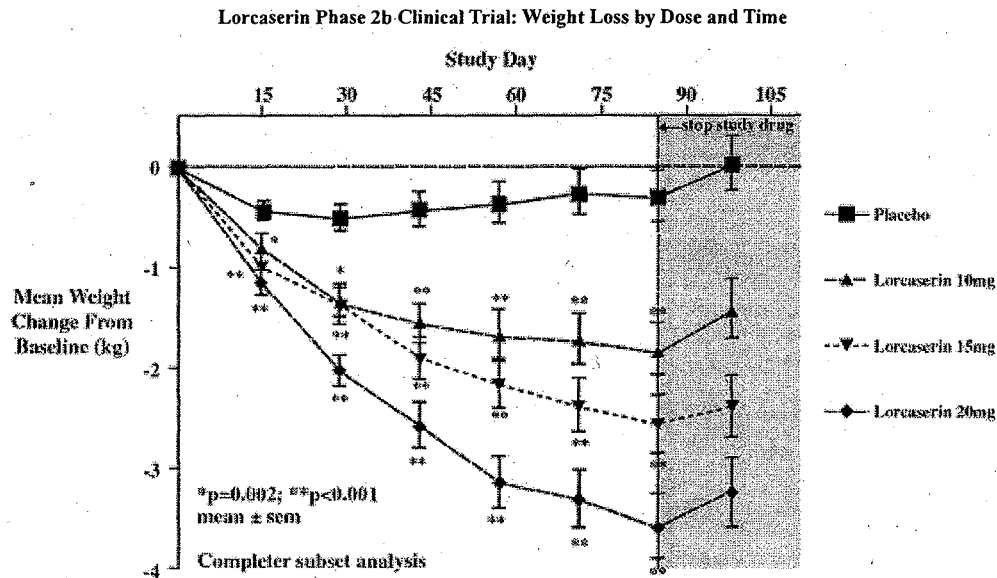
Prior Clinical Development. We have completed multiple Phase 1 and Phase 2 clinical trials of lorcaserin. Our Phase 2a clinical trial included 352 obese patients dosed for 28 days, and our Phase 2b clinical trial included 469 obese patients dosed for 12 weeks. Highly statistically significant, clinically meaningful and progressive weight loss was observed in both Phase 2 clinical trials, with no apparent drug effect on heart valves or pulmonary artery pressure, as assessed by serial echocardiograms. Lorcaserin was also generally well tolerated in both Phase 2 clinical trials.

The randomized, double-blind, multiple-dose, 28-day Phase 2a clinical trial of lorcaserin in obese patients compared doses of 1 mg, 5 mg and 15 mg of lorcaserin to placebo. Patients did not receive any diet or exercise advice, other than to abstain from consuming alcohol during the trial. Over the 28-day treatment period there was a highly statistically significant ($p=0.0002$) mean weight loss of 2.9 pounds in patients taking the 15 mg dose of lorcaserin versus 0.7 pounds for the placebo group. Lorcaserin was generally well tolerated at all doses investigated in the trial. An assessment of follow-up echocardiograms taken at the end of dosing and approximately 90 days after patients received their first doses of lorcaserin indicated no apparent drug effect on heart valves or pulmonary artery pressure.

The randomized, double-blind, multiple-dose, 12-week Phase 2b clinical trial of lorcaserin in obese patients compared doses of 10 mg and 15 mg once daily and 20 mg (10 mg dosed twice daily) of lorcaserin to placebo. Patients did not receive any diet or exercise advice, other than to abstain from consuming alcohol during the trial. The primary endpoint of the trial was weight loss after administration of lorcaserin for 12 weeks. Patients completing the 12-week treatment period with lorcaserin achieved a highly statistically significant ($p<0.001$) mean weight loss of 4.0, 5.7 and 7.9 pounds at daily doses of 10 mg, 15 mg and 20 mg (10 mg dosed twice daily), respectively, compared to 0.7 pounds for the placebo group. Using an intent-to-treat, last-observation-carried-forward analysis, treatment with lorcaserin was also associated with a highly statistically significant ($p<0.001$) mean weight loss of 3.7, 4.8 and 6.8 pounds at daily doses of 10 mg, 15 mg and 20 mg (10 mg dosed twice daily), respectively, in patients taking lorcaserin compared to 0.4 pounds for the placebo group. The proportions of patients completing the 12-week treatment period with lorcaserin who achieved a 5%

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or greater weight loss from baseline were 13% ($p=0.015$), 20% ($p<0.001$) and 31% ($p<0.001$) at daily doses of 10 mg, 15 mg and 20 mg (10 mg dosed twice daily), respectively, compared to 2% in the placebo group. Lorcaserin was generally well tolerated at all doses investigated in the trial. Adverse events occurring in greater than 5% in any of the dosed groups were headache, nausea, dizziness, vomiting, dry mouth, nasopharyngitis, fatigue and urinary tract infection. As demonstrated by the graph below, average weight loss increased progressively at each time point measured throughout the trial for all lorcaserin dose groups and was dose-dependent. As we expected, after patients stopped taking lorcaserin, they started to regain weight.



An assessment of echocardiograms at baseline and day 85 indicated no apparent lorcaserin effect on heart valves or pulmonary artery pressure. No changes in valvular regurgitation greater than one category, and no significant increases in pulmonary artery pressure in any group were identified in the echocardiogram results. No significant differences in the number of patients with increased regurgitation at any value were observed between any treatment group and placebo. Valvular regurgitation, a measure of back flow or leakage of blood through heart valves due to imperfect valve closing, was scored on a five-point scale (absent, trace, mild, moderate or severe) for the mitral and aortic valves. The FDA defines significant valvulopathy as mild or greater aortic valve regurgitation or moderate or greater mitral valve regurgitation. This is one measure used in our Phase 3 program to assess potential effects of lorcaserin on heart valves. As demonstrated by the table below, the incidence of FDA-defined valvulopathy was greater, as a percentage by treatment, in the placebo group versus the combined lorcaserin treated groups.

Table of Contents**Lorcaserin Phase 2b Clinical Trial: Incidence of FDA-Defined Valvulopathy**

	Placebo	Lorcaserin		
		10 mg	15 mg	20 mg
Patients (N)	99	99A 100M	96	96
Aortic (A) Regurgitation	0	0	1	0
Mitral (M) Regurgitation	2	0	1	0
Percent by Dose	2.0%	0.0%	2.1%	0.0%
Percent by Treatment	2.0%	0.7%		

Phase 3 Clinical Development. In September 2006, we initiated the first of three planned Phase 3 clinical trials to evaluate the safety and efficacy of lorcaserin for the treatment of obesity. BLOOM, the first of the three clinical trials, completed enrollment in February of 2007 with 3,181 overweight and obese patients in approximately 100 centers in the United States.

BLOOM is a randomized, double-blind and placebo-controlled trial evaluating a 20 mg dose (10 mg dosed twice daily) of lorcaserin versus placebo over a two-year treatment period in obese patients (Body Mass Index, or BMI, of 30 to 45) with or without co-morbid conditions and overweight patients (BMI of 27 to less than 30) with at least one co-morbid condition. The primary efficacy endpoint is the proportion of patients with a 5% or greater weight reduction from baseline at week 52 as compared to placebo.

Patients in the trial received echocardiograms at screening and at 6, 12, 18 and 24 months after initiating dosing in the trial. In March 2008, we announced the continuation of the BLOOM trial after the independent ESMB conducted the second of its two planned reviews of the unblinded echocardiographic data for patients who had completed 12 months of dosing in the trial. The ESMB's review confirmed that differences, if any, in the rates of FDA-defined valvulopathy in patients treated with lorcaserin and in the control group did not meet their predetermined stopping criteria. The review also confirmed that the rate of FDA-defined valvulopathy in the trial is consistent with our statistical powering assumptions used in the design of the clinical trial program to monitor patients for any increased risk of developing valvulopathy. In September 2007, the ESMB performed its first echocardiographic data review after patients completed six months of dosing in the trial, and reached a similar conclusion.

In December 2007, we initiated BLOSSOM and BLOOM-DM, the second and third Phase 3 clinical trials evaluating lorcaserin's efficacy and safety. These trials are one-year, randomized, double-blind and placebo-controlled clinical trials. BLOSSOM completed enrollment in June 2008 with 4,008 patients, and BLOOM-DM is expected to enroll a total of approximately 600 patients. Consistent with our proposal, the FDA has allowed us to eliminate the requirement to perform echocardiographic testing prior to enrolling patients in both of these trials. As a result, patients with preexisting FDA-defined valvulopathy and other echocardiographic variants and abnormalities were enrolled in the BLOSSOM and BLOOM-DM trials. This is different from the design of BLOOM, the initial Phase 3 trial, in which echocardiography was used to screen for patients with FDA-defined valvulopathy and certain other echocardiographic abnormalities and exclude those patients from enrolling in the trial. Instead, in BLOSSOM and BLOOM-DM, there are no such echocardiographically defined exclusion criteria, although serial echocardiograms are being obtained to extend the lorcaserin safety database. BLOOM, BLOSSOM and BLOOM-DM comprise the entire planned Phase 3 clinical trial program for lorcaserin.

The BLOSSOM trial is evaluating 10 mg and 20 mg daily doses (10 mg dosed once or twice daily) of lorcaserin versus placebo over a one-year treatment period in obese patients (BMI of 30 to 45) with or without co-morbid conditions and overweight patients (BMI of 27 to less than 30) with at least one co-morbid condition.

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at about 100 sites in the United States. The BLOOM-DM trial is evaluating 10 mg and 20 mg daily doses (10 mg dosed once or twice daily) of lorcaserin versus placebo over a one-year treatment period in overweight and obese patients with type 2 diabetes at about 60 sites in the United States.

As in the BLOOM trial, a standardized program of diet and exercise advice is also included in the BLOSSOM and BLOOM-DM trials in accordance with current FDA guidelines, and the proportion of patients with a 5% or greater weight reduction from baseline at week 52 is the primary efficacy endpoint. Secondary endpoints include changes in serum lipids, blood pressure and quality of life; in the BLOOM-DM trial, HbA1c levels and other indicators of glycemic control are also being evaluated. In both of these additional trials, all patients will receive echocardiograms at baseline, at month six and at the end of the study to assess heart valve function and other parameters over time. In contrast to the ongoing BLOOM trial, however, there is no oversight by an independent safety monitoring board.

The complete lorcaserin Phase 3 pivotal program consists of the BLOOM and BLOSSOM trials and has enrolled 7,189 patients. In addition to these Phase 3 clinical trials and the BLOOM-DM trial, several additional smaller trials, such as drug interaction and abuse potential trials, have been or are being conducted. Assuming data from the BLOOM and BLOSSOM trials are positive, we expect to file an NDA for lorcaserin with the FDA by the end of 2009. Data from the BLOOM-DM trial will not be included in the initial FDA submission, and is expected to be filed as a supplement to the NDA when the data become available.

Intellectual Property. As of January 31, 2009, we owned issued patents that cover compositions of matter for lorcaserin and related compounds and methods of treatment utilizing lorcaserin and related compounds in 57 jurisdictions, including the United States, Japan, Germany, France, the United Kingdom, Italy, Spain and Canada, and had applications pending in approximately 13 other jurisdictions, of which those with the largest pharmaceutical markets were China, Brazil and Poland. Based on sales statistics provided by IMS Health, the jurisdictions where lorcaserin patents have been issued accounted for more than 92% of global pharmaceutical sales in 2006, while jurisdictions where lorcaserin patents remain pending accounted for more than 4% of global pharmaceutical sales in that same year. The patent on lorcaserin issued by the United States Patent and Trademark Office is serial number US 6,953,787 and the corresponding patent granted by the European Patent Office is serial number EP 1 411 881 B1. Other of our lorcaserin patent applications, including those directed to the lorcaserin HCl salt, the hemihydrate of the lorcaserin HCl salt as well as its crystalline forms, synthetic routes and intermediates useful in the manufacturing of lorcaserin and pharmaceutical combinations of lorcaserin and phentermine, have all been filed in a lesser number of commercially important jurisdictions. The earliest priority date for the patents on lorcaserin is 2002. The terms of these patents are capable of continuing into 2023 in most jurisdictions without taking into account (i) any patent term adjustment or extension regimes of any country or (ii) any additional term of exclusivity we might obtain by virtue of the later filed patent applications.

APD791

Our lead anti-thrombotic drug candidate, APD791, has completed Phase 1a and Phase 1b clinical trials. APD791 is a novel, oral and selective inverse agonist of the serotonin 2A receptor intended to lower the risk of arterial thrombosis and related conditions by reducing the amplification of platelet aggregation, arterial constriction and intimal hyperplasia, or thickening of the vessel wall, mediated by serotonin. Thrombosis is the formation of a clot, or thrombus, inside a blood vessel that restricts the flow of blood. The formation of a thrombus is often caused by an injury to the wall of the blood vessel, such as the rupture of an atherosclerotic plaque. The injury to the blood vessel activates platelets, which then aggregate and adhere to one another as they start to release certain factors, including serotonin, that facilitate thrombosis. Thrombi that form in diseased atherosclerotic arteries of the heart may cause acute coronary syndrome or myocardial infarction, and thrombi that form in the vessels of the brain may cause stroke. The American Heart Association estimates that in the United States 14.4 million people alive in 2006 had survived either a myocardial infarction or a stroke. To reduce the risk of future events, many patients receive daily anti-thrombotic therapy.

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Many of our existing and potential competitors have substantially greater drug development capabilities and financial, scientific and marketing resources than we do. Additional consolidation in the pharmaceutical industry may result in even more resources being concentrated with our competitors. As a result, our competitors may be able to devote greater resources than we can to the research, development, marketing and promotion of drug discovery techniques or therapeutic products, or to adapt more readily to technological advances than we can. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval or commercializing drugs before we do.

We expect to encounter significant competition for the principal drug candidates that we are developing. Companies that complete clinical trials, obtain regulatory approvals and commence commercial sales of their drug candidates before us may achieve a significant competitive advantage. Furthermore, we may be competing against companies with substantially greater manufacturing, marketing, distribution and selling capabilities, and any drug candidate that we successfully develop may compete with existing therapies that have long histories of safe and effective use.

We may rely on our collaborators for support of development programs and for the manufacturing and marketing of drug candidates. Our collaborators may be conducting multiple drug development efforts within the same disease areas that are the subject of their agreements with us, which may negatively impact the development of drugs that they discover that are subject to our agreements. Generally, our agreements with our collaborators do not preclude them from pursuing development efforts in one or more therapeutic areas of interest in which we have internal development efforts ongoing. In addition, we face and will continue to face intense competition from other companies for such collaborative arrangements, and technological and other developments by others may make it more difficult for us to establish such relationships.

Government Regulation

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, pre-market approval, manufacture, marketing and distribution of pharmaceutical products. These agencies and other regulatory agencies regulate research and development activities and the testing, approval, manufacture, quality control, safety, effectiveness, labeling, storage, recordkeeping, advertising and promotion of drug candidates. Failure to comply with applicable FDA or other requirements may result in civil or criminal penalties, suspension or delays in clinical development, recall or seizure of products, partial or total suspension of production or withdrawal of a product from the market.

In the United States, the FDA regulates drug products under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. The process required by the FDA before our drug candidates may be marketed in the United States generally involves the following:

- completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the FDA's current Good Laboratory Practice, or cGMP, regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug candidate for each proposed indication;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the product is produced to assess compliance with current Good Manufacturing Practice, or cGMP, regulations; and
- FDA review and approval of the NDA prior to any commercial marketing or sale of the drug.

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The development and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our drug candidates will be granted on a timely basis, if at all.

Preclinical tests include laboratory evaluation as well as cGLP studies to evaluate toxicity in animals. The results of preclinical tests, together with manufacturing information and analytical data, are submitted as part of an IND to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30 day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Our IND submissions, or those of our collaborators, may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. Further, an independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the study until completed. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive Good Clinical Practice, or GCP, regulations and regulations for informed consent.

Clinical Trials. For purposes of NDA submission and approval, clinical trials are typically conducted in the following sequential phases, which may overlap:

- *Phase 1 Clinical Trials.* Studies are initially conducted in a limited population to test the drug candidate for safety, dose tolerance, absorption, metabolism, distribution and excretion in healthy humans. In some cases, a sponsor may decide to conduct what is referred to as a "Phase 1b" evaluation, which is an additional, safety-focused Phase 1 clinical trial.
- *Phase 2 Clinical Trials.* Studies are generally conducted in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted indications and to determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials. In some cases, a sponsor may decide to run what is referred to as a "Phase 2b" evaluation, which is a second, confirmatory Phase 2 clinical trial.
- *Phase 3 Clinical Trials.* These are commonly referred to as pivotal studies. When Phase 2 evaluations demonstrate that a dose range of the product is effective and has an acceptable safety profile, Phase 3 clinical trials are undertaken in large patient populations to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites.
- *Phase 4 Clinical Trials.* In some cases, the FDA may condition approval of an NDA for a drug candidate on the sponsor's agreement to conduct additional clinical trials to further assess the drug's safety and effectiveness after NDA approval. In addition, a sponsor may decide to conduct additional clinical trials after the FDA has approved an NDA. Post-approval trials are typically referred to as Phase 4 clinical trials.

New Drug Applications. The results of product development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA. NDAs also must contain extensive manufacturing information. Once the submission has been accepted for filing, the FDA's goal is to review applications within 10 months or, if the application relates to a serious or life-threatening indication, six months. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. The FDA may deny approval of an NDA if the applicable regulatory criteria are not satisfied, or it may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s). Even if such data

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are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials is not always conclusive and the FDA may interpret data differently than we or our collaborators interpret data. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing, including Phase 4 clinical trials, and surveillance programs to monitor the safety effects of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs or other information.

Other Regulatory Requirements. Any products manufactured or distributed by us or our collaborators pursuant to FDA approvals are subject to continuing regulation by the FDA, including recordkeeping and reporting requirements. Adverse event experience with the product must be reported to the FDA in a timely fashion and pharmacovigilance programs to proactively look for these adverse events may be mandated by the FDA. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Following such inspections, the FDA may issue notices on Form 483 and Warning Letters that could cause us to modify certain activities. A Form 483 notice, if issued at the conclusion of an FDA inspection, can list conditions the FDA investigators believe may have violated cGMP or other FDA regulations or guidelines. FDA guidelines specify that a Warning Letter be issued only for violations of "regulatory significance," also known as Official Action Indicated, or OAI. Failure to adequately and promptly correct the observations(s) can result in regulatory action. In addition to Form 483 notices and Warning Letters, failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product, injunctive action or possible civil penalties. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing FDA regulatory requirements. If we or our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, require us to recall a drug from distribution or withdraw approval of the NDA for that drug.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, dissemination of off-label information, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. Failure to comply with these requirements can result in adverse publicity, Warning Letters, corrective advertising and potential civil and criminal penalties.

Physicians may prescribe legally available drugs for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use.

In Zofingen, Switzerland, our Swiss subsidiary, Arena Pharmaceuticals GmbH, or Arena GmbH, operates a drug product facility. In Switzerland, Swissmedic is the central Swiss supervisory authority for therapeutic products. It is a public service organization of the federal government. After an inspection of our Swiss manufacturing facility by the competent regional authorities (Regionales Heilmittelinspektorat der Nordostschweiz, Basel, Switzerland), acting on behalf of Swissmedic, in June and July 2007, Swissmedic issued an operation permit to Arena GmbH for the production of drugs in July 2007. This permit is valid until July 2012.

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of the Canton of Aargau (Amt für Umwelt, AfU). Occupational health and safety is regulated by the EKAS (Eidgenössische Koordinationsstelle für Arbeitssicherheit) guideline (Nr. 6508) for the evaluation of worker safety and reporting to the relevant authorities. The competent authority for the implementation of occupational health and safety regulations is the Canton of Aargau (Amt für Wirtschaft und Arbeit), where exposure limits are set by SUVA (Schweizerische Unfallversicherungsanstalt), which is the Swiss Accident Insurance Fund (AWA).

We may be subject to further such regulations in the future. Although we believe that our operations comply in all material respects with the applicable environmental laws and regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result, and the extent of that liability could exceed our resources. Our compliance with these laws and regulations has not had, and is not expected to have, a material effect upon our capital expenditures, results of operations or competitive position.

Research and Development Expenses

Research and development activities, which include personnel costs, research supplies, facility and equipment costs, clinical and preclinical study fees and manufacturing costs, are the primary source of our expenses. Such expenses related to the development and improvement of our technologies and drug candidates totaled \$204.4 million for the year ended December 31, 2008, \$149.5 million for the year ended December 31, 2007 and \$103.4 million for the year ended December 31, 2006. Research that is sponsored by our collaborators is included in our total research and development expenses. No such funding was recorded in 2008. We estimate that research expenses incurred on projects sponsored by our collaborators totaled \$4.6 million for the year ended December 31, 2007 and \$7.7 million for the year ended December 31, 2006.

Employees

As of February 27, 2009, we had a total of 499 employees, including 422 in research, development and manufacturing and 77 in administration, which includes finance, legal, facilities, information technology and other general support areas. We consider our relationship with our employees to be good.

Available Information

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (the "Exchange Act") are available free of charge on our website (www.arenapharm.com) as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC.

Item 1A. Risk Factors.

Investment in our stock involves a high degree of risk. You should consider carefully the risks described below, together with other information in this Annual Report on Form 10-K and other public filings, before making investment decisions regarding our stock. If any of the following events actually occur, our business, operating results, prospects or financial condition could be materially and adversely affected. This could cause the trading price of our common stock to decline and you may lose all or part of your investment. Moreover, the risks described below are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business, operating results, prospects or financial condition.

Risks Relating to Our Business

We will need additional funds to conduct our planned research and development efforts, we may not be able to obtain such funds and may never become profitable.

We have accumulated a large deficit since inception that has primarily resulted from the significant research and development expenditures we have made in seeking to identify and validate new drug targets and develop

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compounds that could become marketed drugs. We expect that our losses will continue to be substantial for at least the next several years and that our operating expenses will also continue to be substantial, even if we or our collaborators are successful in advancing our compounds or partnered compounds.

We do not have any commercially available drugs, and we have substantially less money than we need to develop our compounds into marketed drugs. It takes many years and potentially hundreds of millions of dollars to successfully develop a preclinical or early clinical compound into a marketed drug, and our efforts may not result in any marketed drugs.

We will need additional funds or a partner to bring lorcaserin to market, if ever, and we may not be able to secure adequate funding or find an acceptable partner at all or on terms you or we believe are favorable. We also believe that due to global economic challenges, and as our cash balances are depleted, it may be difficult for us to obtain additional financing or enter into strategic relationships on terms acceptable to us, if at all. If additional funding is not available, we will have to further scale back or eliminate one or more of our research or development programs or delay the development of one or more of such programs, including our lorcaserin program.

The current global economic environment poses severe challenges to our business strategy, which relies on access to capital from the markets and our collaborators, and creates other financial risks for us.

The global economy, including credit markets and the financial services industry, has been experiencing a period of substantial turmoil and uncertainty. These conditions have generally made equity and debt financing more difficult to obtain, and may negatively impact our ability to complete financing transactions. The duration and severity of these conditions is uncertain, as is the extent to which they may adversely affect our business and the business of current and prospective collaborators and vendors. If the global economy does not improve or worsens, we may be unable to secure additional funding to sustain our operations or to find suitable partners to advance our internal programs, even if we receive positive results from our research and development or business development efforts.

We maintain a portfolio of investments in marketable debt securities which are recorded at fair value. Although we have established investment guidelines relative to diversification and maturity with the objectives of maintaining safety of principal and liquidity, credit rating agencies may reduce the credit quality of our individual holdings which could adversely affect their value. Lower credit quality and other market events, such as changes in interest rates and further deterioration in the credit markets, may have an adverse effect on the fair value of our investment holdings and cash position.

We are focusing our activities and resources on the development of lorcaserin and depend on its success.

We are focusing our near-term research and development activities and resources on lorcaserin, and we believe a significant portion of the value of our company relates to our ability to develop this drug candidate. The development of lorcaserin is subject to many risks, including the risks discussed in other risk factors. If the results of clinical trials and preclinical studies of lorcaserin, the regulatory decisions affecting lorcaserin, the anticipated or actual timing and plan for commercializing lorcaserin, or, ultimately, the market acceptance of lorcaserin do not meet our, your, analysts' or others' expectations, the market price of our common stock could decline significantly.

If we do not partner one or more unpartnered programs or raise additional funds, we may have to further curtail our activities.

In light of our current financial resources, we decided to focus our near-term research and development efforts to our lorcaserin Phase 3 program and our earlier-stage preclinical and research programs. While we believe this strategy will conserve resources, our ability to advance our drug candidate pipeline outside of

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lorcaserin will be limited. Without additional capital or funding from partners, we will need to significantly curtail some of our current and planned activities and expenditures. We believe narrowing or slowing the development of our pipeline would reduce our opportunities for success. Our decision to limit near-term development of drug candidates other than lorcaserin will likely extend the time it will take us to reach the market in these other therapeutic areas and may allow competing products to reach the market before our drug candidates.

Our stock price could decline significantly based on the results and timing of clinical trials and preclinical studies of, and decisions affecting, our most advanced drug candidates.

We announce results of clinical trials and preclinical studies from time to time. For example, we expect to announce the results of a Phase 3 pivotal trial (BLOOM) for our lead drug candidate, lorcaserin, around the end of March 2009 and the results of our other Phase 3 pivotal trial (BLOSSOM) for lorcaserin by the end of September 2009.

The results and timing of clinical trials and preclinical studies can affect our stock price. Preclinical studies include experiments performed in test tubes, in animals, or in cells or tissues from humans or animals. These studies include all drug studies except those conducted in human subjects, and may occur before or after initiation of clinical trials for a particular compound. Results of clinical trials and preclinical studies of lorcaserin or our other drug candidates may not be viewed favorably by us or third parties, including investors, analysts, potential collaborators, the academic and medical community, and regulators. The same may be true of how we design the development programs of our most advanced drug candidates and regulatory decisions (including by us or regulatory authorities) affecting those development programs. Biotechnology company stock prices have declined significantly when such results and decisions were unfavorable or perceived negatively or when a drug candidate did not otherwise meet expectations.

We have drug programs that are currently in clinical trials. In addition to successfully completing clinical trials, to conduct long-term clinical trials and gain regulatory approval to commercialize drug candidates, regulatory authorities require that all drug candidates complete short- and long-term preclinical toxicity and carcinogenicity studies. These preclinical, animal studies are required to help us and regulatory authorities assess the potential risk that drug candidates may be toxic or cause cancer in humans. The results of clinical trials and preclinical studies are uncertain and subject to different interpretations, and the design of these trials and studies (which may change significantly and be more expensive than anticipated depending on results and regulatory decisions) may also be viewed negatively by us, regulatory authorities or other third parties and adversely impact the development and opportunities for regulatory approval and commercialization of our and our partnered drug candidates. We may not be successful in advancing our programs on our projected timetable, if at all. Failure to initiate or delays in the development programs for any of our drug candidates, or unfavorable results or decisions or negative perceptions regarding any of such programs, could cause our stock price to decline significantly. This is particularly the case with respect to our most advanced drug candidate, lorcaserin.

Our development of lorcaserin may be adversely impacted by cardiovascular side effects previously associated with fenfluramine and dexfenfluramine.

We have developed lorcaserin to more selectively stimulate the serotonin 2C receptor because we believe this may avoid the cardiovascular side effects associated with fenfluramine and dexfenfluramine (often used in combination with phentermine, the combination of which was commonly referred to as "fen-phen"). These two drugs were serotonin-releasing agents and non-selective serotonin receptor agonists, and were withdrawn from the market in 1997 after reported incidences of heart valve disease and pulmonary hypertension associated with their usage. We may not be correct in our belief that selectively stimulating the serotonin 2C receptor will avoid these undesired side effects or lorcaserin's selectivity profile may not be adequate to avoid these side effects. Moreover, the potential relationship between the activity of lorcaserin and the activity of fenfluramine and dexfenfluramine may result in increased FDA regulatory scrutiny of the safety of lorcaserin and may raise

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potential adverse publicity in the marketplace, which could affect clinical enrollment or sales if lorcaserin is approved for commercialization.

The development programs for our drug candidates are expensive, time consuming, uncertain and susceptible to change, interruption, delay or termination.

Drug development programs are very expensive, time consuming and difficult to design and implement. Our drug candidates are in various stages of research and development and are prone to the risks of failure inherent in drug development. We will need to complete additional clinical trials and preclinical studies before we can demonstrate that our drug candidates are safe and effective to the satisfaction of the FDA and similar non-US regulatory authorities. These trials are expensive and uncertain processes that take years to complete. Failure can occur at any stage of the process, and successful early clinical or preclinical trials do not ensure that later trials or studies will be successful. In addition, the commencement or completion of our planned clinical trials could be substantially delayed or prevented by several factors, including:

- limited number of, and competition for, suitable patients required for enrollment in our clinical trials;
- limited number of, and competition for, suitable sites to conduct our clinical trials;
- delay or failure to obtain FDA approval or agreement to commence a clinical trial;
- delay or failure to obtain sufficient supplies of our drug candidates for our clinical trials;
- delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or investigators; and
- delay or failure to obtain institutional review board, or IRB, approval to conduct a clinical trial at a prospective site.

Even if the results of our development programs are favorable, the development programs of our most advanced drug candidates, including those being developed by our collaborators, may take significantly longer than expected to complete. In addition, the FDA, other regulatory authorities, our collaborators, or we may suspend, delay or terminate our development programs at any time for various reasons, including:

- lack of effectiveness of any drug candidate during clinical trials;
- side effects experienced by study participants or other safety issues;
- slower than expected rates of patient recruitment and enrollment or lower than expected patient retention rates;
- delays or inability to manufacture or obtain sufficient quantities of materials for use in clinical trials;
- inadequacy of or changes in our manufacturing process or compound formulation;
- delays in obtaining regulatory approvals to commence a study, or "clinical holds," or delays requiring suspension or termination of a study by a regulatory authority, such as the FDA, after a study is commenced;
- changes in applicable regulatory policies and regulations;
- delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites;
- uncertainty regarding proper dosing;
- unfavorable results from ongoing clinical trials and preclinical studies;
- failure of our clinical research organizations to comply with all regulatory and contractual requirements or otherwise perform their services in a timely or acceptable manner;
- scheduling conflicts with participating clinicians and clinical institutions;

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- failure to design appropriate clinical trial protocols;
- insufficient data to support regulatory approval;
- termination of clinical trials by one or more clinical trial sites;
- inability or unwillingness of medical investigators to follow our clinical protocols;
- difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data; or
- lack of sufficient funding to continue clinical trials and preclinical studies.

There is typically a high rate of attrition from the failure of drug candidates proceeding through clinical trials, and many companies have experienced significant setbacks in advanced development programs even after promising results in earlier studies or trials. For example, because our drug candidate for insomnia, APD125, did not meet the primary or secondary endpoints of a Phase 2b clinical trial, we are not planning any further clinical development of APD125. We have experienced setbacks in other development programs and may experience additional setbacks in the future. If we or our collaborators abandon or are delayed in our development efforts related to lorcaserin or any other drug candidate, we may not be able to generate sufficient revenues to continue our operations at the current level or become profitable, our reputation in the industry and in the investment community would likely be significantly damaged, additional funding may not be available to us or may not be available on terms you or we believe are favorable, and our stock price would likely decrease significantly.

Our drug candidates are subject to extensive regulation, and we may not receive required regulatory approvals, or timely approvals, for any of our drug candidates.

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, marketing and distribution, and other possible activities relating to our drug candidates are, and any resulting drugs will be, subject to extensive regulation by the FDA and other regulatory agencies in the United States. Neither our collaborators nor we are permitted to market our drug candidates in the United States until we receive regulatory approval from the FDA. Neither our collaborators nor we have received marketing approval for any of our drug candidates. Specific preclinical data, chemistry, manufacturing and controls data, a proposed clinical trial protocol and other information must be submitted to the FDA as part of an investigational new drug, or IND, application, and clinical trials may commence only after the IND application becomes effective. To market a new drug in the United States, we must submit to the FDA and obtain FDA approval of a New Drug Application, or NDA. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls to demonstrate the safety and effectiveness of the drug candidate.

Obtaining approval of an NDA can be a lengthy, expensive and uncertain process. As part of the Prescription Drug User Fee Act, or PDUFA, the FDA has a goal to review and act on a percentage of all submissions in a given time frame. The general review goal for a drug application is 10 months for a standard application and six months for priority review. The FDA has missed a portion of their PDUFA goals, and it is unknown whether the review of an NDA filing for lorcaserin, or for any of our other drug candidates, will be completed within the FDA review goals or will be delayed. Moreover, the duration of the FDA's review may depend on the number and type of other NDAs that are filed with the FDA around the same time period. For example, we believe that at least two companies are planning to file an NDA for a drug candidate for the treatment of obesity at around the time we expect the FDA will review our NDA for lorcaserin, which may impact the review of our NDA. Furthermore, any drug that acts on the CNS, such as lorcaserin, has the potential to be scheduled as a controlled substance by the Drug Enforcement Administration of the United States Department of Justice, or DEA. DEA scheduling is an independent process that can delay drug launch beyond an NDA approval date.

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In addition, failure to comply with FDA and other applicable regulatory requirements may, either before or after product approval, if any, subject our company to administrative or judicially imposed sanctions, including:

- Form 483 notices and Warning Letters;
- civil and criminal penalties;
- injunctions;
- withdrawal of approved products;
- product seizure or detention;
- product recalls;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements; and
- refusal to approve pending NDAs or supplements to approved NDAs.

Regulatory approval of an NDA or NDA supplement is not guaranteed. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional preclinical studies and clinical trials. The number of preclinical studies and clinical trials that will be required for FDA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to target and the regulations applicable to any particular drug candidate. The FDA can delay, limit or deny approval of a drug candidate for many reasons, including:

- a drug candidate may not be deemed adequately safe and effective;
- FDA officials may not find the data from preclinical studies and clinical trials sufficient;
- the FDA may not approve the manufacturing processes or facilities;
- the FDA may change its approval policies or adopt new regulations; or
- the FDA may not accept our NDA submission (which is expected to be electronic) due to, among other reasons, the formatting of the submission.

We do not expect any drugs resulting from our research and development efforts to be commercially available until at least late 2010. Our most advanced drug candidates, including lorcaserin, have not completed all preclinical studies and the large, pivotal Phase 3 clinical trials for efficacy and safety that are required for FDA approval. Also, we have not previously filed NDAs with the FDA, either by paper or electronically, nor have we previously conducted Phase 3 clinical trials, which are significantly larger and more complex than earlier-stage trials. This lack of corporate experience may impede our ability to successfully complete these trials and obtain FDA approval in a timely manner, if at all, for our drug candidates for which development and commercialization is our responsibility. Even if we believe that data collected from our preclinical studies and clinical trials of our drug candidates are promising and that our information and procedures regarding chemistry, manufacturing and controls are sufficient, our data may not be sufficient to support approval by the FDA or any other United States or foreign regulatory authority. In addition, we believe that the regulatory review of NDAs for drug candidates intended for widespread use by a large proportion of the general population is becoming increasingly focused on safety. In this regard, it is possible that some of our drug candidates, including lorcaserin, will be subject to increased scrutiny to show adequate safety than would drug candidates for more acute or life-threatening diseases such as cancer. Even if approved, drug candidates may not be approved for all indications requested and such approval may be subject to limitations on the indicated uses for which the drug may be marketed. Our business and reputation may be harmed by any failure or significant delay in receiving regulatory approval for the sale of any drugs resulting from our drug candidates. As a result, we cannot predict when or whether regulatory approval will be obtained for any drug we develop.

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In order to market any drugs outside of the United States, we and our collaborators must comply with numerous and varying regulatory requirements of other countries. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks associated with FDA approval as well as additional, presently unanticipated, risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects associated with regulatory approval in the United States, including the risk that our drug candidates may not be approved for all indications requested and that such approval may be subject to limitations on the indicated uses for which the drug may be marketed.

The results of preclinical studies and completed clinical trials are not necessarily predictive of future results, and our current drug candidates may not have favorable results in later studies or trials.

Preclinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of a drug candidate, but rather to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the drug candidate's side effects at various doses and schedules. To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our drug candidates. Favorable results in our early studies or trials may not be repeated in later studies or trials, including continuing preclinical studies and large-scale clinical trials, and our drug candidates in later-stage trials may fail to show desired safety and efficacy despite having progressed through earlier-stage trials. In particular, preclinical data and the limited clinical results that we have obtained for lorcaserin may not predict results from studies in larger numbers of subjects drawn from more diverse populations treated for longer periods of time. They also may not predict the ability of lorcaserin to achieve or sustain the desired effects in the intended population or to do so safely. Unfavorable results from ongoing preclinical studies or clinical trials could result in delays, modifications or abandonment of ongoing or future clinical trials, or abandonment of a clinical program. Preclinical and clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated or terminated, or a clinical program abandoned. In addition, we may report top-line data from time to time, which is based on a preliminary analysis of key efficacy and safety data, and is subject to change following a more comprehensive review of the data related to the applicable clinical trial.

Many of our research and development programs are in early stages of development, and may not result in the commencement of clinical trials.

Many of our research and development programs are in the discovery or preclinical stage of development. The process of discovering compounds with therapeutic potential is expensive, time consuming and unpredictable. Similarly, the process of conducting preclinical studies of compounds that we discover requires the commitment of a substantial amount of our technical and financial resources and personnel. We may not discover additional compounds with therapeutic potential, and any of the compounds for which we are conducting preclinical studies may not result in the commencement of clinical trials. We cannot be certain that results sufficiently favorable to justify commencement of Phase 1 clinical trials will be obtained in these preclinical investigations. Even if such favorable preclinical results are obtained, our financial resources may not allow us to commence Phase 1 clinical trials. If we are unable to identify and develop new drug candidates, we may not be able to maintain a clinical development pipeline or generate revenues.

Our revenues, for at least the short-term, depend upon the actions of our collaborators and our ability to enter into new collaborations.

We expect that, for at least the next few years, our ability to generate significant revenues will depend upon the success of our existing collaborations and our ability to enter into new collaborations. Future revenues from

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and Merck, and included \$9.5 million in amortization of milestone achievements and technology access and development fees received in prior years, \$5.9 million in research funding, and \$3.9 million for patent activities. Prior to entering into the manufacturing services agreement with Siegfried in January 2008, we had not recognized any manufacturing services revenue.

If our collaborators pay us before we recognize such payments as current revenues, the payments are recorded as deferred revenues until earned. As of December 31, 2008, we had \$4.0 million in deferred revenues, the majority of which was attributable to our license agreement with TaiGen Biotechnology Co., Ltd. and is expected to be recognized as revenue in 2010. Absent any new collaborations or achievement of a milestone in one of our existing collaborations, we expect our 2009 revenues will consist of reimbursement for patent activities from our collaborators and manufacturing services revenue under our manufacturing services agreement with Siegfried. Under such agreement, until at least December 31, 2010, Siegfried may sub-contract to us the manufacture of certain drug products previously manufactured by Siegfried for its customers, and we agreed to perform such manufacturing up to certain specified amounts. Also under such agreement, Siegfried guarantees a minimum level of cost absorption, which we will record as revenues, of CHF 7.0 million in 2009 and CHF 6.6 million in 2010. Using the exchange rate in effect on December 31, 2008, this would translate to approximately \$6.6 million and \$6.3 million in manufacturing services revenues in 2009 and 2010, respectively.

Revenues from our collaborators for milestones that may be achieved in the future are difficult to predict, and our revenues may vary significantly from quarter to quarter and year to year. We expect that any significant revenues over the next several years will depend on the clinical success of our partnered programs as well as whether we partner lorcasearin or any of our other current or future drug candidates. Ultimately, we expect our revenues in the long term to primarily depend upon the regulatory approval and commercialization of our partnered or internally developed drugs.

Cost of manufacturing services. Cost of manufacturing services is comprised of direct costs associated with manufacturing drug products for Siegfried under our manufacturing services agreement, including related salaries, other personnel costs and machinery depreciation costs. Cost of manufacturing services was \$8.5 million for the year ended December 31, 2008. Prior to entering into the manufacturing services agreement with Siegfried in January 2008, we had not recorded any cost of manufacturing services.

Research and development expenses. Research and development expenses, which account for the majority of our expenses, consist primarily of costs associated with external clinical and preclinical study fees, manufacturing costs and other related expenses, and the development of our earlier-stage programs and technologies. Our most significant research and development costs are for clinical trials (including payments to contract research organizations, or CROs), preclinical study fees, salaries and personnel, research supplies, and facility and equipment costs. We expense research and development costs to operations as they are incurred when these expenditures relate to our research and development efforts and have no alternative future uses. Other than external expenses for our clinical and preclinical programs, we generally do not track our research and development expenses by project; rather, we track such expenses by the type of cost incurred.

Research and development expenses increased \$54.9 million to \$204.4 million for the year ended December 31, 2008, from \$149.5 million for the year ended December 31, 2007. The difference was due primarily to (i) a \$50.0 million increase in external clinical and preclinical study fees and expenses, including manufacturing costs, due primarily to our Phase 3 clinical trial program for lorcasearin and (ii) an increase of \$3.2 million in salary and other personnel costs as we increased the number of our US research and development employees from 349 at the end of 2007 to 358 at the end of 2008. Nearly all of the increase in the number of research and development employees related to the development of lorcasearin. Although we expect to continue to incur substantial research and development expenses in 2009, primarily related to lorcasearin, we expect our research and development expenses will be significantly lower than the 2008 level as the Phase 3 lorcasearin BLOOM and BLOSSOM studies are expected to be completed in the first half of 2009. In addition, based on top-line data from our Phase 2b clinical trial of APD125 announced in December 2008, we are not planning any

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further clinical development of APD125. Unless we can obtain substantial funds through equity or debt financings or partnerships, we will be unable to advance our earlier-stage programs and would have to significantly reduce our research activities.

Included in the \$123.5 million total external clinical and preclinical study fees and expenses noted in the table above for the year ended December 31, 2008 was \$106.0 million related to our lorcaserin program, \$13.5 million related to our APD125 program, \$1.4 million related to our APD916 program and \$1.1 million related to our APD791 program. Included in the \$73.5 million in external clinical and preclinical study fees and expenses for the year ended December 31, 2007 was \$51.3 million related to our lorcaserin program, \$15.7 million related to our APD125 program and \$3.1 million related to our APD791 program.

Cumulatively through December 31, 2008, we have recorded \$213.0 million, \$43.2 million, \$7.3 million and \$2.3 million in external clinical and preclinical study fees and other related expenses for lorcaserin, APD125, APD791 and APD916, respectively. While expenditures on current and future clinical development programs are expected to be substantial, they are subject to many uncertainties, including whether we have adequate funds and develop our drug candidates independently or with a partner. As a result of such uncertainties, we cannot predict with any significant degree of certainty the duration and completion costs of our research and development projects or whether, when and to what extent we will generate revenues from the commercialization and sale of any of our drug candidates. The duration and cost of clinical trials may vary significantly over the life of a project as a result of unanticipated events arising during clinical development and a variety of factors, including:

- the nature and number of trials and studies in a clinical program;
- the number of patients who participate in the trials;
- the number of sites included in the trials;
- the rates of patient recruitment and enrollment;
- the duration of patient treatment and follow-up;
- the costs of manufacturing our drug candidates; and
- the costs, requirements, timing of, and the ability to secure regulatory approvals.

However, based upon our current plans, we expect to incur \$50.0 million to \$60.0 million in external clinical and preclinical study fees and other related expenses, including manufacturing, in 2009, almost all of which relates to lorcaserin. We do not expect to receive regulatory approval for lorcaserin until at least late 2010, if at all.

General and administrative expenses. General and administrative expenses increased \$3.9 million to \$30.5 million for the year ended December 31, 2008, from \$26.6 million for the year ended December 31, 2007. This increase was primarily comprised of (i) an increase of \$2.1 million in salary and other personnel costs as we increased our general and administrative employees from 68 at the end of 2007 to 77 at the end of 2008, (ii) a decrease of \$1.1 million in non-cash, share-based compensation under Statement of Financial Accounting Standards, or SFAS, No. 123R, "Share-Based Payment" due to additional compensation expense recognized in 2007 as a result of an employee meeting retirement eligibility criteria under our 2006 Long-Term Incentive Plan, as amended, and (iii) an increase of \$0.9 million in patent costs primarily related to our internal programs. To the extent our partners reimburse us for patent activities, the reimbursements are classified as revenues. Such reimbursements totaled \$2.4 million in 2008 and \$3.9 million in 2007. We expect that partner reimbursements for patent costs will be significantly higher in 2009 than in 2008. Further, we expect that our total general and administrative expenses in 2009 will be comparable to 2008, and that, unless a partner pays for commercialization, marketing and business development expenses related to lorcaserin, our total general and administrative expenses will increase significantly beginning in 2010 due primarily to increases in such expenses. However, if we are unable to obtain adequate funds or rely on a partner to pay for these lorcaserin expenses in 2009, we may have to significantly reduce our general and administrative expenditures.

EXHIBIT C

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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2009

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

COMMISSION FILE NUMBER 000-31161

ARENA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

6166 Nancy Ridge Drive, San Diego, CA
(Address of principal executive offices)

23-2908305
(I.R.S. Employer
Identification No.)

92121
(Zip Code)

858.453.7200

(Registrant's telephone number, including area code)

Securities registered pursuant to 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, \$0.0001 par value	NASDAQ Global Market
Preferred Stock Purchase Rights	NASDAQ Global Market

Securities registered pursuant to 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☒

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐ (Do not check if a smaller reporting company)

Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately \$393.7 million as of June 30, 2009, based on the last sale price of the registrant's common stock as reported on the NASDAQ Global Market on such date. For purposes of this calculation, shares of the registrant's common stock held by directors and executive officers have been excluded. This number is provided only for purposes of this Annual Report on Form 10-K and does not represent an admission that any particular person or entity is an affiliate of the registrant.

As of March 10, 2010, there were 101,125,581 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required by Part III of this Annual Report on Form 10-K is incorporated by reference from the registrant's definitive proxy statement for the annual meeting of stockholders to be held in June 2010, which will be filed with the Securities and Exchange Commission within 120 days after the close of the registrant's fiscal year ended December 31, 2009.

Table of Contents**Our Research and Development Programs**

We have developed a pipeline of drug candidates that target attractive market opportunities in several therapeutic areas. Our independent and partnered development-stage programs are as follows:

Development Program (Indication)	Development Status	Commercial Rights
Lorcaserin (weight management)	NDA filed; October 2010 PDUFA date	Arena
APD791 (arterial thrombosis)	Phase I	Arena
APD597 (type 2 diabetes)	Phase I	Ortho-McNeil-Janssen
APD916 (narcolepsy and cataplexy)	IND	Arena
APD811 (pulmonary arterial hypertension)	Preclinical	Arena

Note: The above table does not include our earlier-stage programs.

Due to continuing global economic challenges and our financial condition, we are focusing our activities and resources on our lorcaserin program. In addition to this program, we plan to continue our research activities at the reduced level in place since a June 2009 workforce reduction and to selectively initiate clinical trials for drug candidates based on the potential of a particular candidate and the estimated cost of the related clinical trials. Consistent with this approach, we intend to initiate a Phase I clinical trial of APD916 in 2010. We will continue to evaluate the focus of our activities and resources in light of changes in our financial condition, the status of our lorcaserin program and the global economic environment. We do not expect this approach to impact the progress of APD597 because Ortho-McNeil-Janssen is controlling and funding the development of this program.

Clinical Development Programs**Lorcaserin**

Our most advanced drug candidate, lorcaserin, is for weight management, including weight loss and maintenance of weight loss. In December 2009, after completing a pivotal Phase 3 clinical trial program, we submitted an NDA for lorcaserin to the FDA. The NDA submission is based on a data package from lorcaserin's clinical development program that includes 18 clinical trials totaling 8,576 patients. In February 2010, the FDA accepted our lorcaserin NDA for filing and assigned a PDUFA date of October 22, 2010 for their review of our application.

According to the Centers for Disease Control and Prevention, approximately one-third of US adults were obese in 2007-2008. Studies have shown that a weight loss of 5% to 10% of body weight from baseline can result in meaningful improvements in cardiovascular risk factors (e.g., lipids, blood pressure and blood glucose) and a significant reduction in the incidence of type 2 diabetes. Patients currently have limited pharmaceutical treatment options to help them lose weight.

Mechanism of Action. Lorcaserin is a novel and selective serotonin 2C receptor agonist. The serotonin 2C receptor is a GPCR located in the brain, including the hypothalamus, which is an area of the brain involved in the control of appetite and metabolism. Stimulation of this receptor is strongly associated with feeding behavior and satiety. We conducted preclinical studies examining the activity and serotonin receptor subtype specificity of lorcaserin. In these studies, lorcaserin demonstrated a high affinity and selectivity for the serotonin 2C receptor, with approximately 15 fold and 90-100 fold selectivity *in vitro* over the human serotonin 2A and serotonin 2B receptors, respectively, and no pharmacologic activity at other serotonin receptors, except at concentrations exceeding the expected therapeutic range.

Table of Contents*Phase 3 Clinical Development.*

The lorcaserin Phase 3 pivotal program consists of the BLOOM and BLOSSOM trials, which evaluated 7,190 patients for up to two years. In addition to the pivotal program, we are evaluating the safety and efficacy of lorcaserin for weight management in obese and overweight patients with type 2 diabetes in our Phase 3 BLOOM-DM trial. We plan to file the results of BLOOM-DM as a supplement to the NDA.

We initiated BLOOM in September 2006, and completed enrollment in February 2007 with 3,182 overweight and obese patients in about 100 centers in the United States. BLOOM was a randomized, double-blind and placebo-controlled trial evaluating 10 mg of lorcaserin dosed twice daily versus placebo over a two-year treatment period in obese patients (Body Mass Index, or BMI, of 30 to 45) with or without co-morbid conditions and overweight patients (BMI of 27 to less than 30) with at least one co-morbid condition. All patients received echocardiograms at baseline, Months 6, 12 and 18, and at the end of the trial to assess heart valve function and other parameters over time.

In December 2007, we initiated BLOSSOM and BLOOM-DM, the second and third Phase 3 clinical trials evaluating lorcaserin's efficacy and safety. These trials are one-year, randomized, double-blind and placebo-controlled clinical trials. BLOSSOM completed enrollment in June 2008 with 4,008 patients and BLOOM-DM completed enrollment in June 2009 with 604 patients.

The BLOSSOM trial evaluated 10 mg of lorcaserin dosed once or twice daily versus placebo over a one-year treatment period in obese patients with or without co-morbid conditions and overweight patients with at least one co-morbid condition at about 100 centers in the United States. The BLOOM-DM trial is evaluating 10 mg of lorcaserin dosed once or twice daily versus placebo over a one-year treatment period in overweight and obese patients with type 2 diabetes being treated with other oral agents at about 60 centers in the United States.

A standardized program of diet and exercise advice was included in the Phase 3 trials in accordance with current FDA guidelines, and the proportion of patients achieving 5% or greater weight loss from baseline at Week 52 is the first of three hierarchically ordered primary efficacy endpoints. The other primary efficacy endpoints are the difference in mean weight change compared to placebo at Week 52 and the proportion of patients achieving 10% or greater weight loss compared to placebo at Week 52. Secondary endpoints include changes in serum lipids, blood pressure, HbA1c levels and other indicators of glycemic control and quality of life.

Under the protocols for BLOSSOM and BLOOM-DM, all patients receive echocardiograms at baseline, at Month 6 and at the end of the trial to assess heart valve function and other parameters over time. Consistent with our proposal, the FDA allowed us to eliminate the requirement to perform echocardiographic testing prior to enrolling patients in BLOSSOM and BLOOM-DM. As a result, patients with preexisting FDA-defined valvulopathy and other echocardiographic variants and abnormalities were enrolled in these trials. This is different from the design of BLOOM, the initial Phase 3 trial, in which echocardiography was used to screen for patients with FDA-defined valvulopathy and certain other echocardiographic abnormalities and exclude those patients from enrolling in the trial. Instead, in BLOSSOM and BLOOM-DM, there were no such echocardiographically defined exclusion criteria, although serial echocardiograms were obtained in BLOSSOM and are being obtained in BLOOM-DM to extend the lorcaserin safety database.

Valvular regurgitation, a measure of back flow or leakage of blood through heart valves due to imperfect valve closing, was scored on a five-point scale (absent, trace, mild, moderate or severe) for the mitral and aortic valves. The FDA defines significant valvulopathy as mild or greater aortic valve regurgitation or moderate or greater mitral valve regurgitation.

Phase 3 Results: BLOOM

In BLOOM, lorcaserin patients achieved highly statistically significant categorical and absolute weight loss in Year 1, and over two-thirds of lorcaserin patients that achieved 5% or greater weight loss in Year 1 and

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continued treatment with lorcaserin in Year 2 maintained 5% or greater weight loss. Treatment with lorcaserin also resulted in statistically significant improvements as compared to placebo in multiple secondary endpoints associated with cardiovascular risk. Lorcaserin was very well tolerated, did not result in increased risk of depression or suicidal ideation and was not associated with the development of cardiac valvular insufficiency.

Efficacy

Measurements of efficacy using an intent-to-treat last observation carried forward, or ITT-LOCF, analysis showed that lorcaserin met all primary endpoints. Patients treated with lorcaserin achieved highly statistically significant categorical and average weight loss after one year:

- 47.5% of lorcaserin patients lost at least 5% of their body weight, compared to 20.3% for placebo. This result satisfies one of two alternate efficacy benchmarks in the most recent FDA draft guidance, which provides that a weight-management product can be considered effective if after one year of treatment the proportion of patients who lose at least 5% of baseline body weight in the active-product group is at least 35%, is approximately double the proportion in the placebo-treated group, and the difference between groups is statistically significant.
- 22.6% of lorcaserin patients lost at least 10% of their body weight, compared to 7.7% for placebo.
- Lorcaserin patients achieved an average weight loss of 5.8% of their body weight, or 12.7 pounds, compared to 2.2%, or 4.7 pounds, for placebo.

In addition to the ITT-LOCF data, patients treated with lorcaserin who completed one year of treatment according to the trial's protocol demonstrated the benefits of long-term treatment with lorcaserin:

- 66.4% of lorcaserin patients lost at least 5% of their body weight, compared to 32.1% for placebo, and the average weight loss in this responder population was 26 pounds.
- 36.2% of lorcaserin patients lost at least 10% of their body weight, compared to 13.6% for placebo.
- Lorcaserin patients achieved an average weight loss of 8.2% of their body weight, or 17.9 pounds, compared to 3.4%, or 7.3 pounds, for placebo.

Safety and Tolerability Profile

Treatment with lorcaserin was very well tolerated, resulting in very few adverse events with greater frequency than the placebo group. The most frequent adverse events reported in Year 1 and their rates for lorcaserin and placebo patients, respectively, were as follows: headache (18.0% vs. 11.0%), upper respiratory tract infection (14.8% vs. 11.9%), nasopharyngitis (13.4% vs. 12.0%), sinusitis (7.2% vs. 8.2%) and nausea (7.5% vs. 5.4%). Adverse events of depression, anxiety and suicidal ideation were infrequent and were reported at a similar rate in each treatment group.

The assessment of echocardiograms indicated that lorcaserin was not associated with valvular insufficiency during two years of use, rates of change in individual valvular regurgitation scores and the development of FDA-defined valvulopathy were similar between treatment groups. Rates of new FDA-defined valvulopathy in BLOOM were as follows: lorcaserin 10 mg twice daily (2.7%) and placebo (2.3%) at Week 52 and lorcaserin 10 mg twice daily (2.6%) and placebo (2.7%) at Week 104.

Secondary Endpoints

Treatment with lorcaserin over one year was associated with statistically significant improvements compared to placebo in multiple secondary endpoints, including:

- Blood Pressure: systolic blood pressure, diastolic blood pressure and heart rate.
- Lipids: total cholesterol, LDL cholesterol and triglycerides.

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- Glycemic Parameters: fasting glucose, fasting insulin and insulin resistance.
- Inflammatory Markers of Cardiovascular Risk: high-sensitivity C-Reactive Protein, or CRP, and fibrinogen.

Patient Disposition

BLOOM evaluated 3,182 patients with an average BMI of 36.2 and baseline weight of 220 pounds. The Week 52 completion rate was higher for patients on lorcaserin (54.9%) compared to patients on placebo (45.1%). Discontinuation rates for adverse events were similar in the lorcaserin and placebo groups for Year 1 (7.1% vs. 6.7%) and were the same in Year 2 (3.0%).

Phase 3 Results: BLOSSOM

Our BLOSSOM trial confirmed the BLOOM results and completed the lorcaserin Phase 3 pivotal registration program of 7,190 patients evaluated for up to two years. In BLOSSOM, lorcaserin met all primary efficacy and safety endpoints, and patients treated with lorcaserin achieved highly statistically significant categorical and absolute weight loss. Lorcaserin was very well tolerated and was not associated with depression or suicidal ideation. Treatment with lorcaserin also resulted in statistically significant improvements as compared to placebo in multiple secondary endpoints associated with cardiovascular risk.

Efficacy

Measurements of efficacy using an ITT-LOCF analysis showed that lorcaserin met all primary endpoints. Patients treated with 10 mg of lorcaserin dosed twice daily achieved highly statistically significant categorical and average weight loss after one year:

- 47.2% of lorcaserin patients lost at least 5% of their body weight, compared to 25.0% for placebo. As with BLOOM, this result satisfies one of two alternate efficacy benchmarks in the most recent FDA draft guidance for weight-management products described above in "Phase 3 Results: BLOOM—Efficacy."
- 22.6% of lorcaserin patients lost at least 10% of their body weight, compared to 9.7% for placebo.
- Lorcaserin patients achieved an average weight loss of 5.9%, or 12.7 pounds, compared to 2.8%, or 6.3 pounds, for placebo.

In addition to the ITT-LOCF data, patients treated with 10 mg of lorcaserin dosed twice daily who completed the one-year trial according to the trial's protocol demonstrated the benefits of long-term treatment with lorcaserin:

- 63.2% of lorcaserin patients lost at least 5% of their body weight, compared to 34.9% for placebo.
- 35.1% of lorcaserin patients lost at least 10% of their body weight, compared to 16.1% for placebo.
- Lorcaserin patients achieved an average weight loss of 7.9% of their body weight, or 17.0 pounds, compared to 3.9%, or 8.7 pounds, for placebo.
- The quartile of lorcaserin patients with the greatest weight loss lost an average of 35.1 pounds, or 16.3%, of their body weight. These patients lost 36% more body weight than the top quartile of placebo patients.

Safety and Tolerability Profile

Lorcaserin was very well tolerated. The most frequent adverse events and their rates for lorcaserin twice daily and placebo patients, respectively, were as follows: headache (15.6% vs. 9.2%), upper respiratory tract

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infection (12.7% vs. 12.6%), nasopharyngitis (12.5% vs. 12.0%), nausea (9.1% vs. 5.3%) and dizziness (8.7% vs. 3.9%). Adverse events of depression, anxiety and suicidal ideation were infrequent and were reported at a similar rate in each treatment group.

Echocardiographic evaluations showed no association between lorcaserin and the development of heart valve insufficiency. Rates of new FDA-defined valvulopathy in BLOSSOM at Week 52 were as follows: lorcaserin 10 mg twice daily (2.0%), 10 mg once daily (1.4%) and placebo (2.0%).

Secondary Endpoints

Treatment with lorcaserin over one year was associated with statistically significant improvements or favorable trends compared to placebo in multiple secondary endpoints, including blood pressure and lipids.

Patient Disposition

BLOSSOM evaluated 4,008 patients with an average BMI of 35.9 and baseline weight of 220 pounds. The Week 52 completion rate was higher for patients on lorcaserin 10 mg twice daily (57.2%) and 10 mg once daily (59.0%) compared to patients on placebo (52.0%). Discontinuation rates for adverse events were low and as follows: lorcaserin 10 mg twice daily (7.2%), 10 mg once daily (6.2%) and placebo (4.6%).

Comparison of BLOOM and BLOSSOM Results

In both BLOOM and BLOSSOM, lorcaserin's excellent tolerability allowed patients to begin treatment on the full dose immediately, without a titration period, and achieve rapid weight loss. In both trials, statistically significant weight loss compared to placebo was shown at the first trial visit, two weeks following randomization. In addition, based on the integrated echocardiographic data set from BLOOM and BLOSSOM, lorcaserin did not increase the risk of cardiac valvulopathy according to criteria requested by the FDA.

The efficacy for the BLOOM and BLOSSOM trials after one year of treatment is summarized in the table below.

	BLOOM		BLOSSOM		
	10 mg BID*	Placebo	10 mg BID*	10 mg QD*	Placebo
≥5% weight loss (Per protocol)	66.4%	32.1%	63.2%	53.1%	34.9%
≥5% weight loss (ITT-LOCF)	47.5%	20.3%	47.2%	40.2%	25.0%
≥10% weight loss (Per protocol)	36.2%	13.6%	35.1%	26.3%	16.1%
≥10% weight loss (ITT-LOCF)	22.6%	7.7%	22.6%	17.4%	9.7%
Mean weight loss (Per protocol)	8.2%	3.4%	7.9%	6.5%	3.9%
Mean weight loss (ITT-LOCF)	5.8%	2.2%	5.9%	4.8%	2.8%

* p<0.0001 compared to placebo

Prior Clinical Development of Lorcaserin.

Prior to initiating our pivotal Phase 3 clinical trial program, we completed multiple Phase 1 and Phase 2 clinical trials of lorcaserin. Our Phase 2a clinical trial included 352 obese patients dosed for 28 days, and our Phase 2b clinical trial included 469 obese patients dosed for 12 weeks. Highly statistically significant, clinically meaningful and progressive weight loss was observed in both Phase 2 clinical trials, with no apparent drug effect on heart valves or pulmonary artery pressure, as assessed by serial echocardiograms. Lorcaserin was also well tolerated in both Phase 2 clinical trials.

The randomized, double-blind, multiple-dose, 28-day Phase 2a clinical trial of lorcaserin in obese patients compared doses of 1 mg, 5 mg and 15 mg of lorcaserin to placebo. Patients did not receive any diet or exercise

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advice, other than to abstain from consuming alcohol during the trial. Over the 28-day treatment period there was a highly statistically significant ($p=0.0002$) mean weight loss of 2.9 pounds in patients taking the 15 mg dose of lorcaserin versus 0.7 pounds for the placebo group. Lorcaserin was well tolerated at all doses investigated in the trial. An assessment of follow-up echocardiograms taken at the end of dosing and approximately 90 days after patients received their first doses of lorcaserin indicated no apparent drug effect on heart valves or pulmonary artery pressure.

The randomized, double-blind, multiple-dose, 12-week Phase 2b clinical trial of lorcaserin in obese patients compared doses of 10 mg and 15 mg once daily and 10 mg twice daily of lorcaserin to placebo. Patients did not receive any diet or exercise advice, other than to abstain from consuming alcohol during the trial. The primary endpoint of the trial was weight loss after administration of lorcaserin for 12 weeks. Patients completing the 12-week treatment period with lorcaserin achieved a highly statistically significant ($p<0.001$) mean weight loss of 4.0, 5.7 and 7.9 pounds at doses of 10 mg and 15 mg once daily and 10 mg twice daily, respectively, compared to 0.7 pounds for the placebo group. Using an ITT-LOCF analysis, treatment with lorcaserin was also associated with a highly statistically significant ($p<0.001$) mean weight loss of 3.7, 4.8 and 6.8 pounds at daily doses of 10 mg and 15 mg once daily and 10 mg twice daily, respectively, in patients taking lorcaserin compared to 0.4 pounds for the placebo group. The proportions of patients completing the 12-week treatment period with lorcaserin who achieved a 5% or greater weight loss from baseline were 13% ($p=0.015$), 20% ($p<0.001$) and 31% ($p<0.001$) at doses of 10 mg and 15 mg once daily and 10 mg twice daily, respectively, compared to 2% in the placebo group. Lorcaserin was well tolerated at all doses investigated in the trial. Adverse events occurring in greater than 5% in any of the dosed groups were headache, nausea, dizziness, vomiting, dry mouth, nasopharyngitis, fatigue and urinary tract infection. Average weight loss increased progressively at each time point measured throughout the trial for all lorcaserin dose groups and was dose-dependent.

An assessment of echocardiograms at baseline and Day 85 in the Phase 2a trial indicated no apparent lorcaserin effect on heart valves or pulmonary artery pressure. No changes in valvular regurgitation greater than one category, and no significant increases in pulmonary artery pressure in any group were identified in the echocardiogram results. No significant differences in the number of patients with increased regurgitation at any value were observed between any treatment group and placebo.

Lorcaserin Intellectual Property.

As of February 1, 2010, we owned issued patents that cover compositions of matter for lorcaserin and related compounds and methods of treatment utilizing lorcaserin and related compounds in 62 jurisdictions, including the United States, Japan, Germany, France, the United Kingdom, Italy, Spain and Canada, and had applications pending in approximately 8 other jurisdictions, of which those with the largest pharmaceutical markets were Brazil and Poland. Based on sales statistics provided by IMS Health, the jurisdictions where lorcaserin patents have been issued accounted for more than 93% of global pharmaceutical sales in 2008, while jurisdictions where lorcaserin patents remain pending accounted for more than 3% of global pharmaceutical sales in that same year. The patents on lorcaserin issued by the US Patent and Trademark Office have serial numbers US 6,953,787 and US 7,514,422, while the corresponding patent granted by the European Patent Office is serial number EP 1 411 881 B1. Other of our lorcaserin patent applications, including those directed to the lorcaserin HCl salt, the hemihydrate of the lorcaserin HCl salt as well as its crystalline forms, synthetic routes and intermediates useful in the manufacturing of lorcaserin and pharmaceutical combinations of lorcaserin and phentermine, have all been filed in a lesser number of commercially important jurisdictions. The earliest priority date for the patents on lorcaserin is 2002. The terms of these patents are capable of continuing into 2023 in most jurisdictions without taking into account any patent term adjustment or extension regimes of any country or any additional term of exclusivity we might obtain by virtue of the later filed patent applications.

APD791

Our next most advanced internal drug candidate is an anti-thrombotic drug candidate, APD791, which has completed Phase 1a and Phase 1b clinical trials. We are not planning any additional clinical trials for APD791 at

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The Registration, Evaluation, Authorization and Restriction of Chemicals Regulation (EC) No 1907/2006, commonly referred to as "REACH," is Europe's broad chemicals legislation, which is directly applicable in all EU Member States. REACH creates a new system for gathering information, assessing risks to human health and the environment, and authorizing or restricting the marketing and use of chemicals produced or supplied in the EU. It applies to EU producers, importers and distributors/retailers of products, and users of chemicals in the course of industrial or professional activities. In compliance with REACH, we have registered relevant materials that could be imported into the EU by us or our third-party manufacturers for the production of lorcaserin and select components of other of our more advanced drug candidates.

We may be subject to further such regulations in the future. Although we believe that our operations comply in all material respects with the applicable environmental laws and regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. In the event of such an accident, we could be held liable for any damages that result, and the extent of that liability could exceed our resources. Our compliance with these laws and regulations has not had, and is not expected to have, a material effect upon our capital expenditures, results of operations or competitive position.

Research and Development Expenses

Research and development activities are the primary source of our expenses. Our research and development expenses include personnel costs, research supplies, facility and equipment costs, clinical and preclinical study fees and manufacturing costs. Such expenses totaled \$110.2 million for the year ended December 31, 2009, \$204.4 million for the year ended December 31, 2008 and \$149.5 million for the year ended December 31, 2007. We include research sponsored by collaborators in our total research and development expenses. We estimated that research expenses funded by collaborators totaled \$4.6 million in 2007. Our collaborators did not fund any of our research expenses in 2008 or 2009.

Employees

As of February 28, 2010, we had a total of 358 employees, including 305 in research, development and manufacturing and 53 in administration, which includes finance, legal, facilities, information technology and other general support areas. We consider our relationship with our employees to be good.

Available Information

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, or the Exchange Act, are available free of charge on our website (www.arenapharm.com) as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC.

Item 1A. Risk Factors.

Investment in our stock involves a high degree of risk. You should consider carefully the risks described below, together with other information in this Annual Report on Form 10-K and other public filings, before making investment decisions regarding our stock. If any of the following events actually occur, our business, operating results, prospects or financial condition could be materially and adversely affected. This could cause the trading price of our common stock to decline and you may lose all or part of your investment. Moreover, the risks described below are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business, operating results, prospects or financial condition.

Table of Contents**Risks Relating to Our Business**

We will need additional funds to conduct our planned research, development and commercialization efforts, we may not be able to obtain such funds and we may never become profitable.

We have accumulated a large deficit since inception that has primarily resulted from the significant research and development expenditures we have made in seeking to identify and validate new drug targets and develop compounds that could become marketed drugs. We expect that our losses will continue to be substantial for at least the short term and that our operating expenses will also continue to be substantial, even if we or our current or future collaborators are successful in advancing our compounds.

We do not have any commercially available drugs, and we have substantially less money than we need to develop our compounds into marketed drugs. It takes many years and potentially hundreds of millions of dollars to successfully develop a preclinical or early clinical compound into a marketed drug, and our efforts may not result in any marketed drugs.

We will need additional funds or a collaborative or other agreement with a pharmaceutical company or companies to bring our most advanced drug candidate, lorcaserin, to market, if ever, and we may not be able to secure adequate funding or find a pharmaceutical company to commercialize lorcaserin at all or on terms you or we believe are favorable. We also believe that it may be difficult for us to obtain additional financing or enter into strategic relationships on terms that we or third parties, including investors, analysts, or potential collaborators, view as acceptable, if at all. If adequate funding is not available, we will have to eliminate or further postpone or scale back some or all of our research or development programs or delay the advancement of one or more of such programs, including our plans to commercialize lorcaserin.

The current global economic environment poses severe challenges to our business strategy, which relies on access to capital from the markets or collaborators, and creates other financial risks for us.

The global economy, including credit markets and the financial services industry, has been experiencing a period of substantial turmoil and uncertainty. These conditions have generally made equity and debt financing more difficult to obtain, and may negatively impact our ability to complete financing transactions. The duration and severity of these conditions is uncertain, as is the extent to which they may adversely affect our business and the business of current and prospective collaborators and vendors. If the global economy does not improve or worsens, we may be unable to secure additional funding to sustain our operations or to find suitable collaborators to advance our internal programs, even if we achieve positive results from our research and development or business development efforts.

We maintain a portfolio of investments in marketable debt securities which are recorded at fair value. Although we have established investment guidelines relative to diversification and maturity with the objectives of maintaining safety of principal and liquidity, we rely on credit rating agencies to help evaluate the riskiness of investments, and such agencies may not accurately predict such risk. In addition, such agencies may reduce the credit quality of our individual holdings, which could adversely affect their value. Lower credit quality and other market events, such as changes in interest rates and further deterioration in the credit markets, may have an adverse effect on the fair value of our investment holdings and cash position.

We are focusing our activities and resources on lorcaserin and depend on its marketing approval and commercial success.

We are focusing our near-term activities and resources on lorcaserin, and we believe a significant portion of the value of our company relates to our ability to obtain marketing approval for and commercialize this drug candidate. The marketing approval and successful commercialization of lorcaserin is subject to many risks, including the risks discussed in other risk factors. If the results of clinical trials and preclinical studies of lorcaserin, the regulatory decisions affecting lorcaserin, the anticipated or actual timing and plan for commercializing lorcaserin, or, ultimately, the market acceptance of lorcaserin do not meet our, your, analysts' or

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others' expectations, the market price of our common stock could decline significantly. In 2010, for example, we could learn whether the US Food and Drug Administration, or FDA, refers our New Drug Application, or NDA, for lorcaserin to an advisory committee and, if so, whether that committee's recommendation is positive or negative, and whether the FDA will approve lorcaserin or issue a Complete Response Letter and, if approved, whether the DEA will schedule lorcaserin as a controlled substance and, if so, the level of scheduling.

Our stock price could decline significantly based on the results and timing of clinical trials and preclinical studies of, and decisions affecting, our most advanced drug candidates.

The results and timing of clinical trials and preclinical studies can affect our stock price. Preclinical studies include experiments performed in test tubes, in animals, or in cells or tissues from humans or animals. These studies include all drug studies except those conducted in human subjects, and may occur before or after initiation of clinical trials for a particular compound. Results of clinical trials and preclinical studies of lorcaserin or our other drug candidates may not be viewed favorably by us or third parties, including investors, analysts, potential collaborators, the academic and medical communities, and regulators. The same may be true of how we design the development programs of our most advanced drug candidates and regulatory decisions (including by us or regulatory authorities) affecting those development programs. Stock prices of companies in our industry have declined significantly when such results and decisions were unfavorable or perceived negatively or when a drug candidate did not otherwise meet expectations.

We have drug programs that are currently in clinical trials. In addition to successfully completing clinical trials, to conduct long-term clinical trials and gain regulatory approval to commercialize drug candidates, regulatory authorities require that all drug candidates complete short- and long-term preclinical toxicity and carcinogenicity studies. These preclinical, animal studies are required to help us and regulatory authorities assess the potential risk that drug candidates may be toxic or cause cancer in humans. The results of clinical trials and preclinical studies are uncertain and subject to different interpretations, and the design of these trials and studies (which may change significantly and be more expensive than anticipated depending on results and regulatory decisions) may also be viewed negatively by us, regulatory authorities or other third parties and adversely impact the development and opportunities for regulatory approval and commercialization of our drug candidates and those under collaborative agreements. We may not be successful in advancing our programs on our projected timetable, if at all. Failure to initiate or delays in the development programs for any of our drug candidates, or unfavorable results or decisions or negative perceptions regarding any of such programs, could cause our stock price to decline significantly. This is particularly the case with respect to lorcaserin.

We may report top-line data from time to time, which is based on a preliminary analysis of key efficacy and safety data, and is subject to change following a more comprehensive review of the data related to the applicable clinical trial.

We have significant indebtedness and debt service obligations as a result of our Deerfield secured loan, which may adversely affect our cash flow, cash position and stock price.

We substantially increased our total debt and debt service obligations when we received a \$100.0 million loan from Deerfield Private Design Fund, L.P., Deerfield Private Design International, L.P., Deerfield Partners, L.P., Deerfield International Limited, Deerfield Special Situations Fund, L.P., and Deerfield Special Situations Fund International Limited, or collectively Deerfield, on July 6, 2009. This loan matures on June 17, 2013, and the outstanding principal accrues interest at a rate of 7.75% per annum on the stated principal balance, payable quarterly in arrears. Our agreement with Deerfield sets forth the following schedule of our required principal repayments: \$10.0 million in July 2010, \$20.0 million in July 2011, \$30.0 million in July 2012, and \$40 million at maturity. We may be required to make the scheduled repayments earlier in connection with certain equity issuances. For example, we were required to make the first scheduled repayment of \$10.0 million in connection with the closing of our July 2009 public offering. In addition, we are required to make mandatory prepayments of the loan upon certain changes of control and in the event we issue equity securities (other than certain exempted issuances) at a price of less than \$2.00 per share.

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On or before June 17, 2011, the lenders may elect to provide us with an additional loan in a principal amount of up to \$20.0 million under similar terms as the \$100.0 million loan, with the additional loan also maturing on June 17, 2013.

In the future, if we are unable to generate cash from operations sufficient to meet these debt obligations, we will need to obtain additional funds from other sources, which may include one or more financings. However, we may be unable to obtain sufficient additional funds when we need them on favorable terms or at all. The sale of equity or convertible debt securities in the future may be dilutive to our stockholders, and debt-financing arrangements may require us to enter into covenants that would restrict certain business activities or our ability to incur further indebtedness, and may contain other terms that are not favorable to our stockholders or us.

Also, if we are unable to generate cash from operations or obtain additional funds from other sources sufficient to meet these debt obligations, or we need to use existing cash to fund these debt obligations, we may have to delay or curtail some or all of our research, development and commercialization programs or sell or license some or all of our assets. Our indebtedness could have significant additional negative consequences, including, without limitation:

- increasing our vulnerability to general adverse economic conditions;
- limiting our ability to obtain additional funds; and
- placing us at a possible competitive disadvantage to less leveraged competitors and competitors that have better access to capital resources.

If an event of default occurs under our loan documents, including in certain circumstances the warrants issued in connection with the loan transaction, the lenders may declare the outstanding principal balance and accrued but unpaid interest owed to them immediately due and payable, which would have a material adverse affect on our financial position. We may not have sufficient cash to satisfy this obligation. Also, if a default occurs under our secured loan, and we are unable to repay the lenders, the lenders could seek to enforce their rights under their security interests in substantially all of our assets. If this were to happen, we may lose some or all of our assets in order to satisfy our debt, which could cause our business to fail.

If we do not commercialize lorcaserin with a pharmaceutical company or companies or raise additional funds, we may have to commercialize lorcaserin on our own and curtail certain of our activities.

We may not be able to enter into agreements to commercialize lorcaserin on acceptable terms, if at all. If we are unable to enter into such agreements, and we must develop our own commercialization capabilities for lorcaserin, we will require additional capital to develop such capabilities and the marketing and sale of lorcaserin may be delayed or limited. Even if we were able to develop our own commercialization capabilities, we have not previously commercialized a drug, and our limited experience may make us less effective at marketing and selling lorcaserin than a pharmaceutical company. Our lack of corporate experience and adequate resources may impede our effort to successfully commercialize lorcaserin.

We face competition in our search for pharmaceutical companies to commercialize lorcaserin. If our competitors are able to establish commercialization arrangements with companies who have substantially greater resources than we have, our competitors may be more successful in marketing and selling their drugs, and our ability to successfully commercialize our drug candidates will be limited.

In addition, if we do not enter into a commercialization agreement with a pharmaceutical company on favorable terms or raise adequate capital, we will need to significantly curtail future activities and expenditures. Any such reductions may adversely impact our lorcaserin development and commercialization timeline or narrow or slow the development of our pipeline, which we believe would reduce our opportunities for success.

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Our drug candidates are subject to extensive regulation, and we may not receive required regulatory approvals, or timely approvals, for any of our drug candidates.

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, marketing and distribution, and other possible activities relating to our drug candidates are, and any resulting drugs will be, subject to extensive regulation by the FDA and other regulatory agencies in the United States. Failure to comply with FDA and other applicable regulatory requirements may, either before or after product approval, if any, subject our company to administrative or judicially imposed sanctions.

Neither collaborators nor we are permitted to market our drug candidates in the United States until we receive regulatory approval from the FDA. Specific preclinical data, chemistry, manufacturing and controls data, a proposed clinical trial protocol and other information must be submitted to the FDA as part of an investigational new drug, or IND, application, and clinical trials may commence only after the IND application becomes effective. None of our drug candidates have received marketing approval. To market a new drug in the United States, we must submit to the FDA and obtain FDA approval of an NDA. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls to demonstrate the safety and effectiveness of the drug candidate.

Obtaining approval of an NDA can be a lengthy, expensive and uncertain process. As part of the Prescription Drug User Fee Act, or PDUFA, the FDA has a goal to review and act on a percentage of all submissions in a given time frame. The general review goal for a drug application is 10 months for a standard application and 6 months for priority review. The FDA's review goals are subject to change, and it is unknown whether the review of our NDA filing for lorcaserin, or an NDA filing for any of our other drug candidates, will be completed within the FDA's review goals or will be delayed. Moreover, the duration of the FDA's review may depend on the number and type of other NDAs that are submitted with the FDA around the same time period. We submitted our NDA for lorcaserin in December 2009. VIVUS, Inc., also submitted an NDA with the FDA in December 2009 for a drug candidate for the treatment of obesity. In addition, Orexigen Therapeutics, Inc., has stated that it expects to submit an NDA with the FDA for a drug candidate for the treatment of obesity by the end of April 2010. The review of such NDAs may impact the review of our lorcaserin NDA. Furthermore, any drug that acts on the central nervous system, or CNS, such as lorcaserin, has the potential to be scheduled as a controlled substance by the Drug Enforcement Administration of the US Department of Justice, or DEA. DEA scheduling is an independent process that can delay drug launch beyond an NDA approval date.

Regulatory approval of an NDA or NDA supplement is not guaranteed. The number and types of preclinical studies and clinical trials that will be required for FDA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to target and the regulations applicable to any particular drug candidate. Despite the time and expense exerted in preclinical and clinical studies, failure can occur at any stage, and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional preclinical studies and clinical trials. The FDA can delay, limit or deny approval of a drug candidate for many reasons, including:

- a drug candidate may not be deemed adequately safe and effective;
- FDA officials may not find the data from preclinical studies and clinical trials sufficient;
- the FDA's interpretation and our interpretation of data from preclinical studies and clinical trials may differ significantly;
- the FDA may not approve the manufacturing processes or facilities;
- the FDA may change its approval policies or adopt new regulations; or
- the FDA may not accept an NDA submission due to, among other reasons, the content or formatting of the submission.

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With respect to lorcaserin, the FDA draft guidance document "Developing Products for Weight Management" dated February 2007 provides two alternate benchmarks for the development of drugs for the indication of weight management. The guidance provides that, in general, a product can be considered effective for weight management if after one year of treatment either of the following occurs: (1) the difference in mean weight loss between the active-product and placebo-treated groups is at least 5% and the difference is statistically significant, or (2) the proportion of patients who lose at least 5% of baseline body weight in the active-product group is at least 35%, is approximately double the proportion in the placebo-treated group, and the difference between groups is statistically significant. While we believe the results of our pivotal Phase 3 clinical trials of lorcaserin satisfy the latter of the two alternate efficacy benchmarks, the FDA may disagree with our view or may assert that its draft guidance is not binding or impose other approval conditions that could delay or preclude approval of our lorcaserin NDA.

With the exception of our recently submitted lorcaserin NDA, we have not previously submitted NDAs to the FDA. This lack of corporate experience may impede our ability to obtain FDA approval in a timely manner, if at all, for lorcaserin or our other drug candidates for which development and commercialization is our responsibility. Even if we believe that data collected from our preclinical studies and clinical trials of our drug candidates are promising and that our information and procedures regarding chemistry, manufacturing and controls are sufficient, our data may not be sufficient to support approval by the FDA or any other US or foreign regulatory authority, or regulatory interpretation of these data and procedures may be unfavorable. In addition, we believe that the regulatory review of NDAs for drug candidates intended for widespread use by a large proportion of the general population is becoming increasingly focused on safety. In this regard, it is possible that some of our drug candidates, including lorcaserin, will be subject to increased scrutiny to show adequate safety than would drug candidates for more acute or life-threatening diseases such as cancer. Even if approved, drug candidates may not be approved for all indications requested and such approval may be subject to limitations on the indicated uses for which the drug may be marketed, restricted distribution methods or other limitations required by a Risk Evaluation and Mitigation Strategies, or REMS. Our business and reputation may be harmed by any failure or significant delay in receiving regulatory approval for the sale of any drugs resulting from our drug candidates. As a result, we cannot predict when or whether regulatory approval will be obtained for any drug we develop.

To market any drugs outside of the United States, we and current or future collaborators must comply with numerous and varying regulatory requirements of other countries. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks associated with FDA approval as well as additional, presently unanticipated, risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects associated with regulatory approval in the United States, including the risk that our drug candidates may not be approved for all indications requested and that such approval may be subject to limitations on the indicated uses for which the drug may be marketed.

Even if any of our drug candidates receives regulatory approval, our drug candidates will still be subject to extensive post-marketing regulation.

If we or collaborators receive regulatory approval for our drug candidates in the United States or other jurisdictions, we will also be subject to ongoing obligations and continued regulatory review from the FDA and other applicable regulatory agencies, such as continued adverse event reporting requirements. We may also be subject to additional FDA post-marketing obligations, all of which may result in significant expense and limit our ability to commercialize such drugs in the United States or other jurisdictions.

If any of our drug candidates receive US regulatory approval or approval in other jurisdictions, the FDA or other regulatory agencies may also require that the sponsor of the NDA conduct additional clinical trials to further assess the drug after NDA approval under a post-approval commitment. Such additional studies may be

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- prevalence and severity of any side effects;
- potential or perceived advantages or disadvantages over alternative treatments;
- strength of sales, marketing and distribution support;
- price of our future products, both in absolute terms and relative to alternative treatments;
- the effect of current and future healthcare laws on our drug candidates;
- availability of coverage and reimbursement from government and other third-party payers; and
- product labeling or product insert requirements of the FDA or other regulatory authorities.

If our approved drugs, if any, fail to achieve market acceptance, we may not be able to generate significant revenue to achieve or sustain profitability.

In addition, if lorcaserin is approved for marketing, regulatory authorities may determine that lorcaserin will be a scheduled drug if it is found to have abuse potential or for other reasons. Based on our interpretation of a formal abuse potential clinical trial we conducted, lorcaserin's clinical safety profile and certain other factors, we believe that lorcaserin has a limited abuse potential. If regulatory agencies disagree and lorcaserin were to be scheduled as a controlled substance by the DEA, we would expect it would be a schedule IV or V drug, which we believe would have little or no impact on our ability to commercialize lorcaserin. However, if lorcaserin were scheduled in a more tightly controlled category, such scheduling could negatively impact the ability to prescribe lorcaserin, a patient's willingness to use it and other aspects of our ability to commercialize it.

Our development and commercialization of lorcaserin may be adversely impacted by cardiovascular side effects previously associated with fenfluramine and dexfenfluramine.

We developed lorcaserin to more selectively stimulate the serotonin 2C receptor because we believe this may avoid the cardiovascular side effects associated with fenfluramine and dexfenfluramine (often used in combination with phentermine, the combination of which was commonly referred to as "fen-phen"). These two drugs were serotonin-releasing agents and non-selective serotonin receptor agonists, and were withdrawn from the market in 1997 after reported incidences of heart valve disease and pulmonary hypertension associated with their usage. We may not be correct in our belief that more selectively stimulating the serotonin 2C receptor will avoid these undesired side effects or lorcaserin's selectivity profile may not be adequate to avoid these side effects. Moreover, the potential relationship between the activity of lorcaserin and the activity of fenfluramine and dexfenfluramine may result in increased FDA regulatory scrutiny of the safety of lorcaserin and may raise potential adverse publicity in the marketplace, which could affect clinical enrollment or sales if lorcaserin is approved for commercialization. We have completed two large pivotal lorcaserin trials of one and two years' duration, both of which showed no apparent effects on heart valves or pulmonary artery pressures, but these results will need to be reviewed by the FDA.

The development programs for our drug candidates are expensive, time consuming, uncertain and susceptible to change, interruption, delay or termination.

Drug development programs are very expensive, time consuming and difficult to design and implement. Our drug candidates are in various stages of research and development and are prone to the risks of failure inherent in drug development. Clinical trials and preclinical studies are needed to demonstrate that drug candidates are safe and effective to the satisfaction of the FDA and similar non-US regulatory authorities. These trials are expensive and uncertain processes that take years to complete. Failure can occur at any stage of the process, and successful early clinical or preclinical trials do not ensure that later trials or studies will be successful. In addition, the commencement or completion of our planned clinical trials could be substantially delayed or prevented by several factors, including:

- limited number of, and competition for, suitable patients required for enrollment in our clinical trials;
- limited number of, and competition for, suitable sites to conduct our clinical trials;

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- delay or failure to obtain FDA approval or agreement to commence a clinical trial;
- delay or failure to obtain sufficient supplies of our drug candidates for our clinical trials;
- delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or investigators; and
- delay or failure to obtain institutional review board, or IRB, approval to conduct a clinical trial at a prospective site.

Even if the results of our development programs are favorable, the development programs of our most advanced drug candidates, including those being developed by current or future collaborators, may take significantly longer than expected to complete. In addition, the FDA, other regulatory authorities, collaborators, or we may suspend, delay or terminate our development programs at any time for various reasons, including:

- lack of effectiveness of any drug candidate during clinical trials;
- side effects experienced by study participants or other safety issues;
- slower than expected rates of patient recruitment and enrollment or lower than expected patient retention rates;
- delays or inability to manufacture or obtain sufficient quantities of materials for use in clinical trials;
- inadequacy of or changes in our manufacturing process or compound formulation;
- delays in obtaining regulatory approvals to commence a study, or "clinical holds," or delays requiring suspension or termination of a study by a regulatory authority, such as the FDA, after a study is commenced;
- changes in applicable regulatory policies and regulations;
- delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites;
- uncertainty regarding proper dosing;
- unfavorable results from ongoing clinical trials and preclinical studies;
- failure of our clinical research organizations to comply with all regulatory and contractual requirements or otherwise perform their services in a timely or acceptable manner;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to design appropriate clinical trial protocols;
- insufficient data to support regulatory approval;
- termination of clinical trials by one or more clinical trial sites;
- inability or unwillingness of medical investigators to follow our clinical protocols;
- difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data; or
- lack of sufficient funding to continue clinical trials and preclinical studies.

There is typically a high rate of attrition from the failure of drug candidates proceeding through clinical trials, and many companies have experienced significant setbacks in advanced development programs even after promising results in earlier studies or trials. We have experienced setbacks in our internal and partnered development programs and may experience additional setbacks in the future. If we or our collaborators abandon or are delayed in our development efforts related to lorcaserin or any other drug candidate, we may not be able to generate sufficient revenues to continue our operations at the current level or become profitable, our reputation in the industry and in the investment community would likely be significantly damaged, additional funding may not be available to us or may not be available on terms you or we believe are favorable, and our stock price would likely decrease significantly.

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The results of preclinical studies and completed clinical trials are not necessarily predictive of future results, and our current drug candidates may not have favorable results in later studies or trials.

Preclinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of a drug candidate, but rather to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the drug candidate's side effects at various doses and schedules. To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our drug candidates, except lorcaserin. Favorable results in our early studies or trials may not be repeated in later studies or trials, including continuing preclinical studies and large-scale clinical trials, and our drug candidates in later-stage trials may fail to show desired safety and efficacy despite having progressed through earlier-stage trials. Unfavorable results from ongoing preclinical studies or clinical trials could result in delays, modifications or abandonment of ongoing or future clinical trials, or abandonment of a clinical program. Preclinical and clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated or terminated, or a clinical program to be abandoned.

Many of our research and development programs are in early stages of development, and may not result in the commencement of clinical trials.

Many of our research and development programs are in the discovery or preclinical stage of development. The process of discovering compounds with therapeutic potential is expensive, time consuming and unpredictable. Similarly, the process of conducting preclinical studies of compounds that we discover requires the commitment of a substantial amount of our technical and financial resources and personnel. We may not discover additional compounds with therapeutic potential, and any of our preclinical compounds may not result in the commencement of clinical trials. We cannot be certain that results sufficiently favorable to justify commencement of Phase 1 clinical trials will be obtained in these preclinical investigations. Even if such favorable preclinical results are obtained, our financial resources may not allow us to commence Phase 1 clinical trials. If we are unable to identify and develop new drug candidates, we may not be able to maintain a clinical development pipeline or generate revenues.

Our ability to generate significant revenues, for at least the short term, depend upon the actions of our current and future collaborators.

We expect that, for at least the short term, our ability to generate significant revenues will depend upon the success of our existing collaboration with Ortho-McNeil-Janssen Pharmaceuticals, Inc., or Ortho-McNeil-Janssen, and our ability to enter into new collaborations. Future revenues from our collaboration with Ortho-McNeil-Janssen will depend on, in addition to patent reimbursements, milestone and royalty payments, if any. Thus, we will receive little additional revenues from Ortho-McNeil-Janssen if our own or Ortho-McNeil-Janssen's research, development or, ultimately, marketing efforts are unsuccessful. In addition, we intend to commercialize lorcaserin with a pharmaceutical company or companies, and any such company may not be successful in such efforts.

Typically, collaborators (and not us) control the development of compounds subject to the collaboration after we have met early preclinical scientific milestones. In addition, we may not have complete access to information about the results and status of such collaborators' clinical trials and regulatory programs and strategies. We are not entitled to the more significant milestone payments under our agreement with Ortho-McNeil-Janssen until it has advanced compounds in clinical testing.

Our collaborators may not devote adequate resources to the research, development or commercialization of our compounds and may not develop or implement a successful clinical, regulatory or commercialization strategy. We cannot guarantee that any development, approval or sales milestones in our existing or future collaborations will be achieved in the future, or that we will receive any payments for the achievement of any

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Revenues from collaborators for milestones that may be achieved in the future are difficult to predict, and our revenues may vary significantly from quarter to quarter and year to year. We expect that any significant revenues for at least the short term will depend on whether we enter into an agreement with a pharmaceutical company or companies to commercialize lorcaserin or to collaborate on any of our other current or future drug candidates, as well as the clinical success of our collaboration with Ortho-McNeil-Janssen. Ultimately, we expect our revenues in the long term to primarily depend upon the regulatory approval and commercialization of the drug candidates we discover.

Cost of manufacturing services. Cost of manufacturing services is comprised of direct costs associated with manufacturing drug products for Siegfried under our manufacturing services agreement, including related salaries, other personnel costs and machinery depreciation costs. Cost of manufacturing services was \$6.5 million and \$8.5 million for the years ended December 31, 2009 and 2008, respectively.

Research and development expenses. Research and development expenses, which account for the majority of our expenses, consist primarily of costs associated with external clinical and preclinical study fees, manufacturing costs and other related expenses, and the development of our earlier-stage programs and technologies. Our most significant research and development costs are for clinical trials (including payments to contract research organizations, or CROs), preclinical study fees, salaries and personnel, research supplies, and facility and equipment costs. We expense research and development costs to operations as they are incurred when these expenditures relate to our research and development efforts and have no alternative future uses. Other than external expenses for our clinical and preclinical programs, we generally do not track our research and development expenses by project; rather, we track such expenses by the type of cost incurred.

Research and development expenses decreased by \$94.2 million to \$110.2 million for the year ended December 31, 2009, from \$204.4 million for the year ended December 31, 2008. This difference was due primarily to decreases of (i) \$77.7 million in external clinical and preclinical study fees and expenses due primarily to completing our BLOOM and BLOSSOM lorcaserin trials in 2009, and prioritizing our spending towards activities that supported the lorcaserin NDA filing, (ii) \$7.0 million in salary and other personnel costs as a result of the workforce reduction we completed in June 2009 and (iii) \$6.2 million in research supplies due to having less research personnel and our cost-containment efforts. Although we expect to continue to incur substantial research and development expenses in 2010, primarily related to lorcaserin, we expect our research and development expenses will be significantly lower than the 2009 level due primarily to completion of our BLOOM and BLOSSOM trials. We expect to incur substantial manufacturing costs for lorcaserin in 2010 and beyond, whether we market and commercialize lorcaserin independently or with a pharmaceutical company or companies. We also expect to initiate clinical trials for APD916, our drug candidate for the treatment of narcolepsy and cataplexy, in 2010, but any such Phase 1 trial would involve substantially fewer patients and lower costs than the more expensive Phase 3 trials for lorcaserin.

Included in the \$45.7 million total external clinical and preclinical study fees and expenses noted in the table above for the year ended December 31, 2009 was \$43.3 million related to our lorcaserin program, \$1.3 million related to our APD811 program and \$0.5 million related to our APD125 program. APD811 is our lead drug candidate for the treatment of pulmonary arterial hypertension, and we previously studied APD125 for insomnia. Included in the \$123.5 million total external clinical and preclinical study fees and expenses for the year ended December 31, 2008 was \$106.0 million related to our lorcaserin program, \$13.5 million related to our APD125 program, \$1.4 million related to our APD916 program and \$1.1 million related to the program for our anti-thrombotic drug candidate, APD791.

Cumulatively through December 31, 2009, we have recorded \$256.2 million, \$43.7 million, \$7.3 million, \$2.3 million and \$1.4 million in external clinical and preclinical study fees and other related expenses for lorcaserin, APD125, APD791, APD916 and APD811, respectively. While expenditures on current and future clinical development programs are expected to be substantial, they are subject to many uncertainties, including whether we have adequate funds and develop our drug candidates independently or with a collaborator. As a

EXHIBIT D



Arena Pharmaceuticals Submits New Drug Application to FDA for Lorcaserin for Weight Management

SAN DIEGO, Dec 22, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) announced today that it has submitted a New Drug Application (NDA) to the US Food and Drug Administration (FDA) for lorcaserin, Arena's internally discovered and developed drug candidate for weight management, including weight loss and maintenance of weight loss. The submission is based on an extensive data package from lorcaserin's clinical development program that includes 18 clinical trials totaling 8,576 patients.

William R. Shanahan, M.D., Arena's Vice President and Chief Medical Officer, stated, "Physicians need new, better-tolerated approaches to improve the treatment of patients who are obese or significantly overweight. Based on the robust data package we submitted to the FDA, lorcaserin has the potential to meet this need, offering patients the opportunity to achieve sustainable weight loss in a well-tolerated manner and improve their cardiometabolic health and quality of life."

The pivotal Phase 3 clinical trial program, BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management) and BLOSSOM (Behavioral modification and Lorcaserin Second Study for Obesity Management), evaluated nearly 7,200 patients treated for up to two years and showed that lorcaserin consistently produced significant weight loss with excellent safety and tolerability.

"Today's NDA submission is an important milestone towards realizing lorcaserin's significant commercial potential, and we are excited by the possibility of bringing lorcaserin to patients who need help in managing their weight," said Jack Lief, Arena's President and Chief Executive Officer. "Physician feedback suggests that, if approved, lorcaserin's combination of efficacy, safety and tolerability will position the drug candidate as first-line therapy for weight management."

Phase 3 Program Overview

BLOOM and BLOSSOM comprise the pivotal Phase 3 program and are the basis of the lorcaserin NDA submission. These double-blind, randomized, placebo-controlled trials evaluated 10 mg of lorcaserin dosed once or twice daily versus placebo for up to two years in obese patients, Body Mass Index (BMI) 30 to 45, with or without co-morbid conditions and overweight patients, BMI 27 to 29.9, with at least one co-morbid condition. Positive results from the pivotal program were presented at the 69th Scientific Sessions of the American Diabetes Association and the 27th Annual Scientific Meeting of The Obesity Society.

In addition to the pivotal program, Arena is evaluating lorcaserin in obese and overweight patients with type 2 diabetes in its BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus) trial. BLOOM-DM is planned as a supplement to the NDA.

About Lorcaserin

Lorcaserin is a novel single agent that represents the first in a new class of selective serotonin 2C receptor agonists. The serotonin 2C receptor is expressed in the brain, including the hypothalamus, an area involved in the control of appetite and metabolism. Stimulation of this receptor is strongly associated with feeding behavior and satiety. Arena has patents that cover lorcaserin in the US and other jurisdictions, which in most cases are capable of continuing into 2023 without taking into account any patent term extensions or other exclusivity Arena might obtain.

About Arena Pharmaceuticals

Arena is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing oral drugs that target G protein-coupled receptors, an important class of validated drug targets, in four major therapeutic areas: cardiovascular, central nervous system, inflammatory and metabolic diseases. Arena has submitted a New Drug Application to the FDA for its most advanced drug candidate, lorcaserin for weight management.

Arena Pharmaceuticals(R) and Arena(R) are registered service marks of the company.

Forward-Looking Statements

Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include statements about the development, advancement, therapeutic indication and use, tolerability, safety, selectivity, efficacy and regulatory approval of lorcaserin; the importance of Arena's NDA submission for lorcaserin; lorcaserin's commercial and other potential, including in meeting patients' and physicians' needs, improving treatment, helping patients achieve and sustain weight loss, improving health and quality of life and generating interest; future activities relating to lorcaserin, including submitting the BLOOM-DM results as a supplement to the NDA; lorcaserin's patent coverage; and Arena's strategy, research and development programs, and ability to develop compounds and commercialize drugs. For such statements, Arena claims the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from Arena's expectations. Factors that could cause actual results to differ materially from the forward-looking statements include, but are not limited to, regulatory authorities may not accept Arena's NDA submission; regulatory authorities may not find data from Arena's clinical trials and studies sufficient for regulatory approval; the timing, success and cost of Arena's lorcaserin program and other of its research and development programs; the timing and ability of Arena to receive regulatory approval for its drug candidates; results of clinical trials or preclinical studies may not be predictive of future results; clinical trials and studies may not proceed at the time or in the manner Arena expects or at all; Arena's ability to partner or commercialize lorcaserin or other of its compounds or programs; Arena's ability to obtain additional funds; Arena's ability to obtain and defend its patents; and the timing and receipt of payments and fees, if any, from Arena's collaborators. Additional factors that could cause actual results to differ materially from those stated or implied by Arena's forward-looking statements are disclosed in Arena's filings with the Securities and Exchange Commission. These forward-looking statements represent Arena's judgment as of the time of this release. Arena disclaims any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

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EXHIBIT E



Arena Pharmaceuticals' Lorcaserin for Obesity Passes Major Safety Milestone

- Month-12 Independent Echocardiographic Data Safety Monitoring Board Review Strengthens Lorcaserin's Emerging Cardiovascular Safety Profile -

SAN DIEGO, March 17 /PRNewswire-FirstCall/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) announced today that following a planned review by an independent Echocardiographic Data Safety Monitoring Board (EDSMB) it is continuing BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management), a pivotal trial evaluating the efficacy and safety of lorcaserin hydrochloride for the treatment of obesity. The EDSMB's review of unblinded echocardiographic data performed after patients completed 12 months of dosing in the trial confirmed that differences, if any, in the rates of Food and Drug Administration (FDA)-defined valvulopathy in patients treated with lorcaserin and in the control group did not meet the EDSMB's predetermined stopping criteria. Based on the EDSMB's review of the rate of FDA-defined valvulopathy, Arena has been able to confirm that the statistical power calculations used in the design of the Phase 3 trial program to monitor patients for increased risk of developing valvulopathy are justified. The findings from the month-12 review build on the EDSMB's September 2007 review that evaluated echocardiograms after 6 months of dosing.

"This critical milestone assessing month-12 echocardiographic data strongly supports lorcaserin's cardiovascular safety profile. We believe that this exposure duration, even under a conservative interpretation of the literature, would have been sufficient to observe a fenfluramine like effect on heart valves if present. BLOOM's primary echo endpoint is based on the month-12 data," said Jack Lief, Arena's President and Chief Executive Officer. "We are committed to continued efforts to develop a robust database for submission to the FDA in our efforts to provide patients a novel, safe and effective obesity treatment."

BLOOM, the first of three lorcaserin Phase 3 trials, is a double-blind, randomized, placebo-controlled trial involving nearly 3,200 patients in approximately 100 centers throughout the United States. The trial is evaluating a 20 mg daily dose (10 mg dosed twice daily) of lorcaserin versus placebo over a two-year treatment period in obese patients (Body Mass Index, or BMI, 30 to 45) with or without co-morbid conditions and overweight patients (BMI 27 to less than 30) with at least one co-morbid condition. The proportion of patients with a 5% or greater weight reduction from baseline at week 52 is the primary efficacy endpoint. Patients received echocardiograms at screening, 6 months and 12 months after initiating dosing in the trial, and will receive follow-up echocardiograms at 18 and 24 months. There are no further planned EDSMB meetings.

The BLOSSOM (Behavioral modification and Lorcaserin Second Study for Obesity Management) trial is evaluating 10 mg and 20 mg daily doses (10 mg dosed once or twice daily) of lorcaserin versus placebo over a one-year treatment period in obese patients with or without co-morbid conditions and overweight patients with at least one co-morbid condition at about 100 sites in the United States.

The BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus) trial is evaluating 10 mg and 20 mg daily doses (10 mg dosed once or twice daily) of lorcaserin versus placebo over a one-year treatment period in obese and overweight patients with type 2 diabetes at about 45 sites in the United States.

As in the BLOOM trial, diet and exercise are also included in the BLOSSOM and BLOOM-DM trials, and the primary efficacy endpoint is the proportion of patients with a 5% or greater weight reduction from baseline at week 52. Arena is also studying several key secondary endpoints, including changes in serum lipids and HbA1c and, in the BLOOM-DM trial, other indicators of glycemic control.

In both of these additional trials, all patients will receive echocardiograms at baseline, at month 6, and at the end of the study to assess heart valve function over time. In contrast to the BLOOM trial, however, there are no echocardiographic exclusion criteria and there is no monitoring by an independent monitoring board. The lorcaserin Phase 3 pivotal program is planned to enroll a total of approximately 7,000 patients.

"The month-12 review of the echocardiographic data significantly adds to our confidence in lorcaserin's cardiovascular safety profile," said William R. Shanahan, M.D., Arena's Vice President and Chief Medical Officer. "BLOOM is scheduled to complete about one year from now, and I'm looking forward to additional data demonstrating the potential of this novel compound to address weight loss in a highly targeted manner."

About Lorcaserin

Lorcaserin, Arena's internally discovered oral drug candidate for the treatment of obesity, is in an ongoing Phase 3 program. The compound is the first in a new class of obesity drug candidates targeting the 5-HT_{2C} serotonin receptor, which is located in the hypothalamus, a key area of the brain associated with regulation of food intake and metabolism. Results from Phase 2 studies demonstrated that treatment with lorcaserin produced highly statistically significant, progressive and dose-dependent weight loss over a 12-week period. Lorcaserin was generally well tolerated at all doses in the Phase 2 clinical trials and had no apparent effects on heart valves or pulmonary artery pressure.

About Obesity

Obesity affects tens of millions of people in the United States and poses a serious long-term threat to their health and welfare. The number of overweight and obese people has substantially increased over the past several decades. Approximately two-thirds of all adults in the United States are obese or overweight, and medical and related costs of obesity are \$123 billion per year according to a 2005 report by the International Diabetes Federation. Being obese or overweight is associated with increased risk of a number of conditions, including heart disease, stroke, diabetes, cancer and osteoarthritis. Medical treatment options for obese and overweight people currently are limited.

About Arena Pharmaceuticals

Arena is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing oral drugs in four major therapeutic areas: cardiovascular, central nervous system, inflammatory and metabolic diseases. Arena's most advanced drug candidate, lorcaserin, is being investigated in a Phase 3 clinical trial program for the treatment of obesity. Arena's broad pipeline of novel compounds targeting G protein-coupled receptors, an important class of validated drug targets, includes compounds being evaluated independently and with its partners, Merck & Co., Inc. and Ortho-McNeil Pharmaceutical, Inc.

Arena Pharmaceuticals® and Arena® are registered service marks of the company. "APD" is an abbreviation for Arena Pharmaceuticals Development.

Forward-Looking Statements

Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include statements about the significance of the review of echocardiographic data; the continuation of the Phase 3 program and development of lorcaserin; the sufficiency of the lorcaserin exposure duration to observe a fenfluramine like effect on heart valves; Arena's development of a lorcaserin database and the content and use of such database; Arena's efforts to provide patients a novel, safe and effective obesity treatment; the protocol, design, scope, enrollment, number, timing and other aspects of clinical trials and other studies of lorcaserin and other of Arena's drug candidates; the tolerability, side effects, safety profile, efficacy and the commercial and other potential of lorcaserin and other of Arena's drug candidates; the growth and impact of obesity; the advancement and content of Arena's pipeline; and other statements about Arena's vision, outlook, strategy, preclinical and internal and partnered clinical programs, and ability to develop compounds and commercialize drugs. For such statements, Arena claims the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from Arena's expectations. Factors that could cause actual results to differ materially from the forward-looking statements include, but are not limited to, clinical trials and studies may not proceed at the time or in the manner Arena expects or at all, the results of clinical trials or preclinical studies may not be predictive of future results, Arena's ability to partner lorcaserin, APD125, APD791 or other of its compounds or programs, the timing, success and cost of Arena's research, out-licensing endeavors and clinical trials, Arena's ability to obtain additional financing, Arena's ability to obtain and defend its patents, the timing and receipt of payments and fees, if any, from Arena's collaborators, and Arena's ability to redeem with common stock any outstanding shares of its series B convertible preferred stock. Additional factors that could cause actual results to differ materially from those stated or implied by Arena's forward-looking statements are disclosed in Arena's filings with the Securities and Exchange Commission. These forward-looking statements represent Arena's judgment as of the time of this release. Arena disclaims any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

SOURCE Arena Pharmaceuticals, Inc.

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EXHIBIT F



Arena Pharmaceuticals Announces Fourth Quarter and Full Year 2008 Financial Results

SAN DIEGO, March 12, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) today reported financial results for the fourth quarter and full year ended December 31, 2008.

Arena reported a net loss allocable to common stockholders in the fourth quarter of 2008 of \$62.5 million, or \$0.84 per share, and a net loss allocable to common stockholders in the full year ended December 31, 2008 of \$239.5 million, or \$3.24 per share. This compares with a net loss allocable to common stockholders in the fourth quarter of 2007 of \$40.9 million, or \$0.60 per share, and a net loss allocable to common stockholders in the full year ended December 31, 2007 of \$145.3 million, or \$2.31 per share. The increased net loss in 2008 over 2007 is due primarily to Arena's Phase 3 clinical trial program of lorcaserin hydrochloride, or lorcaserin, for the treatment of obesity. Total revenues in the fourth quarter of 2008 were \$2.7 million, compared to \$4.6 million in the fourth quarter of 2007. Total revenues in the full year ended December 31, 2008 were \$9.8 million, compared to \$19.3 million in the full year ended December 31, 2007. This revenue decrease in 2008 is due primarily to reaching the end of the research funding portion of Arena's collaborations with Merck & Co., Inc., and Ortho-McNeil-Janssen Pharmaceuticals, Inc., in the fourth quarter of 2007.

"We are excited that in only a few weeks we will be announcing top-line data from the first of two pivotal trials evaluating the safety and efficacy of lorcaserin, which has the potential to be the first in a new class of drugs selectively targeting a well validated weight loss receptor," stated Jack Lief, Arena's President and Chief Executive Officer. "Given the challenging economic environment, we will continue to focus our resources on the lorcaserin program. I am optimistic that data from this program, as well as from other programs in our broad pipeline, will continue to generate interest from prospective collaborators and help in our efforts to strengthen our balance sheet."

Research and development expenses totaled \$53.3 million in the fourth quarter of 2008, compared to \$40.7 million in the fourth quarter of 2007. Research and development expenses totaled \$204.4 million in the full year ended December 31, 2008, compared to \$149.5 million in the full year ended December 31, 2007. This increase in research and development expenses in 2008 over 2007 is primarily attributable to the Phase 3 program of lorcaserin. Research and development expenses for all of 2008 included \$5.0 million in non-cash, share-based compensation expense, compared to \$4.2 million in 2007. General and administrative expenses totaled \$8.6 million in the fourth quarter of 2008, compared to \$6.9 million in the fourth quarter of 2007. General and administrative expenses totaled \$30.5 million in the full year ended December 31, 2008, compared to \$26.6 million in the full year ended December 31, 2007. This increase in general and administrative expenses in 2008 over 2007 is primarily attributable to increases in personnel-related expenses, as well as costs related to managing Arena's growing and maturing patent portfolio. General and administrative expenses in 2008 included \$3.5 million in non-cash, share-based compensation expense, compared to \$4.6 million in 2007. Total patent costs, including patent costs related to partnered programs, were \$7.3 million in the full year ended December 31, 2008, compared to \$6.4 million in the full year ended December 31, 2007.

Total interest and other income in 2008 reflected a net expense due to a decrease in interest income, as well as non-cash charges related to a settlement with one of Arena's two warrant holders from its Series B Convertible Preferred Stock financing and a write-down of an investment in TaiGen Biotechnology Co., Ltd. Arena redeemed all of its outstanding shares of Series B Convertible Preferred Stock in November 2008 for \$55.8 million.

Cash, cash equivalents and short-term investments totaled \$110.1 million at December 31, 2008. Approximately 74.1 million shares of Arena's common stock were outstanding at December 31, 2008.

Arena's Recent and 2008 Developments

Lorcaserin

- Announced completion of dosing in BLOOM, a pivotal trial evaluating the efficacy and safety of lorcaserin. Results from the BLOOM trial are expected to be announced around the end of March 2009.
- Announced publication of the Phase 2b clinical trial results of lorcaserin in the December 4, 2008 issue of Obesity, the official peer

reviewed journal of The Obesity Society.

- Reported findings from a planned review by an independent Echocardiographic Safety Monitoring Board, or ESMB, in BLOOM. The ESMB's review of unblinded echocardiographic data performed after patients completed 12 months of dosing in the trial confirmed that differences, if any, in the rates of Food and Drug Administration-defined valvulopathy in patients treated with lorcaserin and in the control group did not meet the ESMB's predetermined stopping criteria.

Other

- Received net proceeds of \$14.6 million as reimbursement for improvements made to one of Arena's facilities.
- Announced the completion of a positive randomized, double-blind, placebo-controlled Phase 1 clinical trial and the initiation of a Phase 2 clinical trial of a second generation oral niacin receptor agonist intended for the treatment of atherosclerosis in partnership with Merck.
- Announced positive results from Phase 1a and Phase 1b clinical trials of APD791 to evaluate the compound's safety, pharmacokinetics and pharmacodynamics. APD791 is Arena's internally discovered oral drug candidate intended for the treatment of arterial thrombosis and other related conditions. In both trials, APD791 inhibited serotonin-mediated amplification of platelet aggregation in a dose-dependent manner. APD791 was also generally well tolerated and rapidly absorbed and exposures were related to dose.
- Announced that APD597, an Arena-discovered oral GPR119 agonist for the treatment of type 2 diabetes, was advanced into a Phase 1 clinical trial in partnership with Ortho-McNeil-Janssen. The advancement of APD597 followed an announcement that initial clinical study results for APD668, a first generation GPR119 agonist discovered by Arena and investigated for the treatment of type 2 diabetes in partnership with Ortho-McNeil-Janssen, suggest that GPR119 agonists may improve glucose control in patients with type 2 diabetes.
- Announced that preliminary data from a Phase 2b clinical trial of APD125, measuring subjective endpoints in patients with primary insomnia, indicated that APD125 did not meet the trial's primary or secondary endpoints. Treatment with APD125 was well tolerated, and there were no reports of serious adverse events or emerging safety findings as compared to placebo. Arena does not anticipate any further clinical development of APD125.
- Entered into strategic cooperation agreements with Siegfried Ltd that are primarily related to the manufacturing of lorcaserin. The agreements include a long-term supply agreement for the purchase of lorcaserin active pharmaceutical ingredient, the purchase of certain drug product facility assets, a manufacturing services agreement and a technical services agreement.

Scheduled Earnings Call

Arena will host both a conference call and webcast to discuss the fourth quarter and full year 2008 financial results and to provide a corporate update today, Thursday, March 12, 2009, at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). Jack Lief, President and Chief Executive Officer and Robert E. Hoffman, Vice President, Finance and Chief Financial Officer will host the conference call.

The conference call may be accessed by dialing 877.741.4240 for domestic callers and 719.325.4753 for international callers. Please specify to the operator that you would like to join the "Arena Pharmaceuticals Fourth Quarter 2008 Earnings Call." The conference call will be webcast live under the investor relations section of Arena's website at www.arenapharm.com, and will be archived there for 30 days following the call. Please connect to Arena's website several minutes prior to the start of the broadcast to ensure adequate time for any software download that may be necessary.

About Arena Pharmaceuticals

Arena is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing oral drugs in four major therapeutic areas: cardiovascular, central nervous system, inflammatory and metabolic diseases. Arena's most advanced drug candidate, lorcaserin, is being investigated in a Phase 3 clinical trial program for the treatment of obesity. Arena's broad pipeline of novel compounds target G protein-coupled receptors, an important class of validated drug targets, and includes compounds being evaluated independently and with partners, Merck & Co., Inc., and Ortho-McNeil-Janssen Pharmaceuticals, Inc.

Arena Pharmaceuticals® and Arena® are registered service marks of the company. "APD" is an abbreviation for Arena Pharmaceuticals Development.

Forward-Looking Statements

Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include statements about the therapeutic indication, tolerability, side effects, efficacy and potential of Arena's or its collaborators' product candidates and compounds; the timing and significance of the results for lorcaserin and other programs in Arena's pipeline, including with respect to potential partnering and Arena's balance sheet; and other statements about Arena's focus, strategy, internal and partnered programs, and ability to develop compounds and commercialize drugs. For such statements, Arena claims the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from Arena's expectations. Factors that could cause actual results to differ materially from the forward-looking statements include, but are not limited to, clinical trials and studies may not proceed at the time or in the manner Arena expects or at all, the results of clinical trials or preclinical studies may not be predictive of future results, Arena's ability to receive regulatory approval for its drug candidates, Arena's ability to partner lorcaserin or other of its compounds or programs, the timing, success and cost of Arena's research, out-licensing endeavors and clinical trials, Arena's ability to obtain additional financing, Arena's ability to obtain and defend its patents and the timing and receipt of payments and fees, if any, from Arena's collaborators. Additional factors that could cause actual results to differ materially from those stated or implied by Arena's forward-looking statements are disclosed in Arena's filings with the Securities and Exchange Commission. These forward-looking statements represent Arena's judgment as of the time of this release. Arena disclaims any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

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Arena Pharmaceuticals, Inc. Condensed Consolidated Statements of Operations (In thousands, except per share amounts)

	Three months ended		Year ended	
	December 31,		December 31,	
	2008	2007	2008	2007
	(unaudited)		(Note)	
Revenues				
Manufacturing services	\$1,973	\$-	\$7,434	\$-
Collaborative agreements	725	4,569	2,375	19,332
Total revenues	2,698	4,569	9,809	19,332
Operating Expenses				
Cost of manufacturing services	2,153	-	8,515	-
Research and development	53,325	40,690	204,374	149,524
General and administrative	8,597	6,923	30,535	26,571

Amortization of acquired technology	565	384	2,314	1,537
Total operating expenses	64,640	47,997	245,738	177,632
Interest and other income (expense), net	(271)	3,042	(1,644)	15,134
Net loss	(62,213)	(40,386)	(237,573)	(143,166)
Dividends on redeemable convertible preferred stock	(268)	(540)	(1,912)	(2,114)
Net loss allocable to common stockholders	\$(62,481)	\$(40,926)	\$(239,485)	\$(145,280)
Net loss per share allocable to common stockholders, basic and diluted	\$(0.84)	\$(0.60)	\$(3.24)	\$(2.31)
Shares used in calculating net loss per share allocable to common stockholders, basic and diluted	74,016	68,409	73,841	62,783

Note: The Condensed Consolidated Statements of Operations has been derived from the audited financial statements for the year ended December 31, 2007 and from the unaudited financial statements for the year ended December 31, 2008.

Condensed Consolidated Balance Sheet Data
(In thousands)

	December 31, 2008	December 31, 2007
	(Note)	
Assets		
Cash, cash equivalents and short-term investments	\$110,129	\$398,185
Accounts receivable	1,823	1,901
Other current assets	5,031	9,162
Land, property and equipment, net	102,740	65,940
Acquired technology and other non-current assets	21,608	12,318
Total assets	\$241,331	\$487,506
Liabilities and Stockholders' Equity		
Accounts payable and other accrued liabilities	\$46,789	\$30,058
Total deferred revenues	4,049	4,049
Total lease financing obligations and other long-term liabilities	72,861	63,100
Redeemable convertible preferred stock	-	53,922
Total stockholders' equity	117,632	336,377
Total liabilities and stockholders' equity	\$241,331	\$487,506

Note: The Condensed Consolidated Balance Sheet Data has been derived from the audited financial statements as of December 31, 2007 and from the unaudited financial statements as of December 31, 2008.

SOURCE Arena Pharmaceuticals, Inc.

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EXHIBIT G



Arena Pharmaceuticals Announces Positive Lorcaserin Pivotal Phase 3 Obesity Trial Results: Meets All Primary Efficacy and Safety Endpoints

-- Lorcaserin Very Well Tolerated Throughout Two-Year Study -- Conference Call Scheduled for Today at 8:30 a.m. EDT

SAN DIEGO, March 30, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) announced today positive top-line results from BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management), the first of two pivotal trials evaluating the safety and efficacy of lorcaserin for weight management. Statistical significance ($p < 0.0001$) was achieved on all three of the hierarchically ordered co-primary endpoints for patients treated with lorcaserin versus placebo. Treatment with lorcaserin was generally very well tolerated. An assessment of echocardiograms indicates no apparent drug-related effect on the development of US Food and Drug Administration (FDA)-defined valvulopathy over the two-year treatment period.

Primary Endpoint Analysis

The hierarchically ordered endpoints were the proportion of patients achieving 5% or greater weight loss after 12 months, the difference in mean weight loss compared to placebo after 12 months, and the proportion of patients achieving 10% or greater weight loss after 12 months. Compared to placebo, using an intent-to-treat last observation carried forward (ITT-LOCF) analysis, treatment with lorcaserin was associated with highly statistically significant ($p < 0.0001$) categorical and average weight loss from baseline after 12 months:

- 47.5% of lorcaserin patients lost greater than or equal to 5% of their body weight from baseline compared to 20.3% in the placebo group. This result satisfies the efficacy benchmark in the most recent FDA draft guidance.
- Average weight loss of 5.8% of body weight, or 12.7 pounds, was achieved in the lorcaserin group, compared to 2.2% of body weight, or 4.7 pounds, in the placebo group. Statistical separation from placebo was observed by Week 2, the first post-baseline measurement.
- 22.6% of lorcaserin patients lost greater than or equal to 10% of their body weight from baseline, compared to 7.7% in the placebo group.

Lorcaserin patients who completed 52 weeks of treatment according to the protocol lost an average of 8.2% of body weight, or 17.9 pounds, compared to 3.4%, or 7.3 pounds, in the placebo group ($p < 0.0001$).

"The BLOOM results, demonstrating lorcaserin's medically important weight loss coupled with the tolerability and safety profile displayed in this trial, differentiate lorcaserin from approved drugs or other agents in clinical trials," commented Steven R. Smith, M.D., Co-Principal Investigator and Professor and Assistant Director for Clinical Research at the Pennington Biomedical Research Center. "Obesity is a widespread disease; having a well tolerated and effective therapy that can be used by the majority of patients who need weight reduction could also have beneficial effects on co-morbid conditions, such as diabetes, lipid disorders, and cardiovascular disease."

Safety and Tolerability Profile

Lorcaserin was generally very well tolerated. The most frequent adverse events reported in Year 1 and their rates for lorcaserin and placebo patients, respectively, were as follows: headache (18.0% vs. 11.0%), upper respiratory tract infection (14.8% vs. 11.9%), nasopharyngitis (13.4% vs. 12.0%), sinusitis (7.2% vs. 8.2%) and nausea (7.5% vs. 5.4%). The most frequent adverse events reported in Year 2 and their rates for lorcaserin and placebo patients, respectively, were as follows: upper respiratory tract infection (14.5% vs. 16.1%), nasopharyngitis (16.4% vs. 12.6%), sinusitis (8.6% vs. 6.9%), arthralgia (6.6% vs. 6.2%) and influenza (6.6% vs. 6.0%). In patients crossing over from lorcaserin to placebo after Year 1, the rates of these Year 2 adverse events were: 11.0%, 13.8%, 10.6%, 6.0% and 4.9%, respectively.

Adverse events of depression, anxiety and suicidal ideation were infrequent and reported at a similar rate in each treatment group, and no seizures were reported. Serious adverse events occurred with similar frequency in each group throughout the trial without apparent relationship to lorcaserin. One death occurred during the trial, which was a patient in the placebo arm.

"The BLOOM trial, having met all of its primary endpoints and the FDA categorical efficacy benchmark as stated in their guidance, suggests lorcaserin has the potential to become the first in a new class of effective and very well tolerated weight management therapeutics that selectively target the serotonin 2C receptor," said William R. Shanahan, M.D., Arena's Vice President and Chief Medical Officer. "We look forward to building on these positive top-line data with the BLOSSOM study results expected around the end of September leading to an NDA submission by the end of this year. We also look forward to working with the FDA during the approval process to bring this treatment to patients in need of new options."

Echocardiogram Assessment

Using an ITT-LOCF analysis, the assessment of echocardiograms performed at baseline and after patients completed 6, 12, 18 and 24 months of dosing indicated no apparent drug-related effect on the development of FDA-defined valvulopathy (moderate or greater mitral insufficiency and/or mild or greater aortic insufficiency).

Lorcaserin met the primary safety endpoint of no significant difference in rates of valvulopathy at 12 months. Rates of valvulopathy at 6, 12, 18 and 24 months for lorcaserin versus placebo were 2.1% vs. 1.9%, 2.7% vs. 2.3%, 2.9% vs. 3.1% and 2.6% vs. 2.7%. At 18 and 24 months, rates of valvulopathy for lorcaserin patients crossing over to placebo were 3.6% and 1.9%, respectively.

The FDA has requested that Arena rule out a 1.5-fold or greater risk of valvulopathy with 80% power. Assuming similar results in BLOSSOM (Behavioral modification and LOrcaserin Second Study for Obesity Management), the integrated data set from the two trials will be more than sufficiently large to meet this requirement.

"The echocardiographic safety data is very reassuring," commented Neil J. Weissman, M.D., Co-Principal Investigator, Director, Cardiac Ultrasound and Ultrasound Core Labs, President, MedStar Research Institute, and Professor of Medicine, Georgetown University. "In this double-blind, prospective study, there was no evidence of a difference in the development of valve disease in the large number of patients on lorcaserin versus control for up to two years of continuous use. No prospective valvulopathy trial has ever studied this many patients for this period of time, particularly under such well-controlled circumstances."

Secondary Endpoint Analysis

Treatment with lorcaserin was also associated with statistically significant improvements (ITT-LOCF) in a range of secondary endpoints compared to treatment with placebo, including:

- Total cholesterol
- LDL cholesterol
- Triglycerides
- Blood pressure

Changes in HDL cholesterol were similar in the two groups. Analysis of the above and additional endpoints, including glucose, insulin and waist circumference, is ongoing and will be announced at a later date.

During Year 2 of the trial, patients continuing on lorcaserin were better able to maintain more of the Week 52 weight loss than Year 1 lorcaserin patients re-randomized to placebo in Year 2.

Patient Disposition

Patient demographic characteristics at baseline were well balanced across the treatment groups. The Week 52 completion rate was higher for patients on lorcaserin (55.4%) compared to those on placebo (45.1%). The difference is primarily attributed to higher discontinuation rates for "Subject Decision" (19.2% lorcaserin vs. 27.7% placebo), which includes "Lack of Efficacy" (1.7% lorcaserin vs. 5.5% placebo). Discontinuations for adverse events (7.1% lorcaserin vs. 6.7% placebo) and other reasons were similar.

Completion rates for Year 2 were similar across the treatment groups: 74.3%, 72.7%, and 68.9% for patients continuing on lorcaserin for both years, patients taking placebo both years, and patients switching from lorcaserin to placebo in Year 2, respectively. Discontinuations for adverse events were also similar across the treatment groups.

"The positive outcome of the BLOOM trial serves as a very significant milestone for Arena, demonstrating lorcaserin's potential

to provide a new treatment option for patients who need to lose weight and keep it off," stated Jack Lief, Arena's President and Chief Executive Officer. "Given lorcaserin's status as the only novel, single agent weight loss therapeutic in Phase 3 development, as well as data that continues to support our expectation for a well-tolerated and efficacious drug, I expect to have a range of commercialization options to consider."

BLOOM Trial Design

BLOOM, the first of three lorcaserin Phase 3 trials, is a double-blind, randomized, placebo-controlled trial involving 3,182 patients in approximately 100 sites in the US. The trial evaluated 10 mg of lorcaserin dosed twice daily versus placebo over a two-year treatment period in obese patients (Body Mass Index, or BMI, 30 to 45) with or without co-morbid conditions and overweight patients (BMI 27 to less than 30) with at least one co-morbid condition. The trial did not include any dose titration or run-in period. Patients were randomized in a 1:1 ratio to lorcaserin or placebo at baseline. At Week 52, 856 patients taking lorcaserin were re-randomized in a 2:1 ratio to continue lorcaserin or to switch to placebo, and 697 patients on placebo were continued on placebo. Patients received echocardiograms at screening, and at 6, 12, 18 and 24 months after initiating dosing in the trial; patients with FDA-defined valvulopathy were excluded from enrolling in the trial.

Phase 3 Program Overview

The Phase 3 program consists of three trials, BLOOM, BLOSSOM and BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus), and is planned to enroll a total of approximately 7,800 patients. BLOOM and BLOSSOM comprise the Phase 3 pivotal registration program. BLOSSOM has enrolled 4,008 patients and is evaluating 10 mg of lorcaserin dosed once or twice daily versus placebo over a one-year treatment period in obese patients with or without co-morbid conditions and overweight patients with at least one co-morbid condition at about 100 sites in the US. Results are expected around the end of September 2009. BLOOM-DM is currently enrolling and is evaluating 10 mg of lorcaserin dosed once or twice daily versus placebo over a one-year treatment period in obese and overweight patients with type 2 diabetes at about 60 sites in the US. Approximately 600 patients are expected to be enrolled in BLOOM-DM, which is planned as a supplement to the lorcaserin NDA.

A standardized program of moderate diet and exercise guidance is included in the Phase 3 program. The program's hierarchically ordered co-primary efficacy endpoints are: the proportion of patients achieving 5% or greater weight loss after 12 months, the difference in mean weight loss compared to placebo after 12 months, and the proportion of patients achieving 10% or greater weight loss after 12 months. Arena is also studying several key secondary endpoints, including changes in serum lipids and HbA1c levels and, in the BLOOM-DM trial, other indicators of glycemic control. In BLOSSOM and BLOOM-DM all patients will receive echocardiograms at baseline, at month 6, and at the end of the study to assess heart valve function over time. In contrast to the BLOOM trial, however, there are no echocardiographic exclusion criteria for entry into these trials and there is no monitoring by an independent monitoring board.

Conference Call & Webcast

Arena will host a conference call and webcast to discuss the results today, Monday, March 30, 2009 at 8:30 a.m. Eastern Time (5:30 a.m. Pacific Time). Jack Lief, President and Chief Executive Officer, Dominic P. Behan, Ph.D., Senior Vice President and Chief Scientific Officer, William R. Shanahan, M.D., Vice President and Chief Medical Officer, and Christen M. Anderson, M.D., Ph.D., Vice President, Clinical Development, will host the conference call.

The conference call may be accessed by dialing 877.874.1565 for domestic callers and 719.325.4758 for international callers. Please specify to the operator that you would like to join the "Lorcaserin BLOOM Trial Results" conference call. The conference call will be webcast live under the investor relations section of Arena's website at www.arenapharm.com, and will be archived there for 30 days following the call. Please connect to Arena's website several minutes prior to the start of the broadcast to ensure adequate time for any software download that may be necessary.

About Lorcaserin

Lorcaserin is a novel single agent that represents the first in a new class of selective serotonin 2C receptor agonists. The serotonin 2C receptor is located in areas of the brain involved in the control of appetite and metabolism, such as the hypothalamus. Stimulation of this receptor is strongly associated with feeding behavior and satiety. Lorcaserin is currently being evaluated in a Phase 3 program expected to enroll approximately 7,800 patients and potentially represents a targeted treatment option for the millions of patients who need to better manage their weight. Arena has patents that cover lorcaserin in the US and other jurisdictions, which in most cases are capable of continuing into 2023 without taking into account any patent term extensions or other exclusivity Arena might obtain.

About Obesity

A 2007 report by the US Department of Health and Human Services states that approximately one-third of US adults are obese

and two-thirds have been told by a health care provider that they are overweight. Medical and related costs of obesity are \$123 billion per year according to a 2005 report by the International Diabetes Federation. Studies have shown that weight loss of 5% to 10% is medically significant and results in meaningful improvements in cardiovascular risk factors and a significant reduction in the incidence of type 2 diabetes. Diet and exercise should form the basis of healthy weight loss, but pharmaceutical treatment options for obesity are currently limited for the many patients that require additional help in achieving and maintaining medically important weight loss.

About the FDA Draft Guidance

The FDA draft guidance document for developing products for weight management dated February 2007 provides recommendations regarding the development of drugs for the indication of weight management. It contains two alternate efficacy benchmarks. The guidance provides that, in general, a product can be considered effective for weight management if after one year of treatment either of the following occurs: (1) the difference in mean weight loss between the active-product and placebo-treated groups is at least 5% and the difference is statistically significant, or (2) the proportion of subjects who lose greater than or equal to 5% of baseline body weight in the active-product group is at least 35%, is approximately double the proportion in the placebo-treated group, and the difference between groups is statistically significant.

About Arena Pharmaceuticals

Arena is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing oral drugs in four major therapeutic areas: cardiovascular, central nervous system, inflammatory and metabolic diseases. Arena's most advanced drug candidate, lorcaserin, is being investigated in a Phase 3 clinical trial program for weight management. Arena's broad pipeline of novel compounds target G protein-coupled receptors, an important class of validated drug targets, and includes compounds being evaluated independently and with partners, including Merck & Co., Inc., and Ortho-McNeil-Janssen Pharmaceuticals, Inc.

Arena Pharmaceuticals® and Arena® are registered service marks of the company. "APD" is an abbreviation for Arena Pharmaceuticals Development.

Forward-Looking Statements

Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include statements about the development, therapeutic indication, tolerability, safety, selectivity, efficacy and potential of lorcaserin; the significance of the review of echocardiographic data and lorcaserin's effect on the development of FDA-defined valvulopathy; the protocol, design, scope, enrollment and other aspects of the lorcaserin trials; the continued advancement of the related program; the significance of the BLOOM results; the impact of weight loss on health, including improving cardiovascular risk factors and reducing type 2 diabetes; future activities, results and announcements relating to lorcaserin, including the BLOSSOM results, the submission of an NDA for lorcaserin and the submission of the BLOOM-DM results as a supplement to the NDA; the potential of lorcaserin to meet the FDA's requirements for approval and the approval of lorcaserin for marketing; commercialization options and the coverage of lorcaserin patents; and about Arena's strategy, internal and partnered programs, and ability to develop compounds and commercialize drugs. For such statements, Arena claims the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from Arena's expectations. Factors that could cause actual results to differ materially from the forward-looking statements include, but are not limited to, Arena's ability to obtain additional funds, the timing, success and cost of Arena's lorcaserin program and other of its research and development programs, the results of clinical trials or preclinical studies may not be predictive of future results, clinical trials and studies may not proceed at the time or in the manner Arena expects or at all, Arena's ability to partner lorcaserin or other of its compounds or programs, the timing and ability of Arena to receive regulatory approval for its drug candidates, Arena's ability to obtain and defend its patents, and the timing and receipt of payments and fees, if any, from Arena's collaborators. Additional factors that could cause actual results to differ materially from those stated or implied by Arena's forward-looking statements are disclosed in Arena's filings with the Securities and Exchange Commission. These forward-looking statements represent Arena's judgment as of the time of this release. Arena disclaims any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

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EXHIBIT H

Arena Pharmaceuticals, Inc.
Company ▲

ARNA
Ticker ▲

Q1 2009 Earnings Call
Event Type ▲

May 11, 2009
Date ▲

MANAGEMENT DISCUSSION SECTION

Operator: Good day, everyone, and welcome to today's Arena Pharmaceuticals first quarter 2009 financial results conference. Just as a reminder, today's call is being recorded.

At this time, I would like to turn the call over to Arena's Vice President, Finance and Chief Financial Officer, Mr. Robert Hoffman. Please go ahead, sir.

Robert E. Hoffman, Vice President, Finance and Chief Financial Officer

Thank you. Good afternoon, and welcome to Arena Pharmaceuticals' first quarter 2009 financial results conference call. I'm Robert Hoffman, Arena's Vice President, Finance and Chief Financial Officer. Joining me on today's call is Jack Lief, our President and Chief Executive Officer. Also in the room and available to help address any questions after our prepared remarks are Dominic Behan, our Senior Vice President and Chief Scientific Officer, and Christen Anderson, our Vice President of Clinical Development.

Bill Shanahan is traveling today and cannot join us, but Dr. Anderson directly oversees the clinical development of lorcaserin, including the recent positive BLOOM trial and will be available to answer your questions later in the call. After Jack provides an introduction, I'll review our financial results for the first quarter 2009. I'll then again turn the call over to Jack for additional comments and then we'll be happy to take any of your questions.

Before we begin, I'd like to point out that we'll be making numerous forward-looking statements during this conference call. Such forward-looking statements include statements about our clinical trials and results, internal and partnered programs, drug candidate pipeline, technologies, financial guidance, assumptions, strategy, plans and other statements that are not historical facts.

Such statements may include the words, may, plan, will, believe, expect, potential, intend or similar words. You're cautioned to not place undue reliance on these forward-looking statements, which are only projections and reflect the company's beliefs, expectations and assumptions based on currently available operating, financial and competitive information and speak only as of the time they are made.

Risks and uncertainties that could cause actual results to differ materially from those described in our forward-looking statements include our ability to obtain additional funds from collaborators and investors, the timing, success and cost of clinical trials, preclinical studies and research activities, the regulatory process, the timing and outcome of our partnership efforts, whether our assumptions prove to be correct and other risks identified in our SEC reports. For a discussion of these and other factors, please refer to the risk factors described in our filings with the SEC. For forward-looking statements, we claim the protection of the Private Securities Litigation Reform Act of 1995.

Now I'd like to turn the call over to Jack Lief.

Jack Lief, Co-Founder, Chairman, President and Chief Executive Officer

Good afternoon, everyone, and welcome to our first quarter 2009 financial results conference call. On today's call, I will first discuss lorcaserin and our strategy moving forward. Then I'll turn it over to Robert to review our financials. I will return with additional comments to provide a business update and review upcoming milestones and then open the call for your questions.

In late March, we announced positive top line results from our BLOOM trial. We believe the data are compelling. I'd like to briefly address three of the questions that I believe are on the minds of

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investors. Namely first, is lorcaserin approvable? Second, what is the commercial potential of lorcaserin and third, what are our plans for partnering and financing?

My answer to the first question is, yes. We believe that if the BLOSSOM results, which we expect to announce by the end of September, are consistent with BLOOM, lorcaserin is approvable. Let me be clear about what the FDA efficacy criteria are for approving new weight management drugs. The FDA draft guidance document for Developing Products for Weight Management dated February 2007 provides specific recommendations regarding the development of drugs for this indication.

The guidance document contains two alternate efficacy benchmarks. The guidance provides that a product can be considered effective for weight management, if after one year of treatment, using an intent-to-treat last observation carry-forward analysis, either of the following occur. One, the difference in mean weight loss between active product and placebo-treated groups is at least 5% and the difference is statistically significant; or the proportion of patients who lose greater than or equal to 5% of baseline body weight in the active group is at least 35%, is approximately double the proportion in the placebo-treated group and the difference between the groups is statistically significant.

Despite the clear language in the FDA guidance, there still seems to be confusion among some investors and even more so in the media regarding whether a drug must meet both of these criteria to be approved. I cannot emphasize too strongly that a product for weight management must achieve only one of these two alternate FDA efficacy benchmarks for approval. And notably, marketed drugs do not satisfy both benchmarks.

Lorcaserin caused significant weight loss that exceeded the FDA's categorical benchmark for efficacy. 47.5% of lorcaserin patients lost at least 5% of their body weight from baseline compared to 20.3% in the placebo group. Patients on lorcaserin lost a medically important amount of weight in a well-tolerated manner. Lorcaserin helped nearly half the patients to lose at least 5% of their body weight and nearly a quarter to lose 10% or more of their body weight.

Based on the results from the BLOOM trial meeting the FDA's efficacy criteria and coupled with a strong tolerability profile that includes no signal of FDA valvulopathy at any time point over the two-year treatment period; we believe that lorcaserin is approvable for weight management, both here in the U.S. and eventually in Europe as well. If BLOSSOM is consistent with BLOOM, we believe lorcaserin has the potential to become the first in a new class of effective and well-tolerated weight management therapeutics.

This brings me to the second question regarding the commercial potential of lorcaserin. After it is approved, why do we think doctors will prescribe lorcaserin for their overweight and obese patients to help manage the risks associated with obesity? And will patients use lorcaserin? Independent research, which is consistent with our own market research, indicate that physicians are looking for weight management therapeutics for their patients, with the following three attributes.

One, a product physicians can prescribe to the majority of their patients; two, a product that will enable their patient to lose weight quickly and stay on the drug long term; and three, a product that will result in patients losing enough weight to improve their cardiometabolic health. First, patients on lorcaserin in the BLOOM trial generally tolerated the drug very well. The only adverse event that exceeded placebo by 5% or greater was headache. We know from BLOOM and previous trials that headaches associated with lorcaserin are typically mild and transient. We think that this tolerability profile will provide physicians with the confidence to use lorcaserin as a first-line therapy for the majority of their patients.

Second, we also know that lorcaserin patients lost weight quickly. In fact about one-third of lorcaserin patients lost at least 5% of their weight in only eight weeks. Furthermore, tolerability issues did not mandate elements in the trial that high prescribers do their best to avoid, such as

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forced titration or run-in periods. We think the combination of fast weight loss, plus an excellent tolerability profile will encourage patients to stay on the treatment. The one year completion rate was 10% higher for patients on lorcaserin compared to those on placebo. And notably discontinuations for adverse events were similar between active and placebo groups, something that is rarely seen in obesity trials.

Lastly, and perhaps most importantly, patients achieved medically-important weight loss in the trial. Patients completing their first year of BLOOM have achieved an average weight loss of 18 pounds. In addition, using ITT analysis, almost half of lorcaserin patients lost 5% of their body weight and almost a fourth of these patients lost 10% of their weight. Studies show that this amount of weight loss has important beneficial effects on comorbid conditions, as shown in our secondary endpoint analysis.

While some in the investment community have shrugged at the efficacy result, physicians and patients have not. Each day they are faced with the difficulty of losing a medically-important amount of weight in a well-tolerated manner and keeping it off. They also understand the significance of the medical benefits associated with this amount of weight loss.

In conclusion, the BLOOM results indicate that lorcaserin delivers a desired profile for physicians and particularly primary-care physicians who want a well-tolerated and effective treatment. Therefore, we believe that a strong revenue opportunity exists for this type of weight management therapy, since it appears suitable for the majority of obese patients.

I'll now move on to the third question regarding our plans for partnering and financing. It is difficult to predict what the exact agreements will look like. And based on the unpredictable nature of both, it would be inappropriate to provide too much color on the details for expected timing of these announcements. I can assure you that we are working diligently in both of these areas. We continue to have discussions with potential partners and we continue to look at various strategies to finance Arena. Potential sources of improving our cash position in 2009 include partnership opportunities for lorcaserin and our earlier-stage programs, asset transactions that include real estate, accessing the markets via equity or debt and implementing additional cost reductions.

We will provide more specific information on partnership and financing agreements, if and when such agreements are concluded. Before I turn the call over to Robert to discuss our financials, I'd like to reiterate the opportunity that we believe exists with lorcaserin and our focus to complete the BLOSSOM trial on schedule and submit our NDA by the end of this year.

We are pleased that the ongoing analysis of the BLOOM trial continues to produce medically-important results, and we look forward to presenting these and additional data at the upcoming American Diabetes Association meeting in June. Robert?

Robert E. Hoffman, Vice President, Finance and Chief Financial Officer

Thank you, Jack. In the first quarter of 2009, we recorded revenues of approximately \$2.7 million compared to first quarter 2008 revenues of approximately 2.6 million. First quarter 2009 revenues included 1.4 million in manufacturing services revenue under our manufacturing services agreement with Siegfried and 1.3 million for patent activities from our collaborations with Merck and Ortho-McNeil-Janssen.

In the first quarter of 2009, we recorded cost of manufacturing services of 1.4 million compared to 2.3 million in the first quarter of 2008. Cost of manufacturing services comprised of direct costs associated with manufacturing drug products for Siegfried, including related salaries, other personnel costs and machinery depreciation costs.

EXHIBIT I



Arena Pharmaceuticals Reports Positive, Highly Significant BLOSSOM Trial Results for Weight Management; NDA Submission on Track for December

- Lorcaserin Meets all Primary Endpoints and FDA Benchmark -
- 63% of Lorcaserin Patients Who Complied with the Protocol Lost at Least 5% of Their Weight -
- Lorcaserin Patients in the Top Quartile Achieved Average Weight Loss of 16% or 35 Pounds -
- Combined Phase 3 BLOOM and BLOSSOM Data Set Confirms Lorcaserin's Excellent Safety and Tolerability Profile and Rules Out Heart Valve Effect -
- Conference Call and Webcast Presentation Scheduled for 8:00 a.m. ET on September 18, 2009 -

SAN DIEGO, Sept 18, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) reported today positive, highly significant top-line results from the BLOSSOM (Behavioral modification and Lorcaserin Second Study for Obesity Management) trial. BLOSSOM confirms the results previously reported for the BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management) trial and completes the lorcaserin Phase 3 pivotal registration program of 7,190 patients evaluated for up to two years. Arena plans to submit a New Drug Application, or NDA, for lorcaserin to the US Food and Drug Administration, or FDA, in December.

In the one-year BLOSSOM trial, lorcaserin met all primary efficacy and safety endpoints. Patients achieved highly significant categorical and absolute weight loss. Lorcaserin was very well tolerated and was not associated with depression or suicidal ideation. The integrated echocardiographic data set from BLOSSOM and BLOOM rules out a risk of valvulopathy in lorcaserin patients according to criteria requested by the FDA. Treatment with lorcaserin also resulted in significant improvements as compared to placebo in multiple secondary endpoints associated with cardiovascular risk.

"Today there are extremely limited options to meet the needs of physicians and patients in the real world clinical practice of weight management," said Steven R. Smith, M.D., Executive Director of the Florida Hospital Clinical Research Institute. "Physicians need options that have the potential to help the typical obese patient lose significant weight by staying on a safe and well-tolerated treatment. The clinical data show lorcaserin is a solution that could provide physicians with a weight-loss medication applicable for broad use in the majority of their patients who need to lose weight and improve their health. BLOSSOM demonstrated that nearly two-thirds of lorcaserin patients lost a medically meaningful amount of body weight while avoiding unwanted side effects and a complicated titration program."

"History has taught us that the marriage of efficacy and safety is of critical importance in treating patients. Neither is sufficient without the other. With its excellent safety and tolerability profile, we expect lorcaserin to change the way primary care doctors treat the broad cross-section of overweight and obese patients with pharmacotherapy," said Jack Lief, Arena's President and Chief Executive Officer. "With the completion of our robust Phase 3 pivotal program, we will focus on the NDA filing, work with the FDA during the review process and prepare for the commercialization of lorcaserin."

Arena plans to present detailed data from both the BLOOM and BLOSSOM trials at the 27th Annual Scientific Meeting of The Obesity Society, scheduled for October 24-28 in Washington, D.C.

Efficacy

Per Protocol Results

Lorcaserin was highly effective in helping patients achieve significant weight loss using multiple measurements. Patients treated with 10 mg of lorcaserin dosed twice daily (BID) who completed the 52-week trial according to protocol demonstrated the benefit of long-term treatment with lorcaserin:

- 63.2% of patients lost at least 5% of their body weight ($p < 0.0001$);
- 35.1% of patients lost at least 10% of their body weight ($p < 0.0001$);
- Patients lost an average of 17.0 pounds, or 7.9% of their body weight;
- and

- The quartile of lorcaserin patients with the greatest weight loss (among those with a Week 52 weight recorded) lost an average of 35.1 pounds, or 16.3% of their body weight.

Of the placebo patients who completed the trial, 34.9% and 16.1% achieved at least 5% and 10% weight loss, respectively, and the average weight loss was 8.7 pounds, or 3.9%. The top quartile of lorcaserin patients lost 36% more body weight than the top quartile of placebo patients.

For the patients treated with 10 mg of lorcaserin dosed once daily (QD) and completing the 52-week trial according to protocol, 53.1% lost at least 5% of their body weight and 26.3% lost at least 10% of their body weight. The average weight loss in the lorcaserin 10 mg once daily group was 14.3 pounds, or 6.5%. As with the higher dose, all results were highly statistically significant ($p < 0.0001$ compared to placebo).

Intent-to-Treat Last Observation Carried Forward (ITT-LOCF) Results

Measurements of efficacy using ITT-LOCF analysis also showed that lorcaserin met all primary endpoints. This analysis includes all patients who were randomized and returned for at least one weight measurement. Patients treated with 10 mg of lorcaserin once or twice daily achieved highly statistically significant categorical and average weight loss after 12 months:

Lorcaserin 10 mg Twice Daily

- 47.2% of patients treated with 10 mg of lorcaserin dosed twice daily lost at least 5% of their body weight compared to 25.0% for placebo ($p < 0.0001$). This result satisfies the efficacy benchmark in the most recent FDA draft guidance which provides that a weight-management product can be considered effective if the proportion of patients who lose at least 5% of baseline body weight in the active-product group is at least 35%, is approximately double the proportion in the placebo-treated group, and the difference between groups is statistically significant;
- 22.6% of patients treated with 10 mg of lorcaserin dosed twice daily lost at least 10% of their body weight compared to 9.7% for placebo ($p < 0.0001$);

Lorcaserin 10 mg Once Daily

- 40.2% of patients treated with 10 mg of lorcaserin dosed once daily lost at least 5% of their body weight ($p < 0.0001$); and
- 17.4% of patients treated with 10 mg of lorcaserin dosed once daily lost at least 10% of their body weight ($p < 0.0001$).

Patients who took lorcaserin 10 mg twice daily achieved an average weight loss of 5.9% of their body weight, compared to 2.8% for placebo ($p < 0.0001$). Similarly, patients who took lorcaserin 10 mg once daily achieved an average weight loss of 4.8% of their body weight ($p < 0.0001$).

BLOSSOM Confirms BLOOM

In BLOSSOM, as in BLOOM, lorcaserin's excellent tolerability allowed patients to begin treatment at the full dose immediately, without a titration period, and achieve rapid weight loss. As in BLOOM, significant weight loss compared to placebo was shown at the first trial visit, two weeks following randomization.

The efficacy for the BLOOM and BLOSSOM trials after one year of treatment are summarized in the table below.

BLOOM

BLOSSOM

	10 mg BID*	Placebo	10 mg BID*	10 mg QD*	Placebo
>/=5% weight loss (Per protocol)	66.4%	32.1%	63.2%	53.1%	34.9%
>/=5% weight loss (ITT-LOCF)	47.5%	20.3%	47.2%	40.2%	25.0%
>/=10% weight loss (Per protocol)	36.2%	13.6%	35.1%	26.3%	16.1%
>/=10% weight loss (ITT-LOCF)	22.6%	7.7%	22.6%	17.4%	9.7%
Mean weight loss (Per protocol)	8.2%	3.4%	7.9%	6.5%	3.9%
Mean weight loss (ITT-LOCF)	5.8%	2.2%	5.9%	4.8%	2.8%

* p<0.0001 compared to placebo

"Lorcaserin demonstrated consistent results in the BLOOM and BLOSSOM trials, which together evaluated nearly 7,200 patients for up to two years," said William R. Shanahan, M.D., Arena's Vice President and Chief Medical Officer. "These results support lorcaserin's potential to meet the need for a safe, effective and well-tolerated weight loss medication. There are only two drugs that are approved by the FDA for long-term treatment, and new mechanistic and better tolerated approaches could greatly improve the treatment of patients who are obese or significantly overweight."

Safety and Tolerability Profile

Lorcaserin was very well tolerated. No adverse event rate in the lorcaserin group exceeded the placebo group by more than 4%. The most frequent adverse events and their rates for patients who took lorcaserin twice daily, lorcaserin once daily or placebo, respectively, were as follows: upper respiratory infection (12.7%, 14.5%, 12.6%); nasopharyngitis (12.5%, 11.7%, 11.8%) and headache (10.0%, 10.5%, 7.6%).

Adverse events of depression, anxiety and suicidal ideation were infrequent and were reported at a similar rate in each treatment group. Serious adverse events, or SAEs, occurred infrequently: one death occurred in the placebo group, no SAEs of seizure were reported and the number of neuropsychiatric SAEs in lorcaserin patients did not exceed the number in the placebo group.

Cardiovascular Safety

The integrated BLOOM and BLOSSOM echocardiography data set rules out a risk of valvulopathy in lorcaserin patients according to criteria requested by the FDA. Echocardiographic evaluations showed no association between lorcaserin and the development of heart valve insufficiency. Rates of new FDA-defined valvulopathy in BLOSSOM at Week 52 were as follows: lorcaserin 10 mg twice daily (2.0%), 10 mg once daily (1.4%) and placebo (2.0%).

"The echocardiographic safety data show no risk of valvulopathy," commented Neil J. Weissman, M.D., Director, Cardiac Ultrasound and Ultrasound Core Labs, President, MedStar Research Institute, and Professor of Medicine, Georgetown University. "In the individual and combined BLOOM and BLOSSOM data sets there is no evidence of a difference in the development of valve disease in lorcaserin patients versus control for up to two years of continuous use. No prospective echocardiographic program has ever studied this many patients for this period of time."

Secondary Endpoints

Treatment with lorcaserin over one year was associated with significant improvements or strongly favorable trends compared to placebo in multiple secondary endpoints, including blood pressure and lipids.

Patient Disposition

BLOSSOM evaluated 4,008 patients with an average body mass index, or BMI, of 35.9 and baseline weight of 220 pounds. The Week 52 completion rate was higher for patients on lorcaserin 10 mg twice daily (57.2%) and 10 mg once daily (59.0%) compared to patients on placebo (52.0%). Discontinuations for adverse events were low and as follows: lorcaserin 10 mg twice daily (7.2%), 10 mg once daily (6.2%) and placebo (4.6%).

Conference Call & Webcast

Arena will host a conference call and webcast presentation to discuss the results at 8:00 a.m. Eastern Time (5:00 a.m. Pacific Time) on September 18, 2009. Jack Lief, President and Chief Executive Officer; Dominic P. Behan, Ph.D., Senior Vice President and Chief Scientific Officer; William R. Shanahan, M.D., Vice President and Chief Medical Officer; and Christen M. Anderson, M.D., Ph.D., Vice President, Clinical Development, will host the conference call and webcast.

The conference call may be accessed by dialing 888.312.3047 for domestic callers and 719.325.2234 for international callers. Please specify to the operator that you would like to join the "Lorcaserin BLOSSOM Trial Results" conference call. The conference call and slide presentation will be webcast live under the investor relations section of Arena's website at www.arenapharm.com, and will be archived there for 30 days following the call. Please connect to Arena's website several minutes prior to the start of the broadcast to ensure adequate time for any software download that may be necessary.

BLOSSOM Trial Design

BLOSSOM is a double-blind, randomized, placebo-controlled trial that enrolled 4,008 patients in approximately 100 sites in the US. The trial evaluated 10 mg of lorcaserin dosed once or twice daily versus placebo over a one-year treatment period in obese patients (BMI 30 to 45) with or without co-morbid conditions and overweight patients (BMI 27 to less than 30) with at least one co-morbid condition. The trial did not include dose titration or a run-in period. Patients were randomized at baseline in a 2:2:1 ratio to lorcaserin 10 mg twice daily, placebo or lorcaserin 10 mg once daily. Patients received echocardiograms at baseline, month 6 and at the end of the trial to assess heart valve function over time. In contrast to the BLOOM trial, there were no echocardiographic exclusion criteria for entry into BLOSSOM and there was no oversight or interim data review monitoring by an independent safety monitoring board.

Phase 3 Program Overview

The lorcaserin Phase 3 program consists of three trials: BLOOM, BLOSSOM and BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus). Enrollment in the lorcaserin Phase 3 program is complete with approximately 7,800 patients. Positive results from BLOOM were presented at the 69th Scientific Sessions of the American Diabetes Association in June 2009. BLOOM and BLOSSOM comprise the Phase 3 pivotal registration program and will be the basis for the lorcaserin NDA submission. BLOOM-DM, which is planned as a supplement to the NDA, is evaluating 10 mg of lorcaserin dosed once or twice daily versus placebo over a one-year treatment period in obese and overweight patients with type 2 diabetes at about 60 sites in the US.

A standardized program of moderate diet and exercise guidance is included in the Phase 3 program. The program's hierarchically ordered co-primary efficacy endpoints are: the proportion of patients achieving 5% or greater weight loss after 12 months, the difference in mean weight loss compared to placebo after 12 months, and the proportion of patients achieving 10% or greater weight loss after 12 months. Arena is also studying several key secondary endpoints, including changes in serum lipids, markers of inflammation and insulin resistance, and in the BLOOM-DM trial, other indicators of glycemic control.

About the FDA Draft Guidance

The FDA draft guidance document "Developing Products for Weight Management" dated February 2007 provides recommendations regarding the development of drugs for the indication of weight management. It contains two alternate efficacy benchmarks. The guidance provides that, in general, a product can be considered effective for weight management if after one year of treatment either of the following occurs: (1) the difference in mean weight loss between the active-product and placebo-treated groups is at least 5% and the difference is statistically significant, or (2) the proportion of subjects who lose greater than or equal to 5% of baseline body weight in the active-product group is at least 35%, is approximately double the proportion in the placebo-treated group, and the difference between groups is statistically significant.

About Lorcaserin

Lorcaserin is a novel single agent that represents the first in a new class of selective serotonin 2C receptor agonists. The serotonin 2C receptor is expressed in the brain, including the hypothalamus, an area involved in the control of appetite and metabolism. Stimulation of this receptor is strongly associated with feeding behavior and satiety. Arena has patents that cover lorcaserin in the US and other jurisdictions, which in most cases are capable of continuing into 2023 without taking into account any patent term extensions or other exclusivity Arena might obtain.

About Weight Management

The National Institutes of Health reported in 2007 that about 65% of US adults are overweight or obese. A 2009 publication in Health Affairs estimated the annual medical burden of obesity in the US to be \$147 billion in 2008. Studies have shown that weight loss of 5% to 10% is medically significant and results in meaningful improvements in cardiovascular risk factors and a significant reduction in the incidence of type 2 diabetes in patients with glucose intolerance.

About Arena Pharmaceuticals

Arena is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing oral drugs in four major therapeutic areas: cardiovascular, central nervous system, inflammatory and metabolic diseases. Arena's most advanced drug candidate, lorcaserin, is being investigated in a Phase 3 clinical trial program for weight management. Arena has a broad pipeline of novel compounds targeting G protein-coupled receptors, an important class of validated drug targets, which includes compounds being evaluated independently and with partners, including Merck & Co., Inc., and Ortho-McNeil-Janssen Pharmaceuticals, Inc.

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Forward-Looking Statements

Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include statements about the significance of the BLOSSOM and BLOOM results and the completion of the lorcaserin Phase 3 pivotal registration program; the development, advancement, therapeutic indication, tolerability, safety, selectivity and efficacy of lorcaserin; the protocol, design, scope, enrollment and other aspects of the lorcaserin trials; the engineering of weight management drug candidates; the FDA's guidance, process and requirements; the potential of the lorcaserin Phase 3 program and its results to satisfy the FDA's approval requirements, including with regard to efficacy and safety; the risk of developing valvulopathy; future activities, results and announcements relating to lorcaserin, including submitting an NDA for lorcaserin, working with the FDA during the review process, submitting the BLOOM-DM results as a supplement to the NDA, and commercializing lorcaserin; lorcaserin's commercial and other potential, including in managing weight, changing treatment, improving health and generating interest; the impact of weight loss on health; the treatment of patients with new mechanistic and better tolerated approaches; lorcaserin's patent coverage; and Arena's focus, strategy, internal and partnered programs, and ability to develop compounds and commercialize drugs. For such statements, Arena claims the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from Arena's expectations. Factors that could cause actual results to differ materially from the forward-looking statements include, but are not limited to, the timing, success and cost of Arena's lorcaserin program and other of its research and development programs; results of clinical trials or preclinical studies may not be predictive of future results and top-line results are preliminary; clinical trials and studies may not proceed at the time or in the manner Arena expects or at all; Arena's ability to partner or commercialize lorcaserin or other of its compounds or programs; the timing and ability of Arena to receive regulatory approval for its drug candidates; Arena's ability to obtain additional funds; Arena's ability to obtain and defend its patents; and the timing and receipt of payments and fees, if any, from Arena's collaborators. Additional factors that could cause actual results to differ materially from those stated or implied by Arena's forward-looking statements are disclosed in Arena's filings with the Securities and Exchange Commission. These forward-looking statements represent Arena's judgment as of the time of this release. Arena disclaims any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

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EXHIBIT J

Arena Pharmaceuticals, Inc.

Company ▲

ARNA
Ticker ▲Lorcaserin BLOSSOM Trial
Results Call
Event Type ▲Sep. 18, 2009
Date ▲**MANAGEMENT DISCUSSION SECTION**

Operator: Good day, everyone, and welcome to today's Arena Pharmaceuticals Conference Call. As a reminder, today's call is being recorded. At this time, I would like to turn the call over to Mr. Robert Hoffman. Please go ahead, sir.

Robert E. Hoffman, C.P.A., Vice President, Finance and Chief Financial Officer

Thank you. Good morning and thank you for your participation this morning. Today's speakers are Jack Lief, our President and CEO; Dominic Behan, our Senior Vice President and Chief Scientific Officer; Bill Shanahan, our Vice President and Chief Medical Officer; and Christy Anderson, our Vice President, Clinical Development. Before we begin, I'd like to point out that we will be making forward-looking statements during this conference call.

Such forward-looking statements include the statements about our clinical trials and results, future development and activities, internal and partnered programs, guidance, strategy, and other statements that are not historical facts. Such statements may include the words plan, will, believe, expect, promise, potential, intend, or similar words. You're cautioned to not place undue reliance on these forward-looking statements, which are only predictions and reflect the company's beliefs, expectations and assumptions based upon available information and speak only as of the time they are made.

Risks and uncertainties that could cause actual results to differ materially from those described in our forward-looking statements include the timing and success and cost of research and development, the regulatory process and FDA approval, the timing and outcome of our partnering and commercialization efforts, our ability to obtain and defend our patents, our ability to obtain additional funds and other risks identified in our SEC reports.

For a discussion of these and other factors, please refer to the risk factors described in our SEC filings. For the forward-looking statements, we claim the protection of the Private Securities Litigation Reform Act of 1995.

Now I'd like to turn the call over to Jack Lief.

Jack Lief, Co-Founder, Chairman, President and Chief Executive Officer

Thanks, Robert. Today, we have reached an important milestone for our company. As many of you know, Dominic and I founded Arena about 12 years ago with a vision to discover and develop selective pharmaceuticals that have the potential to advance human health. Our work in the weight management area began with a hypothesis that we could engineer a highly selective drug to meet the combined efficacy and safety needs of physicians and their patients. Today, I'm happy to announce that we have moved a big step towards achieving this objective.

The top-line results of BLOSSOM support three points that we want to share this morning. First, the BLOSSOM data confirmed BLOOM. Statistically, we met all the primary efficacy and safety endpoints and the FDA criteria for approval as stated in the draft guidance.

We showed that lorcaserin has an excellent safety and tolerability profile. Second, research shows that physicians are dissatisfied with current treatment. Lorcaserin can change the way primary care doctors treat the broad overweight and obese population. Third, we're on a path to success with the completion of our robust pivotal program that has evaluated more than 7,000 patients for up to two years. Our focus now is submitting the NDA by year-end, working with the FDA during the review process and preparing for the launch and commercialization of lorcaserin.

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Before we jump into the data, I would like to take a step back and discuss the problem. Today, primary care physicians write majority of prescriptions for weight loss medication. Most prescriptions are written by a small group of less than 10,000 primary care physicians. Pharmaceutical options are very limited. The drug most commonly prescribed is phentermine, an oral amphetamine class agent that is indicated for short-term use as monotherapy. The current drugs approved for long-term use, bring other concerns related to their risk benefit profile.

As you can see, the real world of weight management is a dissatisfied primary care market. History has taught us that the marriage of efficacy, safety and tolerability is of critical importance in treating patients. Neither is sufficient without the other. Simply put, there's a clear-cut need for drugs such as lorcaserin that physicians can prescribe confidently to a majority of their patients. Bill and Christy will now review the BLOSSOM data. Bill?

William R. Shanahan, Jr., M.D., J.D., Vice President and Chief Medical Officer

Thank you, Jack. As in the BLOOM trial that we reported earlier this year, the BLOSSOM trial enrolled a broad cross-section of relatively healthy obese patients. To address the challenge of weight management in the clinical practice setting, we wanted to study the effects of lorcaserin on overweight and obese patients that primary care physicians might see in their offices today. It's critical for these patients to manage their weight now in order to improve their cardiometabolic health since they cannot modify risk factors like age and family history.

BLOSSOM was a one-year study that evaluated 4,008 patients. Patients were randomized in a 2:2:1 ratio with 1,603 patients randomized to each of the lorcaserin 10 mg daily and placebo groups and 802 patients randomized to the lorcaserin 10 mg once daily group. The co-primary efficacy endpoints at week 52 were the proportion of patients achieving at least 5% weight loss, mean weight loss compared to placebo, and the proportion of patients achieving at least 10% weight loss.

About 80% of the patients in this trial were women and the average age was 44 years. Patients had an average BMI of 36 and a baseline weight of 220 pounds. The study enrolled patients with a BMI of 27 to under 30, with at least one co-morbid condition and patients with a BMI of 30 to 45 with or without a co-morbid condition.

In contrast to BLOOM, patients with FDA-defined valvulopathy at baseline were included. Patients with type 2 diabetes and uncontrolled hypertension were excluded. Patients with type 2 diabetes are being evaluated in our BLOOM-DM study, which is ongoing and scheduled to complete in mid-2010. About 96% of the randomized patients were included in the Intent-to-Treat Last Observation Carried Forward population. The per protocol population, those patients who completed the study and complied with the protocol, included about 52% of the lorcaserin group and 48% of the placebo patients.

The week 52 completion rate was higher for lorcaserin and placebo patients, 57.2 on lorcaserin twice daily, 59% on lorcaserin once daily and 52% on placebo. Discontinuations or adverse events were low and as follows; lorcaserin twice daily at 7.2%, once daily at 6.2%, and placebo at 4.6%. Christy will now review the results. Christy?

Christen M. Anderson, M.D., Ph.D., Vice President, Clinical Development

Thank you, Bill. Lorcaserin met all of BLOSSOM's primary efficacy and safety endpoints and helped patients achieve significant weight loss with a remarkable tolerability and safety profile. The primary efficacy endpoints were analyzed using ITT-LOCF, which is required for regulatory permission and includes all patients who are randomized and return for at least one weight measurement.

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Patients treated with 10 mg of lorcaserin once or twice daily achieved highly statistically significant categorical and average weight loss after 12 months. 47.2% of patients treated with lorcaserin dosed twice daily lost at least 5% of their body weight compared to 25% for placebo. 22.6% of patients treated with lorcaserin dosed twice daily lost at least 10% of their body weight compared to 9.7% for placebo. 40.2% of patients treated with lorcaserin dosed once daily lost at least 5% of their body weight and 17.4% of those patients lost at least 10% their body weight.

Patients who took lorcaserin twice daily achieved an average weight loss of 5.9% compared to 2.8% for placebo. Patients who took lorcaserin once daily achieved an average weight loss of 4.8%. These results satisfied the efficacy benchmark in the most recent FDA draft guidance, which provides that a weight management product can be considered effective if the proportion of patients who lose at least 5% of baseline body weight in the active product group is at least 35%, is approximately double the proportion of the placebo treated group and the difference between the groups is statistically significant.

To better predict lorcaserin's efficacy in people who use it as instructed, we also analyzed the data using a per protocol population. Patients treated with lorcaserin dosed once or twice daily and who completed the 52-week trial according to protocol, demonstrated the benefit of long-term treatment with lorcaserin and achieved highly statistically significant weight loss. 63.2% of lorcaserin twice-daily patients lost at least 5% of their body weight and 35.1% of these patients lost at least 10% of their body weight. 53.1% of lorcaserin once daily patients lost at least 5% of their body weight and 26.3% of these patients lost at least 10% of their body weight.

Patients on lorcaserin twice daily lost an average of 17 pounds or 7.9% of their body weight and patients on lorcaserin once daily lost an average of 14.3 pounds or 6.5% of their body weight. Although we're still analyzing data from subgroups of the patients who were studied, we can say that the most responsive 25% of lorcaserin patients achieved sizable weight loss. The top quartile lost an average of 35 pounds or 16.3%. We believe that this example demonstrates lorcaserin's ability to help a significant number of patients achieve considerable weight loss.

The BLOSSOM efficacy results are consistent with the BLOOM results. The combined data set shows that about two-thirds of patients who complete a year of treatment with twice daily lorcaserin according to the protocol lost at least 5% of their weight and over one-third of these patients lost at least 10% of their weight. Using the more conservative ITT analysis, nearly half of the lorcaserin patients lost a minimum of 5% of their weight.

As part of the safety monitoring program for lorcaserin, an important goal was to rule out a risk of echocardiographic heart valve changes in lorcaserin patients according to criteria requested by the FDA. We designed an unprecedented program, with over 7,000 patients who received highly standardized echocardiograms every six months for up to two years. Today, we are pleased to announce that the integrated echocardiographic data from BLOOM and BLOSSOM proved our initial hypothesis correct.

It is possible to engineer a drug that selectively addresses the serotonin 2C receptor responsible for efficacy, while avoiding the receptors responsible for heart valve damage. Echocardiographic evaluations in the BLOSSOM trial showed no association between lorcaserin and the development of heart valve insufficiency. Rates of new FDA valvulopathy in BLOSSOM at week 52 were as follows; 2.0% for both the lorcaserin twice daily group and the placebo group and 1.4% for the lorcaserin once daily group. In both trials, pulmonary artery systolic pressure did not increase in any group.

We are pleased to delivery a single agent that achieves rapid and clinically meaningful efficacy [inaudible] with remarkable safety and tolerability. Because lorcaserin is very well tolerated, patients were able to begin treatment at the full dose immediately without a titration period and achieve

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rapid weight loss. In fact, significant weight loss compared to placebo was shown at the first study visit two weeks following randomization.

Lorcaserin is further differentiated from approved drugs for weight management and those in development by its excellent safety and tolerability profile. The adverse event profile from the BLOSSOM study is quite impressive. The most frequent adverse events were upper respiratory infection, nasopharyngitis and headache. As you can see in this slide, most adverse events occurred at similar rates in the lorcaserin and placebo groups and no adverse event in the lorcaserin group exceeded the placebo group by more than 4%. In addition, there was no signal for depression or suicidal ideation and anxiety was infrequent in all groups.

On preliminary review, Serious Adverse Events or SAEs appear as predicted for this patient population. One death occurred in the placebo group. No SAEs of seizure were reported; and the number of neuropsychiatric SAEs in lorcaserin patients did not exceed the number in the placebo group.

Since we've only reviewed top-line BLOSSOM data so far, only limited data for secondary endpoints are available. Using ITT-LOCF analysis, statistically significant improvements were achieved for HDL-cholesterol and triglycerides, and strong favorable trends were observed for LDL-cholesterol and systolic and diastolic blood pressure. We have also included the strong per protocol results. Analysis of patients with abnormal baseline values is ongoing.

Taken together, the robust data set from both BLOOM and BLOSSOM showed that treatment with Lorcaserin over one year was associated with significant improvements compared to placebo in multiple secondary endpoints that are known cardiovascular risk factors. We look forward to presenting more detailed data at the upcoming Obesity Society Meeting.

I will now turn the call over to our Co-Founder and Chief Scientific Officer, Dominic Behan.

Dominic P. Behan, Ph.D., Co-Founder, Senior Vice President and Chief Scientific Officer

Thank you, Christy. As you can see from the data, we believe lorcaserin is a game changer. We have shown that it is possible to engineer an efficacious weight management drug candidate with an excellent safety and tolerability profile. We've approached this weight management issue based on all understanding of the unmet need in the real world. Independent research suggests that physicians want a weight loss medication that is applicable to the broad patient population. They want a drug that results in near term rapid weight loss and a drug that enables patients to be compliant and therefore stay on treatment for the long term.

And the weight loss achieved needs to result in improvements in cardiometabolic risk factors. With a drug that has lorcaserin's profile, the chance that patients will stay on the drug for a sufficient time to achieve medically important weight loss is therefore much higher. Safety and tolerability are the foundation for compliance in the broad population of obese and overweight patients.

The future of healthcare relies on the delivery of innovative, novel treatments designed selectively to maximize the intended effect and avoid safety and tolerability issues. We look forward to the opportunity to provide patients with lorcaserin and advance human health through innovative science. I'd like to thank everyone, whose efforts have helped us reach this very important milestone in Arena's history. Jack?

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Thanks, Dominic. As you've heard, we believe that lorcaserin will reenergize the weight management category. How? Initially by displacing phentermine and other currently available agents for patients who need better longer-term therapy; then by expanding from current patients to others who have tried pharmacotherapy in the past but failed, and new patients who are looking for better options that are safe and well tolerated.

And finally by prolonging the duration of treatment from less than three months with currently available agents to a timeframe that allows for the full benefit of the drug to be realized. Importantly, lorcaserin is protected with strong competition of matter patent that cover 95% of the global pharmaceutical market and continue until at least 2023.

The potential momentum in the weight management category combined with strong intellectual property protection is why we believe lorcaserin represents a compelling commercial opportunity. With the full data set in hand, we will continue discussions with a variety of parties for a potential commercial agreement and we'll provide an update when it is appropriate to do so.

Before I open up the call to your questions, I'd like to reiterate that first BLOSSOM data confirmed BLOOM.

Second, research shows that lorcaserin has the potential to change the way primary care doctors treat the broad population of overweight and obese people. Lastly, we're on a path to success with the completion of our robust Phase 3 pivotal program that evaluated more than 7,000 patients for up to two years. Our focus now is submitting the NDA by year-end, working with the FDA during the review process and preparing for the launch of commercialization of lorcaserin.

I would like to point out that we only have top-line results from the BLOSSOM study and may not be able to answer all of your questions. We look forward to presenting detailed data from both BLOOM and BLOSSOM in a scientific forum at next month's meeting of the Obesity Society in Washington D.C. We're also working to publish the study results in highly regarded peer-reviewed journals.

We're happy to take your questions now. Brendon ?

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QUESTION AND ANSWER SECTION

Operator: Thank you. [Operator Instructions] And we'll take our first question from Bret Holley with Oppenheimer.

<Q – Bret Holley>: Yeah. Hi, hello. Thanks for taking my questions. I'm just curious on the statement you just made Jack on the research, which says that lorcaserin will change the way PCPs treat. I look to get more details on that and in particular why you think that lorcaserin will actually replace phentermine because most of the people that we talk to will actually use lorcaserin in combination with phentermine?

<A – Jack Lief>: Well, there might be some physicians that might be interested in doing that but phentermine is a 50-year old amphetamine class drug that has its own set of side-effects that we've seen. Lorcaserin side-effects are not really meaningfully different than placebo, but patients lose twice as much weight on lorcaserin than placebo. So we think that it's a compelling story, this marriage of efficacy, safety, and tolerability. We also know from independent market research that although phentermine is the most prescribed agent, physicians would be willing to switch from phentermine as well as other agents to lorcaserin that they said that they were relatively dissatisfied, yet it was one of the few ways that they could use.

<Q – Bret Holley>: So I guess a follow-up question to that is, you allowed the – there are physicians that would want to use combination in a patient who is not having any kind of problems on phentermine, what kind of logical limitation would there be to actually about adding lorcaserin on top of phentermine and the follow-up question to that is, if that's true and that's going to be even a somewhat common practice in the field, why don't you use safety for the combination?

<A – Jack Lief>: Yeah, so, so, general practice physicians prefer starting the patients out on single agents. They would consider adding something to that or switching depending if they weren't satisfied with results. So while it's possible that some physicians might want to go there, we think that lorcaserin alone will satisfy what physicians really want, which is to have the drug that they can prescribe the vast majority of their patients and have these patients stay on the drug long enough, because it's really well tolerated, to achieve that cardiometabolic endpoints that they are trying to look for.

<A – Dominic Behan>: That's the – this is Dominic Behan, that's the true unmet need in the real world, which is the marriage, as Jack said, between the efficacy and the tolerability and the safety. I mean, you can't have one without the other. In order to address this issue in the broad diverse obese population, it's very important that you have all of those attributes in your drug, and we have clearly shown that lorcaserin's profile meets that unmet need in the real world.

<Q – Bret Holley>: And I guess my last question is on the pooled data, I think you said that there were nearly 50% of patients who lost 5%, can you give us the precise number on lorcaserin in the pooled data BID for categorical weight loss and the precise number for placebo please?

<A – Jack Lief>: Well, in the BLOOM study, of course – if you're referring to both studies, or just the BLOSSOM study?

<Q – Bret Holley>: I'm asking about the pooled data. You referred to approximately 50% lost 5% of their weight and in the pooled data between the trials, I am wondering what's the precise number and what is the placebo number?

<A – Jack Lief>: Christy?

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<A – Christen Anderson>: So without putting everyone to sleep with a statistical discussion here. What we needed to do with this non-inferiority analysis was to show the upper bound of the 90% confidence interval was below the non-inferiority margin. We accomplished that, again, I'm not going to go through specific numbers now. We're kind of saving some of the thunder here for the Obesity Society Meeting. But our upper bound of the 90 and 95% confidence interval is well below the non-inferiority margin. So we did accomplish what we negotiated with the FDA and basically ruled out the individual studies and in the pooled analysis. They pretty agreed upon risk of valvulopathy.

<Q – Jim Birchenough>: Just a final question, I'll jump back in the queue. Have you guys completed the abuse liability study and what were the results and presumably you have to include that in your NDA, so I'm just wondering if we can get an update there?

<A – Jack Lief>: Yeah. Christy?

<A – Christen Anderson>: Yes. We have completed that study. The abuse liability study is going to be – we've submitted it for presentation at a couple of upcoming meetings, which we'll announce soon. The results were generally quite favorable. It shows very little to no abuse potential for lorcaserin. And again we will give you advance notice of when those specific numerical data will be presented at two different scientific conferences.

<Q – Jim Birchenough>: Okay. Thanks for taking the questions,

<A – Jack Lief>: Pleasure.

Operator: We'll move on to our next question from Hank Beinstein with Gagnon Securities.

<Q>: Good morning and thanks for taking the question. Jack, could you refresh our memories as to the amount of capital that's been expended on both the BLOOM and the BLOSSOM studies from inception until this most recent announcement?

<A – Jack Lief>: Well, that's an excellent question. Certainly the Phase 3 program, the external costs have been at least \$200 million, that's just the external cost. The internal costs, obviously, are quite significant. My estimate is that somewhere between 500 million and \$1 billion have been spent – will have been spent by the time lorcaserin is approved sometime hopefully next year. So it's certainly a considerable expense.

The good news is we've already spent the vast proportion of that very little is left to do. So we look forward to re-energizing this weight management market by displacing these old drugs like amphetamine like phentermine and driving patients to the physician's office for better weight management, who may have failed – tried, but failed the previous pharmacotherapy adding some patients that, that are looking for new ways of addressing their need to manage their weight and because we tested our drug for two years, I think most physicians will be comfortable with long-term use of our compound and of course as I've mentioned the intellectual properties competition of Matter Patents are quite strong here.

<Q>: So to put a big picture on this, if the total cost approaches \$1 billion, when it's finally submitted that's more than double the current market capitalization of the company as it stands today. What kind of a price tag would you be looking for with respect to the partnerships that you're potentially going to be entertaining? And the second part of that question is, have any negotiations started with respect to any large pharmaceutical companies at this time?

<A – Jack Lief>: Yeah. So we have a good manufacturing facility that currently manufactures GMP products for – that's used by numerous companies throughout U.S. and the world in Switzerland.

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We expect to provide finished product to our partners, that's manufactured in our Swiss facility in terms of upfront and milestone payments obviously we're still in discussions there. I think most partners are waiting to see this data. This is a very important event that we're talking about right now, the BLOSSOM data. We expect to capture the benefit of lorcaserin in our spend via transfer pricing to a large extent.

<Q>: I guess my question though was, are you expecting to recover anywhere between the 500 million and \$1 billion in the form of upfront payments or get margins on gross margins on the manufacture of the drug, is that...

<A – Jack Lief>: Oh yeah.

<Q>: ...potentially what you're looking at in the near-term?

<A – Jack Lief>: Yeah, obviously the drug – we need to get the drug approved first before we get to gross margins, but there's no question in my mind that we will fully recover numerous times the cost to compensate us for the risk that we've taken in developing lorcaserin. I expect lorcaserin will be quite successful in the marketplace as first-line therapy that physicians will be able to use for the vast majority of their patients, both existing and new patients.

So I think this really is a game changer in the weight management area. If you look at drugs to treat hypertension, physicians have numerous choices of mechanisms to use, in weight management there are only two and the side effects actually limit the usefulness of these drugs. So I think physicians really, really need another choice, another mechanism, a new mechanism and as you've seen the adverse events, side effects are not really meaningfully different than placebo, but patients do lose a lot of weight on average, double placebo and some patients lose 35 pounds or more. And so that's – it's a very effective drug, very safe and that's what physicians are looking for.

<A – Dominic Behan>: Yeah, I mean, this is Dominic Behan. In order to have an effective, viable, commercial drug applicable to the board diverse population, this marriage that Jack talked about of efficacy, tolerability and safety is absolutely critical, absolutely critical. And we have captured that profile very nicely with lorcaserin.

<Q>: Thank you very much and congratulations.

<A – Jack Lief>: Thank you.

<A – Dominic Behan>: Thank you.

Operator: We'll move on to our next question from Michael Castor with SIO Capital.

<Q>: Hello, this is Mike Sukhatme with Michael here. Just want to get some clarification, what were the patient numbers with valvulopathy in each arm, the actual end?

<A – Jack Lief>: Christy has presented the...

<A – Christen Anderson>: Yeah.

<A – Jack Lief>: [inaudible].

<A – Christen Anderson>: I'm trying to see if I have the specific numbers here.

<Q>: Thank you very much.

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<A – Christen Anderson>: I'm sorry, the numbers – I don't have the pooled numbers in front of me. The number of total patients in the lorcaserin group is slightly higher than the total number of people in the placebo group at week...

<Q>: [inaudible]

<A – Christen Anderson>: Well, week 52, by the time we have the week 52 echos, since the dropout rate was higher in placebo, therefore the actual number of valvulopathies is slightly higher to give you obviously the exactly matched percentages.

<Q>: Okay.

<A – Christen Anderson>: Again, I'm sorry I don't have the specific number sitting here on the papers in front of me.

<Q>: You said you had the pooled like numerator and denominator. That would be helpful as well if that's what you said you have instead.

<A – Christen Anderson>: Again, you got to let us save some of the thunder here for our Scientific Meeting that's upcoming. I'll just reiterate that we did rule out the risk of valvulopathy, the way we agreed to with the FDA and I think this just supports both our hypothesis for the mechanism of the drug and supports the safety of the drug. This is a huge milestone that we've met here. So, try to be patient with this and we'll get you all the specific numbers at Obesity Society in just a few weeks.

<Q>: Okay.

<A – William Shanahan, Jr.>: Yeah, keep it in mind that the receptor, the target that lorcaserin goes after is not found in the heart basically. So the 2C receptor is largely, essential in the brain and so that's very consistent. The mechanism is very consistent with the clinical as well as preclinical experience that we know for lorcaserin. So we're excited to be able to support all of these hypotheses regarding the – having a selective drug that only addresses this hypothalamus target.

<A – Jack Lief>: I mean suffice it to say, I mean this is likely the largest pivotal program ever performed to look at heart safety in the context of valvulopathy. So as Christy pointed out this is a tremendous milestone for the company, but also a very important scientific observation that we've shown that we can design selectivity and avoid this. And that's the responsibility that we take seriously that the public deserve to know.

<Q>: I understood, that's why I wanted the data. But I guess I'll have to wait. And then just to clarify your seizure, SAE comments in the press release and in your earlier comments, has there been any seizures in the clinical trials program so far in any of the arms?

<A – Jack Lief>: Bill, if you want to address that?

<A – William Shanahan, Jr.>: Well, we can. As we said in BLOOM, we saw no seizures and we did not see any seizures in this study either. We have one patient who had the history of fainting and having seizure like activity during phlebotomy. And this patient had one of these episodes during his trial.

<Q>: So he had a syncope episode.

<A – William Shanahan, Jr.>: Right.

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<Q>: Okay.

<A – William Shanahan, Jr.>: During phlebotomy.

<A – Jack Lief>: Yeah, so...

<A – William Shanahan, Jr.>: Blood drawing. So this is something that happens not uncommonly unfortunately that people do – a reasonable number of people do pass out when they get their blood drawn, have a faint.

<A – Jack Lief>: Both for placebo and...

<A – William Shanahan, Jr.>: Yeah, sure. So [inaudible].

<A – Jack Lief>: Yeah.

<Q>: Say again.

<A – William Shanahan, Jr.>: Yeah, the drug.

<Q>: Right, right, right. But this one patient just happened to be in the 10 BID arm or...

<A – William Shanahan, Jr.>: That's right.

<Q>: Okay. Okay. Thank you very much.

<A – Jack Lief>: Sure. We have time for one more.

Operator: Okay. Our final question comes from Carol Werther with Summer Street Research.

<Q – Carol Werther>: Thanks for taking the question. How do you anticipate the label will need in regards to the echocardiogram, would patients need one at baseline and would they need a follow-up or do we know that yet?

<A – Jack Lief>: Yeah, Bill.

<A – William Shanahan, Jr.>: Yeah, well the short answer is we don't know that yet, because it's going to be something the FDA will decide, but we believe that our data has really ruled out any risk of valvulopathy. So we don't think it's going to be needed, at least from our perspective I think you're going to see a lot more data, as Christy mentioned in at the Obesity Society to really reassure you, I think I'd refer you to Neil Weissman's covered in our press release also, we've added this independently to and you're going to see a lot more data. But it's all there and reassuring, we previously presented in the BLOOM trial at the Diabetes Association, we also showed single valve shifts and we're conducting a similar analysis here, no matter how you look at these data they just don't show a signal.

<A – Jack Lief>: Yeah keep in mind that we accepted all comers in that BLOSSOM trial, not just patients without valvulopathy irrespective of their heart valve functions, so we think that there shouldn't be – there won't be any issues. Is there a follow-up question, Carol?

<Q – Carol Werther>: Yeah. I just want to know if there is any single one rate-limiting step for getting the NDA in?

<A – Jack Lief>: Well, Christy you want to answer that question? There's a lot of work that goes into it.

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<A – Christen Anderson>: We've I think put together pretty much all of the data that we now need for this NDA. We have favorable results on everything that we've compiled so far, I think we have the people, the processes and the passion in place to get the NDA together by the end of the year. The key challenge right now is just sitting down and writing it. And again we have the people and the drive and we're going to get it done.

<A – William Shanahan, Jr.>: Carol I'll add, I think rate limiter is sleep.

<Q – Carol Werther>: All right. Well, thank you congratulations.

<A – Jack Lief>: Yes, thank you and – [inaudible] yeah, thanks.

Jack Lief, Co-Founder, Chairman, President and Chief Executive Officer

In closing, I'd like to remind everybody that the BLOSSOM trial does confirm BLOOM. Lorcaserin, we believe lorcaserin can change the way primary care physicians can treat their patients, give them new options to the broad cross-section of their patients. The robust Phase 3 pivotal program is completed now.

The NDA is on track for a December filing. And now our focus is on the regulatory process and preparing with our potential commercialization of partner for commercialization. So thank you all for being on the call and we look forward to presenting more data at the Obesity Society Meeting coming up next month. Thank you.

Operator: That does conclude today's call. Thank you for your participation.

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EXHIBIT K



Arena Pharmaceuticals' Lorcaserin to be Featured in Multiple Presentations at Obesity 2009

- Line-Up Includes Late-Breaking Abstract of BLOSSOM Phase 3 Trial Results and Physician Symposium with Spotlight on Lorcaserin's Mechanism of Action -

SAN DIEGO, Oct 12, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) announced today that lorcaserin will be featured in multiple presentations at Obesity 2009, the 27th Annual Scientific Meeting of The Obesity Society in Washington, DC.

The line-up includes a late-breaking abstract oral presentation of results from BLOSSOM (Behavioral modification and Lorcaserin Second Study for Obesity Management), a Phase 3 trial for which Arena reported positive, highly significant top-line results in September. Arena will also present new data analyses from lorcaserin's successful Phase 3 pivotal program in oral and poster sessions. In an independent clinical symposium, expert academic scientists and physicians will spotlight the 5HT-2C mechanism for weight management.

"The positive results from our Phase 3 pivotal program highlight lorcaserin's potential to provide physicians with a treatment option that combines three important attributes - efficacy, safety and tolerability - critical to broad applicability in the majority of their patients to help manage weight and improve cardiometabolic health," stated William R. Shanahan, M.D., Arena's Vice President and Chief Medical Officer. "The breadth of presentations featuring lorcaserin at The Obesity Society's annual scientific meeting speaks to the strong interest physicians have in this drug candidate."

Obesity 2009: Presentation Schedule

Saturday, October 24, 2009

Pre-Conference Session: Pharmacotherapy Update

Time: 1:00 - 3:45 p.m. Eastern Time (ET)

Chairs: Ken Fujioka, M.D., Louis J. Aronne, M.D., and Richard Pratley, M.D.

Presenter: Christen M. Anderson, M.D., Ph.D.

Sunday, October 25, 2009

Poster Session: "Long-Term Treatment with Lorcaserin was not Associated with Depression or Suicidal Ideation"

Time: on display 1:00 - 7:30 p.m. ET; presenters will be available to address questions from 1:00 - 2:00 p.m. and 6:30 - 7:30 p.m. ET

Presenters: William R. Shanahan, M.D., Christen M. Anderson, M.D., Ph.D., and Meredith Fidler, Ph.D.

Oral Abstract Presentation: "Lorcaserin Treatment was Associated With Improvements in Cardiovascular Risk Factors and Weight Loss in the BLOOM Trial"

Time: 6:00 - 6:15 p.m. ET

Presenter: Steven Smith, M.D.

Monday, October 26, 2009

Related Symposium: Spotlight on 5HT-2C

Time: 8:30 - 10:00 a.m. ET

Chairs: Jonathan Purnell, Ph.D., and Robert Berkowitz, M.D.

Speakers: Laurence Tecott, M.D., Ph.D.: Neuroscience of 5HT-2C; Steven Smith, M.D.: Lorcaserin - Clinical Results; Neil Weissman, M.D., F.A.C.C.: A Primer of Valvulopathy in Obesity

Tuesday, October 27, 2009

Oral Abstract Presentation: Late-Breaking Clinical Trial Symposium, BLOSSOM Abstract
Time: 10:40 - 11:00 a.m. ET
Presenter: Lee Kaplan, M.D.

Phase 3 Program Overview

The lorcaserin Phase 3 program consists of three trials: BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management), BLOSSOM and BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus). Enrollment in the lorcaserin Phase 3 program is complete with approximately 7,800 patients. Positive results from BLOOM were presented at the 69th Scientific Sessions of the American Diabetes Association in June 2009 and positive top-line results from BLOSSOM were reported in September 2009. BLOOM and BLOSSOM comprise the Phase 3 pivotal registration program and will be the basis for the lorcaserin NDA submission. BLOOM-DM, which is planned as a supplement to the NDA, is evaluating 10 mg of lorcaserin dosed once or twice daily versus placebo over a one-year treatment period in obese and overweight patients with type 2 diabetes at about 60 sites in the US.

A standardized program of moderate diet and exercise guidance is included in the Phase 3 program. The program's hierarchically ordered co-primary efficacy endpoints are: the proportion of patients achieving 5% or greater weight loss after 12 months, the difference in mean weight loss compared to placebo after 12 months, and the proportion of patients achieving 10% or greater weight loss after 12 months. Arena is also studying several key secondary endpoints, including changes in serum lipids, markers of inflammation and insulin resistance, and in the BLOOM-DM trial, other indicators of glycemic control.

About Lorcaserin

Lorcaserin is a novel single agent that represents the first in a new class of selective 5HT-2C receptor agonists. The 5HT-2C receptor is expressed in the brain, including the hypothalamus, an area involved in the control of appetite and metabolism. Stimulation of this receptor is strongly associated with feeding behavior and satiety. Arena has patents that cover lorcaserin in the US and other jurisdictions, which in most cases are capable of continuing into 2023 without taking into account any patent term extensions or other exclusivity Arena might obtain.

About Arena Pharmaceuticals

Arena is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing oral drugs in four major therapeutic areas: cardiovascular, central nervous system, inflammatory and metabolic diseases. Arena's most advanced drug candidate, lorcaserin, is being investigated in a Phase 3 clinical trial program for weight management. Arena has a broad pipeline of novel compounds targeting G protein-coupled receptors, an important class of validated drug targets, which includes compounds being evaluated independently and with partners, including Merck & Co., Inc., and Ortho-McNeil-Janssen Pharmaceuticals, Inc.

Arena Pharmaceuticals® and Arena® are registered service marks of the company. "APD" is an abbreviation for Arena Pharmaceuticals Development.

Forward-Looking Statements

Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include statements about the significance of the lorcaserin results and the success of the lorcaserin Phase 3 program; lorcaserin's commercial and other potential; the importance of efficacy, safety and tolerability and the combination of such attributes; interest in lorcaserin; the development, advancement, therapeutic indication, tolerability, safety, selectivity and efficacy of lorcaserin; the protocol, design, scope, enrollment and other aspects of the lorcaserin trials; the Phase 3 pivotal registration program; the potential of the lorcaserin Phase 3 program and its results to satisfy the FDA's approval requirements; future activities, results and announcements relating to lorcaserin, including submitting an NDA for lorcaserin and the BLOOM-DM results as a supplement to the NDA; lorcaserin's patent coverage; and Arena's strategy, internal and partnered programs, and ability to develop compounds and commercialize drugs. For such statements, Arena claims the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from Arena's expectations. Factors that could cause actual results to differ materially from the forward-looking statements include, but are not limited to, the timing, success and cost of Arena's lorcaserin program and other of its research and development programs; results of clinical trials or preclinical studies may not be predictive of future results; clinical trials and studies may not

proceed at the time or in the manner Arena expects or at all; Arena's ability to partner or commercialize lorcaserin or other of its compounds or programs; the timing and ability of Arena to receive regulatory approval for its drug candidates; Arena's ability to obtain additional funds; Arena's ability to obtain and defend its patents; and the timing and receipt of payments and fees, if any, from Arena's collaborators. Additional factors that could cause actual results to differ materially from those stated or implied by Arena's forward-looking statements are disclosed in Arena's filings with the Securities and Exchange Commission. These forward-looking statements represent Arena's judgment as of the time of this release. Arena disclaims any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

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EXHIBIT L



Arena Pharmaceuticals Announces Third Quarter 2009 Financial Results and Recent Developments

SAN DIEGO, Nov 09, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) today reported financial results for the third quarter ended September 30, 2009.

Arena reported a lower net loss allocable to common stockholders in the third quarter of 2009 of \$34.8 million, or \$0.38 per share, compared to a net loss allocable to common stockholders in the third quarter of 2008 of \$56.2 million, or \$0.76 per share, and a net loss allocable to common stockholders in the first nine months of 2009 of \$123.4 million, or \$1.51 per share, compared to a net loss allocable to common stockholders in the first nine months of 2008 of \$177.0 million, or \$2.40 per share.

"The successful completion of the lorcaserin pivotal program in the third quarter was a critical milestone for Arena," stated Jack Lief, Arena's President and Chief Executive Officer. "The positive results were received with support and enthusiasm at The Obesity Society's annual meeting last month. Participating physicians shared with us three clear themes: the pressing need for new weight management treatments, the paramount importance of safety in treating overweight and obese patients, and that weight reduction should translate into improvements in cardiometabolic health. If approved, the unique combination of efficacy, safety and tolerability positions lorcaserin as first-line therapy."

As expected, research and development expenses declined significantly to \$22.1 million in the third quarter of 2009 from \$47.5 million in the third quarter of 2008. Research and development expenses declined to \$89.0 million in the first nine months of 2009 from \$151.0 million in the first nine months of 2008. This decrease is primarily due to the completion of the BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management) and BLOSSOM (Behavioral modification and Lorcaserin Second Study for Obesity Management) Phase 3 clinical trials evaluating the safety and efficacy of lorcaserin for weight management, and prioritizing spending towards activities that support filing a New Drug Application, or NDA, for lorcaserin. Arena expects its research and development expenses to continue to decline this year due to completing the BLOOM and BLOSSOM clinical trials and expected cost savings from the second-quarter workforce reduction and other cost-containment measures. Research and development expenses in the first nine months of 2009 included \$2.9 million in non-cash, share-based compensation expense, compared to \$3.3 million in the first nine months of 2008. General and administrative expenses totaled \$5.4 million in the third quarter of 2009, compared to \$5.9 million in the third quarter of 2008, and \$18.7 million in the first nine months of 2009, compared to \$21.9 million in the first nine months of 2008. This decrease is primarily attributable to lower salary and other personnel costs resulting from the workforce reduction. General and administrative expenses in the first nine months of 2009 included \$2.2 million in non-cash, share-based compensation expense, compared to \$2.8 million in the first nine months of 2008.

At September 30, 2009, cash, cash equivalents and short-term investments totaled \$143.5 million and approximately 92.7 million shares of common stock were outstanding.

Arena's Recent and Third Quarter Developments

- Announced positive, highly significant top-line results from the BLOSSOM trial. Lorcaserin patients achieved highly significant categorical and absolute weight loss over 52 weeks of treatment. About two-thirds (63.2%) of lorcaserin patients dosed twice daily who completed the trial according to protocol lost at least 5% of their weight, compared to 34.9% of patients on placebo, and more than one-third (35.1%) of these lorcaserin patients lost at least 10% of their weight, compared to 16.1% for placebo. The average weight loss for lorcaserin patients dosed twice daily was 17.0 pounds, compared to 8.7 pounds for placebo. The top quartile of lorcaserin patients who completed the trial according to protocol and had their Week 52 weight recorded lost an average of 35.1 pounds. Lorcaserin was very well tolerated and no excess depression or suicidal ideation was observed with lorcaserin treatment. The incidence of new FDA-defined valvulopathy from the integrated echocardiographic data set from BLOSSOM and BLOOM did not differ from placebo.

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- Announced a late-breaking oral presentation from the pivotal BLOSSOM trial and additional positive data from the pivotal BLOOM trial at the 27th Annual Scientific Meeting of The Obesity Society. The new BLOSSOM data demonstrate improvements in patients' body composition, cardiovascular risk factors and quality of life. The new BLOOM data demonstrate that lorcaserin significantly improved markers of cardiovascular risk and glycemic parameters and was not associated with depression or suicidal ideation. Lorcaserin patients who completed the BLOOM trial according to protocol lost 31% of their excess body weight, compared to 12% for the placebo group.
- Completed dosing in all lorcaserin clinical trials Arena expects to be included in the NDA it plans to submit to the FDA by the end of 2009.
- Completed a public offering of 12.5 million shares of common stock, resulting in net proceeds to Arena of \$49.7 million.
- Received net proceeds of \$95.6 million from a \$100.0 million loan provided by Deerfield Management. The outstanding principal accrues interest until maturity in June 2013 at a rate of 7.75% per annum. In connection with the loan, Arena issued Deerfield warrants for 28 million shares of its common stock at an exercise price of \$5.42 per share. On or before June 17, 2011, Deerfield may make a one-time election to provide Arena with up to an additional \$20.0 million under similar terms, with the additional loan also maturing in June 2013. For each additional \$1.0 million in funding, Arena will issue Deerfield additional warrants for 280,000 shares of its common stock at an exercise price of \$5.42 per share. Arena repaid Deerfield the first scheduled principal repayment of \$10.0 million upon completion of its public offering in July.

Scheduled Earnings Call

Arena will host both a conference call and webcast to discuss the third quarter 2009 financial results and to provide a business and financial update tomorrow, Tuesday, November 10, 2009, at 8:30 a.m. Eastern Time (5:30 a.m. Pacific Time). Jack Lief, President and Chief Executive Officer, and Robert E. Hoffman, Vice President, Finance and Chief Financial Officer, will host the conference call.

The conference call may be accessed by dialing 888.452.4024 for domestic callers and 719.325.2385 for international callers. Please specify to the operator that you would like to join the "Arena Pharmaceuticals' Third Quarter 2009 Financial Results Call." The conference call will be webcast live under the investor relations section of Arena's website at www.arenapharm.com, and will be archived there for 30 days following the call. Please connect to Arena's website several minutes prior to the start of the broadcast to ensure adequate time for any software download that may be necessary.

Upcoming Corporate Presentations

Arena is planning to present at upcoming investment and industry conferences, including:

- Piper Jaffray 21st Annual Health Care Conference, December 1-2, 2009, New York, New York
- 28th Annual J.P. Morgan Healthcare Conference, January 11-14, 2010, San Francisco, California

About Arena Pharmaceuticals

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Arena Pharmaceuticals(R) and Arena(R) are registered service marks of the company. "APD" is an abbreviation for Arena Pharmaceuticals Development.

Forward-Looking Statements

Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include statements about the development, advancement, therapeutic indication and use, tolerability, safety, selectivity, efficacy, and regulatory approval of lorcaserin; the protocol, design, scope and other aspects of the lorcaserin trials; lorcaserin's commercial and other potential, including as a first-line therapy; the significance of the lorcaserin trial results and the completion of the lorcaserin Phase 3 pivotal registration program; the need for new treatments and the importance of safety in treating overweight and obese patients; the FDA's approval process and requirements; the potential of the lorcaserin Phase 3 program and its results to satisfy the FDA's approval requirements; financial guidance, including expected cost savings and decline in research and development expenses; Arena's agreements with Deerfield and rights and future activities thereunder; future activities, results and announcements relating to lorcaserin, including submitting an NDA for lorcaserin and commercializing lorcaserin; the impact of weight loss on health; Arena's strategy, plans, internal and partnered programs, and ability to develop compounds and commercialize drugs. For such statements, Arena claims the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from Arena's expectations. Factors that could cause actual results to differ materially from the forward-looking statements include, but are not limited to, the timing, success and cost of Arena's lorcaserin program and other of its research and development programs; regulatory authorities may not find data from Arena's clinical trials and studies sufficient for regulatory approval; the timing and ability of Arena to receive regulatory approval for its drug candidates; results of clinical trials or preclinical studies may not be predictive of future results; clinical trials and studies may not proceed at the time or in the manner Arena expects or at all; Arena's ability to partner or commercialize lorcaserin or other of its compounds or programs; Arena's ability to obtain additional funds; Arena's ability to obtain and defend its patents; and the timing and receipt of payments and fees, if any, from Arena's collaborators. Additional factors that could cause actual results to differ materially from those stated or implied by Arena's forward-looking statements are disclosed in Arena's filings with the Securities and Exchange Commission. These forward-looking statements represent Arena's judgment as of the time of this release. Arena disclaims any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

Arena Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations
(In thousands, except per share amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2009	2008	2009	2008
	(unaudited)		(unaudited)	
Revenues				
Manufacturing services	\$1,737	\$1,442	\$4,663	\$5,461
Collaborative agreements	882	415	3,042	1,650
Total revenues	2,619	1,857	7,705	7,111
Operating Expenses				
Cost of manufacturing services	1,705	1,743	4,702	6,362
Research and development	22,147	47,475	88,972	151,050
General and administrative	5,423	5,924	18,725	21,938
Restructuring charges	-	-	3,324	-
Amortization of acquired technology & other intangibles	582	580	1,721	1,748
Total operating expenses	29,857	55,722	117,444	181,098
Interest and Other Income (Expense)				
Interest income	75	1,332	291	6,529
Interest expense	(7,339)	(1,399)	(10,991)	(4,367)
Gain from valuation of				

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derivative liabilities	2,472	-	345	-
Warrant settlement expense	-	(242)	-	(2,236)
Loss on extinguishment of debt	(2,479)	-	(2,479)	-
Other	(326)	(1,453)	(859)	(1,299)
	----	-----	-----	-----
Total interest and other expense, net	(7,597)	(1,762)	(13,693)	(1,373)
	-----	-----	-----	-----
Net loss	(34,835)	(55,627)	(123,432)	(175,360)
Dividends on redeemable convertible preferred stock	-	(557)	-	(1,644)
	---	----	----	-----
Net loss allocable to common stockholders	\$ (34,835)	\$ (56,184)	\$ (123,432)	\$ (177,004)
	=====	=====	=====	=====
Net loss per share allocable to common stockholders, basic & diluted	\$ (0.38)	\$ (0.76)	\$ (1.51)	\$ (2.40)
	=====	=====	=====	=====
Shares used in calculating net loss per share allocable to common stockholders, basic & diluted	90,995	73,923	81,518	73,782
	=====	=====	=====	=====

Arena Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheet Data
(In thousands)

	September 30, 2009	December 31, 2008
	----- (unaudited)	----- (Note)
Assets		
Cash, cash equivalents & short-term investments	\$143,481	\$110,129
Accounts receivable	1,628	1,823
Other current assets	4,037	5,031
Land, property & equipment, net	96,700	102,740
Acquired technology & other non-current assets	21,499	21,608
	-----	-----
Total assets	\$267,345	\$241,331
	=====	=====
Liabilities and Stockholders' Equity		
Accounts payable and accrued liabilities	\$16,893	\$46,789
Total deferred revenues	4,049	4,049
Derivative liabilities	11,715	-
Notes payable	52,974	8,567
Total lease financing obligations & other long-term liabilities	79,154	64,294
Total stockholders' equity	102,560	117,632
	-----	-----
Total liabilities & stockholders' equity	\$267,345	\$241,331

=====

Note: The Condensed Consolidated Balance Sheet Data has been derived from the audited financial statements as of that date.

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EXHIBIT M

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Q3 2009 Earnings Call

Event Type▲

Nov. 10, 2009

Date▲

MANAGEMENT DISCUSSION SECTION

Operator: Good day, everyone, and welcome to Arena Pharmaceuticals Third Quarter 2009 Financial Results Conference Call. This call is being recorded.

At this time for opening remarks and introductions, I would like to turn the call over to Arena's Vice President, Finance and Chief Financial Officer, Mr. Robert Hoffman. Mr. Hoffman, please go ahead, sir.

Robert E. Hoffman, Vice President, Finance and Chief Financial Officer

Thank you, Jennifer. Good morning, and welcome to Arena Pharmaceuticals' third quarter 2009 financial results conference call. I'm Robert Hoffman, Arena's Vice President of Finance and Chief Financial Officer.

Joining me on the call today are Jack Lief, our President and Chief Executive Officer; and Christy Anderson, our Vice President of Clinical Development. Also available to address your questions are Dominic Behan, our Senior Vice President and Chief Scientific Officer; and Bill Shanahan, our Vice President and Chief Medical Officer.

Before we begin, I'd like to point out that we'll be making numerous forward-looking statements during this conference call. Such forward-looking statements include statements about our internal and partnered programs, financial guidance, strategy and plans, drug development, approval and commercialization and other statements that are not historical facts.

Such statements include the words, plan, will, expect, or similar words. You are cautioned not to place undue reliance on these forward-looking statements, which are only predictions and reflects the company's beliefs, expectations, and assumptions based on currently available information and speak only as of the time they are made.

Risks and uncertainties that could cause actual results to differ materially from those described in our forward-looking statements include the timing, success and cost of clinical trials, preclinical studies and research activities, the timing and outcome with the regulatory process, the timing and outcome of our partnership efforts, our ability to obtain additional funds from collaborators and investors, whether our assumptions prove to be correct, and other risks identified in our SEC reports.

For a discussion of these and other factors, please refer to the risk factors described in our filings with the Securities and Exchange Commission. For forward-looking statements, we claim the protection of the Private Securities Litigation Reform Act of 1995.

Now I'd like to turn the call over to our President and CEO, Jack Lief. Jack?

Jack Lief, Co-Founder, Chairman, President and Chief Executive Officer

Thanks, Robert. Good morning. Before Robert covers the financials for the quarter, we will update you on the lorcaserin program, share what we learned at the Obesity Society's Annual Scientific Meeting and discuss the compelling investment opportunity that Arena presents.

Let me begin by telling you that our lorcaserin program remains on track. We presented new Phase III data at the Obesity Society Meeting that Christy will speak to. I am pleased to report at this time we have all of the data in hand that will be included in the new drug application that we are planning to submit to the FDA next month. Also next month, results from the abuse liability study will be

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presented at the 48th annual meeting of the American College of Neuropsychopharmacology. BLOOM-DM, our one-year study evaluating lorcaserin in patients with type 2 diabetes is ongoing and we expect to announce results in the second half of next year. BLOOM-DM will be filed as a supplement to lorcaserin NDA. Also of note, we've recently completed a market research study individually interviewing 50 primary care physicians who are high prescribers of weight loss drugs.

Confirming what we've already -- what we've heard previously, physician satisfaction with currently available drugs for weight management is very low. Over half of the physicians interviewed gave one of the lowest possible ratings to current drugs. Side effects and lack of long-term efficacy are the primary reasons for this dissatisfaction.

But what is really important about this latest research is that for the first time, we shared with doctors the actual Phase III clinical data for lorcaserin and their response was overwhelmingly enthusiastic. Based on multiple detailed descriptions of the efficacy safety and tolerability data from the BLOOM trial, a great majority of respondents rated their likelihood to prescribe at the highest possible levels.

If lorcaserin is approved, doctors that participated in our market research told us, they would feel confident prescribing lorcaserin to the majority of their overweight and obese patients, and predicted substantial levels of use if lorcaserin proves as safe and effective in practice as it did in our pivotal program.

They expect that initially about one quarter of lorcaserin prescriptions will come from switching patients currently taking other obesity medications. More importantly, doctors said about 75% will come from new patients including those who would otherwise not have received a prescription for weight management. If projected market-wide, this translates into significant potential lorcaserin revenue from such market expansion. We are excited about these new data and plan to provide more details on our recent findings as we move forward.

With pivotal data in hand, and a clear commercial opportunity ahead of us, we intend to establish a partnership to help us commercialize lorcaserin. We will provide additional information when it is available.

Christy Anderson, our Vice President of Clinical Development, will now discuss the feedback we received at the recent Obesity Society Meeting. Christy?

Christen M. Anderson, M.D., Ph.D., Vice President of Clinical Development

Thanks, Jack. As Jack mentioned, we recently participated in Obesity 2009, The 27th Annual Scientific Session of Obesity Society. This meeting was an excellent opportunity to present, discuss results from the complete lorcaserin pivotal program with the scientific and medical community.

The late breaking BLOSSOM data were presented by Dr. Lee Kaplan of the Massachusetts General Hospital and BLOOM data were presented in an oral session by Dr. Steve Smith of Florida Hospital and the Burnham Institute. We presented additional BLOOM data at the preconference pharmacology update and in a poster session.

Lorcaserin was also featured in a symposium called Spotlight on 5HT-2C, a 90-minute session focused on lorcaserin's mechanism of action. The new data presented at the Obesity Society Meeting expanded on previous data announcements and patients who took lorcaserin weight loss was associated with improved body composition, cardiovascular risk factors, glycemic parameters and quality of life and was not associated with excess depression or suicidal ideation compared to placebo.

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The pivotal Phase III clinical trial program evaluated nearly 72,000 patients treated for up to two years and showed that lorcaserin consistently produced significant weight loss with excellent tolerability. The BLOOM and BLOSSOM results were comparable and demonstrated the following key lorcaserin effects after one year of treatment according to protocol.

About two-thirds of patients achieved at least 5% weight loss and over one-third achieved at least 10% weight loss. On average, patients lost 17 to 18 pounds or about 8% of their weight.

Secondary end points including body composition, lipids, cardiovascular risk factors and glycemic parameters improved compared to placebo. Heart rate and blood pressure went down, an important finding with an obesity drug. Lorcaserin did not increase the risk cardiac valvulopathy. Lorcaserin improved quality of life and there was no signal for depression or suicidal ideation and importantly, the only adverse event that exceeded placebo rate by 5% was generally mild or moderate trenchant headaches.

We have also performed some post hawk analyses of the data from the individual pivotal studies that demonstrate just how well lorcaserin works. Based on a normal BMI of 25, BLOOM patients lost about one-third of their excess body weight and the average weight loss was £35 or 16% of body weight for the top quartile of BLOSSOM patients. Lorcaserin's overall profile of medically meaningful efficacy combined with excellent safety and tolerability was received with support and enthusiasm from the physicians in attendance at Obesity 2009. Their feedback was helpful and conveyed three clear, concise things.

First, doctors need new weight management treatments and they want new mechanistic approaches, specifically physicians want drugs with improved risk management profiles that lead to better, longer-term treatment. Second, safety is of paramount importance in treating overweight or obese patients. Physicians want safe and effective drugs that their patients can tolerate, patients must be able to stay on treatments long enough to reduce their weight and sustain the weight loss.

And third, physicians emphasize that weight reduction should translate into improvements in cardio metabolic health. It's important to see parameters such as blood pressure, cholesterol, triglycerides and heart rate move in the right direction. At the Obesity Society meeting, the heart.org, interviewed Dr. Lee Kaplan who focused on lorcaserin's success in passing the weight loss and valvular hurdles in the BLOSSOM study.

This resulting article was one of that week's most read stories on this cardiology focused website that provides clinical and other news to the medical community. Overall the feedback that we received from our participation in the Obesity Society meeting was very positive and supports our belief that it's approved the combination of efficacy, safety and tolerability, positions lorcaserin as first line therapy for the majority of overweight and obese patients. Jack?

Jack Lief, Co-Founder, Chairman, President and Chief Executive Officer

Thanks, Christy. The consistent feedback we have received from doctors at Obesity 2009 and our market research emphasize the compelling investment opportunity that Arena presents. Lorcaserin has a unique competitive profile and is differentiated from currently approved treatments for weight management and those in development by a number of important characteristics.

Lorcaserin has the right combination of meaningful efficacy with a safety profile that is similar to placebo and avoids increased blood pressure and heart rate, depression, suicidal ideation and cardiac toxicity. Lorcaserin has demonstrated an outstanding tolerability profile reflected by the low incidence of withdrawals due to adverse events. Lorcaserin's tolerability profile allows patients to start on the full dose without a titration period.

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This is important to the real life medical practice because many primary care physicians don't have the resources to monitor a titration period for their patients. Two-year data support lorcaserin's long-term safety profile and demonstrate maintenance of weight loss in the second year of treatment.

Very importantly, strong global composition of matter patent coverage of a new chemical entity with first expiration in 2023 for this novel single agent and market research shows that lorcaserin has a significant commercial opportunity with physicians who expect to displace currently available agents with lorcaserin as first line therapy and expand the weight management category.

Robert Hoffman will now review our financials.

Robert E. Hoffman, Vice President, Finance and Chief Financial Officer

Thank you, Jack. In the third quarter of 2009 we recorded revenues of approximately 2.6 million compared to third quarter 2008 revenues of approximately 1.9 million. In the first nine months of 2009, we recorded revenues approximately 7.7 million compared to first nine months of 2008 revenues of approximately 7.1 million.

Revenues in the first nine months of 2009 included 4.7 million in manufacturing services revenue under our manufacturing services agreement with Siegfried and 3 million for patent activities from our collaborations with Merck and Ortho-McNeil-Janssen. Research and development expenses continue to decrease significantly over the prior year expenses.

In the third quarter of 2009, research and development expenses were approximately \$22.1 million compared to approximately \$47.5 million in the third quarter of 2008. This \$25.4 million or 53% decrease was primarily attributable to a decrease in clinical study, fees and expenses of approximately \$20.2 million due to completing our BLOOM and BLOSSOM trials as we prioritized our spending towards completing activities that support filing an NDA for lorcaserin.

Research and development expenses also decreased significantly in the first nine months of 2009 as compared to 2008. In the first nine months of 2009, research and development expenses were approximately \$89 million compared to approximately \$151 million the first nine months of 2008. This \$62 million decrease was primarily attributable to a decrease of \$51.1 million in external clinical and preclinical study fees and expenses, which was primarily due to completing our BLOOM and BLOSSOM trials.

Research and development expenses in the first nine months of 2009 included \$39.8 million in external clinical fees and expenses, 96% or \$38.4 million of which related to lorcaserin. This compares to \$90.9 million in external clinical fees and expenses in the first nine months of 2008 of which 85% or \$77.5 million related to lorcaserin. Research and development expenses in the first nine months of 2009 included \$2.9 million in non-cash, share-based compensation, compared to \$3.3 million in the first nine months of 2008.

Although we expect to continue to incur substantial research and development expenses in 2009 primarily related to lorcaserin, we expect our total 2009 research and development expenses to be significantly lower than the 2008 level as a large majority of expenses from our BLOOM and BLOSSOM trials have been recognized through the first nine months of 2009. BLOOM DM is continuing but is a much smaller Phase III study than BLOOM or BLOSSOM.

In addition, we do not plan to initiate in the near term any other clinical trials. Further contributing to the decrease in 2009, research and development expenses is the workforce reduction of approximately 130 employees that we completed in June.

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QUESTION AND ANSWER SECTION

Operator: [Operator Instructions] We'll go ahead and take our first question from Craig Gordon with Cowen & Co.

<Q – Craig Gordon>: Hi, good morning. Congratulations on all the progress you've made.

<A – Jack Lief>: Thanks, Craig.

<Q – Craig Gordon>: A couple questions. In the NDA submission, do you guys plan on submitting proposals both for Phase 4 commitments as well as a REMS program?

<A – Jack Lief>: Bill?

<A – William Shanahan, Jr.>: Yes. So we specifically discussed this issue with the FDA at our preNDA meeting and this will be a review issue but at the time -- at the present time we don't see a safety signal to pursue, so we are going to continue to evaluate our data, file the NDA and then have discussions with the FDA after that.

<Q – Craig Gordon>: Okay. Great. And in terms of a partnership, I guess in the past there's been a discussion that perhaps it could come, I guess, year end this year or perhaps the first half of 2010. Is that still a realistic time line or is it more likely to come perhaps after the FDA panel or approval?

<A – Jack Lief>: Well, you know, partnering is an important goal for Arena. We're working hard on this and when we have something to announce, we will. We believe lorcaserin's unique profile allows it to be first line therapy and so therefore, it's very attractive to partners and obviously we can't comment on who we're talking to or anything like that, but when we do have something to announce, we definitely will.

<Q – Craig Gordon>: Great. Thanks for taking my questions.

<A – Jack Lief>: Pleasure.

Operator: And our next question will come from Terence Flynn with Lazard Capital Markets.

<Q – Terence Flynn>: Hi. First question, just in terms of the market research you guys recently conducted, did you ask any questions specifically about combination use of lorcaserin with phentermine?

<A – Jack Lief>: No, we did not.

<Q – Terence Flynn>: Okay. And just a follow-up on the partnership discussions. I was wondering, I know you guys have guided to -- you'd like to provide drug substance to a partner and take a royalty. In the event that, let's say, you can't get terms which you view as favorable, would you consider launching lorcaserin with a specialty sales force?

<A – Jack Lief>: Well, you know, as we said, we intend to partner but we do have contingency plans in place should we not reach a proper agreement. And if we need to execute our commercialization plans, I don't expect a delayed launch for lorcaserin. So, yes, we do have such contingency plans in place.

<Q – Terence Flynn>: Okay. And what type of sales force or what size sales force, I guess, do those contingency plans assume?

EXHIBIT N



Arena Pharmaceuticals Announces FDA Acceptance of Lorcaserin NDA for Filing

SAN DIEGO, Feb. 24, 2010 /PRNewswire via COMTEX News Network/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) announced today that its New Drug Application (NDA) for lorcaserin, Arena's internally discovered and developed drug candidate for weight management, including weight loss and maintenance of weight loss, has been accepted for filing by the US Food and Drug Administration (FDA). Arena submitted the lorcaserin NDA on December 22, 2009, and expects to learn the Prescription Drug User Fee Act (PDUFA) date in the next few weeks. The PDUFA date is the target date for the FDA to complete its review of an NDA.

"The FDA's acceptance of the lorcaserin NDA is a significant milestone towards our goal of providing physicians and their patients with a new mechanistic approach to achieve sustainable weight loss in a well-tolerated manner," said Jack Lief, Arena's President and Chief Executive Officer. "We look forward to working with the FDA to facilitate a thoughtful and efficient review of the lorcaserin NDA."

The NDA is based on a data package from lorcaserin's development program that includes 18 clinical trials totaling 8,576 patients. The pivotal Phase 3 clinical trial program, BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management) and BLOSSOM (Behavioral modification and Lorcaserin Second Study for Obesity Management), evaluated nearly 7,200 patients treated for up to two years. In both trials, lorcaserin produced statistically significant weight loss with excellent safety and tolerability.

Phase 3 Program Overview

BLOOM and BLOSSOM comprise the pivotal Phase 3 program and are the basis of the lorcaserin NDA. These double-blind, randomized, placebo-controlled trials evaluated obese patients, Body Mass Index (BMI) 30 to 45, with or without co-morbid conditions and overweight patients, BMI 27 to 29.9, with at least one co-morbid condition. Positive results from the pivotal program were presented at the 69th Scientific Sessions of the American Diabetes Association and the 27th Annual Scientific Meeting of The Obesity Society.

In addition to the pivotal program, Arena is evaluating lorcaserin in obese and overweight patients with type 2 diabetes in its BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus) trial. Arena plans to file the results of BLOOM-DM as a supplement to the NDA.

About Lorcaserin

Lorcaserin is a novel single agent that represents the first in a new class of selective serotonin 2C receptor agonists. The serotonin 2C receptor is expressed in the brain, including the hypothalamus, an area involved in the control of appetite and metabolism. Stimulation of this receptor is strongly associated with feeding behavior and satiety. Arena has patents that cover lorcaserin in the US and other jurisdictions, which in most cases are capable of continuing into 2023 without taking into account any patent term extensions or other exclusivity Arena might obtain.

About Arena Pharmaceuticals

Arena is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing oral drugs that target G protein-coupled receptors, an important class of validated drug targets, in four major therapeutic areas: cardiovascular, central nervous system, inflammatory and metabolic diseases. Arena's most advanced drug candidate, lorcaserin, is intended for weight management, including weight loss and maintenance of weight loss, and has completed a pivotal Phase 3 clinical trial program. Arena submitted an NDA for lorcaserin to the FDA in December 2009, and the FDA has accepted the NDA for filing.

Arena Pharmaceuticals(R) and Arena(R) are registered service marks of the company.

Forward-Looking Statements

Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. Such

forward-looking statements include statements about the development, advancement, therapeutic indication and use, tolerability, safety, selectivity, efficacy and regulatory review and approval of lorcaserin; the significance of the FDA's acceptance of the lorcaserin NDA for filing; lorcaserin's commercial and other potential, including in providing a new approach to achieve weight loss; future activities and events relating to lorcaserin, including the receipt of a PDUFA date, working with the FDA in the regulatory review process and submitting the BLOOM-DM results as a supplement to the NDA; lorcaserin's patent coverage; and Arena's goals, strategy, research and development programs, and ability to develop compounds and commercialize drugs. For such statements, Arena claims the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from Arena's expectations. Factors that could cause actual results to differ materially from the forward-looking statements include, but are not limited to, regulatory authorities may not find data from Arena's clinical trials and other studies sufficient for regulatory approval; the timing and ability of Arena to receive regulatory approval for its drug candidates; the timing, success and cost of Arena's lorcaserin program and other of its research and development programs; results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results; clinical trials and other studies may not proceed at the time or in the manner Arena expects or at all; Arena's ability to partner or commercialize lorcaserin or other of its compounds or programs; Arena's ability to obtain adequate funds; Arena's ability to obtain and defend its patents; and the timing and receipt of payments and fees, if any, from Arena's collaborators. Additional factors that could cause actual results to differ materially from those stated or implied by Arena's forward-looking statements are disclosed in Arena's filings with the Securities and Exchange Commission. These forward-looking statements represent Arena's judgment as of the time of this release. Arena disclaims any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

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EXHIBIT O



Arena Pharmaceuticals Receives PDUFA Date for Lorcaserin NDA

FDA Assigns October 22, 2010, PDUFA Date -

SAN DIEGO, Feb. 26, 2010 /PRNewswire via COMTEX News Network/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) announced today that the US Food and Drug Administration (FDA) has assigned a Prescription Drug User Fee Act (PDUFA) date of October 22, 2010, for the review of the lorcaserin New Drug Application (NDA). The acceptance of the lorcaserin NDA filing confirms that the application is sufficiently complete to permit a substantive review, and the PDUFA date is the goal date for the FDA to complete its review of the NDA.

Lorcaserin is Arena's internally discovered and developed drug candidate for weight management, including weight loss and maintenance of weight loss, and is intended for obese patients or overweight patients with at least one weight-related co-morbid condition.

Jack Lief, Arena's President and Chief Executive Officer, stated, "With an October PDUFA date for the lorcaserin NDA, we are another step closer to our goal of improving the treatment of obesity. We believe that lorcaserin, if approved, will be well positioned as first-line therapy to help patients achieve sustainable weight loss in a well-tolerated manner."

The NDA is based on a data package from lorcaserin's development program that includes 18 clinical trials totaling 8,576 patients. The pivotal Phase 3 clinical trial program, BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management) and BLOSSOM (Behavioral modification and Lorcaserin Second Study for Obesity Management), evaluated nearly 7,200 patients treated for up to two years. In both trials, lorcaserin produced statistically significant weight loss with excellent safety and tolerability.

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In addition to the pivotal program, Arena is evaluating lorcaserin in obese and overweight patients with type 2 diabetes in its BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus) trial. Arena plans to file the results of BLOOM-DM as a supplement to the NDA.

About Lorcaserin

Lorcaserin is a novel single agent that represents the first in a new class of selective serotonin 2C receptor agonists. The serotonin 2C receptor is expressed in the brain, including the hypothalamus, an area involved in the control of appetite and metabolism. Stimulation of this receptor is strongly associated with feeding behavior and satiety. Arena has patents that cover lorcaserin in the US and other jurisdictions, which in most cases are capable of continuing into 2023 without taking into account any patent term extensions or other exclusivity Arena might obtain.

About Arena Pharmaceuticals

Arena is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing oral drugs that target G protein-coupled receptors, an important class of validated drug targets, in four major therapeutic areas: cardiovascular, central nervous system, inflammatory and metabolic diseases. Arena's most advanced drug candidate, lorcaserin, is intended for weight management, including weight loss and maintenance of weight loss, and has completed a pivotal Phase 3 clinical trial program. Arena submitted an NDA for lorcaserin to the FDA on December 22, 2009, and the FDA has assigned an October 22, 2010, PDUFA date for the review of the application.

Arena Pharmaceuticals(R) and Arena(R) are registered service marks of the company.

Forward-Looking Statements

Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include statements about the development, advancement, therapeutic indication and use, tolerability, safety, selectivity, efficacy and regulatory review and approval of lorcaserin; the significance of the acceptance of the NDA filing and the PDUFA date assignment; the potential timing for the FDA to complete its review of the lorcaserin NDA; lorcaserin's commercial and other potential, including in improving the treatment of obesity and in being first-line therapy to help patients achieve sustainable weight loss in a well-tolerated manner; future activities and events relating to lorcaserin, including submitting the BLOOM-DM results as a supplement to the NDA; lorcaserin's patent coverage; and Arena's goals, strategy, research and development programs, and ability to develop compounds and commercialize drugs. For such statements, Arena claims the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from Arena's expectations. Factors that could cause actual results to differ materially from the forward-looking statements include, but are not limited to, regulatory authorities may not find data from Arena's clinical trials and other studies sufficient for regulatory approval; the timing and ability of Arena to receive regulatory approval for its drug candidates; the timing, success and cost of Arena's lorcaserin program and other of its research and development programs; results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results; clinical trials and other studies may not proceed at the time or in the manner Arena expects or at all; Arena's ability to partner or commercialize lorcaserin or other of its compounds or programs; Arena's ability to obtain adequate funds; Arena's ability to obtain and defend its patents; and the timing and receipt of payments and fees, if any, from Arena's collaborators. Additional factors that could cause actual results to differ materially from those stated or implied by Arena's forward-looking statements are disclosed in Arena's filings with the Securities and Exchange Commission. These forward-looking statements represent Arena's judgment as of the time of this release. Arena disclaims any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

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EXHIBIT U

Moderator: Robert Hoffman
12-22-10/7:30 a.m. CT
Confirmation # 33963912
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Moderator: Robert Hoffman
December 22, 2010
7:30 a.m. CT

Operator: Good morning and welcome to the Arena Pharmaceuticals conference call. At this time I would like to turn the call over to Arena's Chief Financial Officer, Mr. Robert Hoffman. Please go ahead.

Robert Hoffman: Thank you. Good morning and welcome to Arena Pharmaceuticals conference call. I'm Robert Hoffman, Arena's Chief Financial Officer. Joining me on the call are Jack Lief our President and Chief Executive Officer, Dominic Behan our Chief Scientific Officer, Bill Shanahan our Chief Medical Officer and Christy Anderson our Vice President of Lorcaserin Development.

Before I turn the call over to Jack, I'd like to point out that we will make forward-looking statements during this conference call. Such forward-looking statements include statements about our views related to the complete response letter, discussions with the FDA, and potential resubmission of the Lorcaserin NDA, the process, timing, and outcomes of regulatory review, the potential approval and commercialization of Lorcaserin, (R and A) size strategy and plans, our internal and collaborative programs, financial guidance and other statements that are not historical facts.

Such statements include the words plan, will, expect, or similar words. You're cautioned to not place undue reliance on these forward-looking statements which are only predictions that reflect the company's beliefs, expectations, and assumptions based on currently available information, and speak only as of the time they are made.

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Risks and uncertainties that could cause actual results to differ materially from those described in our forward-looking statements include: regulatory authorities may not find data and other information related to our studies and trials sufficient for approval, the regulatory process is uncertain, our response to the CRL for the Lorcaserin NDA may not be submitted in a timely manner, or the information provided in such response may not satisfy the FDA.

The FDA may request additional information or have additional recommendations related to the Lorcaserin NDA, unexpected or unfavorable new data, decisions by (ASI) related to our marketing supply agreement, and the commercialization of Lorcaserin. The timing, results, and cost of clinical trials, pre-clinical studies, and research activities, our ability to obtain adequate funding, satisfactory resolution of litigation, and other risks identified in our (FCC) reports.

For a discussion of these and other factors, please refer to the risk factors described in our filings with the FCC. For forward-looking statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Now I'll turn the call over to our President and Chief Executive Officer, Jack Lief.

Jack Lief: Thanks Robert. Good morning, happy holidays and thank you for joining us. The purpose of this morning's call is to provide you with information regarding our plan to address the issues raised in the Lorcaserin complete response letter or CRL that we received from the FDA in October.

Following receipt of the CRL we requested an end of review meeting with the agency. Our goal for this meeting was to obtain additional clarity on the FDA's position and discuss our plans to respond to the CRL. We and (ASI) accomplished that goal. The discussions during the meeting, along with the FDA's written communication prior to the meeting, have provided us with further guidance and reinforced our position that we have a path forward to seek approval of Lorcaserin.

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We expect to receive the FDA meeting minutes in January but based on guidance we've received so far, we are already making progress on responding to the FDA's recommendations and expect to resubmit the Lorcaserin NDA by the end of 2011.

As we continue discussions with the FDA to refine elements of our plans, we may identify ways to shorten this timeline. The majority of our activities relate to the three non-clinical issues outlined in the CRL. (Dr. Anderson) will review these and other activities involved in addressing the CRL. Christy?

Christy Anderson: Thanks Jack. I will first summarize each of the three non-clinical topics that Jack mentioned. The first non-clinical issue was diagnostic uncertainty in the classification of mammary masses in female rats. As we discussed previously, we provided interim, preliminary tissue diagnoses from our two year rat carcinogenicity study to the FDA which will prepare while the study was being conducted in addition to the final peer review study report that was generated when this study was completed.

Some of the preliminary tissue diagnosis for mammary tumors differed from the spinal diagnoses in the study report. In particular, some mammary tumor types were re-characterized from benign to malignant and vice versa. To address this issue, we have already convened a pathology working group of five independent pathologists to review the relevant tissues from the rat carcinogenicity study and to re-adjudicate the diagnoses of female rat mammary tumors in a blinded fashion as requested by the agency. The agency has reviewed and agreed to our protocol.

The second non-clinical issue was an unresolved exposure response relationship for Lorcaserin emergent mammary adenocarcinoma. The FDA has asked that we demonstrate the mechanism by which Lorcaserin causes mammary tumors in rats and that this mechanism is reasonably irrelevant to human risk.

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Based on our discussions with the FDA, we believe that the agency accept that prolactin release, if demonstrated, is a viable mechanism for tumors in rats, and that prolactin mediated mammary tumors in rats are reasonably irrelevant to human risk.

We also note that the agency has previously accepted this mechanism for other drugs such as anti-psychotics that induce prolactin release and mammary tumors in rodents. To establish that Lorcaserin's effect on mammary tumors is prolactin mediated, the FDA has requested experimental evidence that demonstrates clear, persistent increases in prolactin in intact female rats at doses of Lorcaserin associated with mammary tumors in rats.

As you may recall, in the experiment submitted with the NDA, we demonstrated prolactin increases in female rats by controlling experimental variability using ovariectomized hormone replaced animals. With additional experimentation we've identified ways to control the sources of variability in measurement of prolactin in intact female rats and believe that we will be able to demonstrate persistent increases in serum prolactin in these animals. To address this issue we have initiated non-clinical studies to provide the requested evidence to the agency.

The third non-clinical issue was an unidentified mode of action and unclear safety margins for Lorcaserin emergent brain astrocytoma. This issue involves the observation of astrocytomas in the carcinogenicity study in male rats that received the highest doses of Lorcaserin. The agency asks that in the absence of information about the mechanism by which these tumors form, we clarify the safety margin in rats relative to humans.

In other words, the agency asks that we try to estimate the Lorcaserin concentrations in the human brain as compared to the rat brain. To address this issue we've initiated several non-clinical experiments. We also plan to initiate a small clinical study to enroll approximately ten volunteers who will be dosed with Lorcaserin for about a week followed by parallel cerebrospinal fluid and blood collection.

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Although Lorcaserin cannot be readily measured in the human brain, the concentration in cerebrospinal fluid, which can be measured, will provide an additional estimate of brain levels. We'd also like to discuss a labeling issue. This is one area where we plan to seek additional clarity. The FDA stated in the CRL that based on its review of the material submitted in the NDA, it would recommend placement of Lorcaserin in Schedule IV of the Controlled Substances Act.

The agency also communicated that completing certain pre-clinical studies and submitting data in our complete response will provide new information that will be reviewed and considered in the abuse potential assessment and final scheduling recommendation. We're preparing to initiate these studies pending additional discussions with the Controlled Substances staff.

Lastly the FDA requested that we submit the final study report for BLOOM-DM. Last month we announced top line results from this trial that we've shared with the agency and the final study report is now complete. The agency has stated that they will review the data when we submit our application and that the data will contribute to the agency's overall benefit-risk assessment of Lorcaserin.

Based on the BLOOM-DM results, we believe that Lorcaserin can help address the weight management treatment challenges of obese and overweight patients with Type 2 diabetes, and that the data supports the benefit-risk profile of Lorcaserin. We look forward to the FDA's review of the BLOOM-DM results and to presenting more detailed data at upcoming medical meetings. I will now turn the call back to Jack.

Jack Lief:

Thanks Christy. In summary, we are encouraged by the outcome of the end of review meeting. We have additional clarity on our next steps as we seek to obtain the FDA's approval of Lorcaserin.

We're confident that we have a path forward to pursue and look forward to continued collaboration with (ASI) along the way. Arena and (ASI) are committed to resubmitting a thorough response to the CRL as soon as

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James Birchenough: And just a follow up on the re-adjudication of the mammary masses.

There was obviously this reclassification from the interim reports to the final report. How do you get this diagnostics uncertainty? It seems like adenocarcinoma should be something that both pathologists can pick up. And what gives you confidence that the final report was really the accurate representation of adenocarcinoma burden? And following Bill's question, will you share that data as well?

Jack Lief: I'll let Bill Shanahan address that question.

Bill Shanahan: So with the carcinogenicity studies, we provided interim updates to the agency that were based on initial impressions by a single pathologist. And the working process at the CRO and in many CROs is that the data are the final peer review, the analysis. So this is based on a final analysis. And that's why there, in some cases, were some changes between the initial impression before the final peer review. And that's what's caused the issue.

Male: So just (inaudible) all be clear, we sent draft reports periodically to the agency while the study was going on. This is not a normal process but the agency requested this. We complied of course. And then the actual data is generated by the final peer reviewed process, which has a final report.

And now, we have this panel of five experts who have re-reviewed all of the data in a completely blinded fashion and are preparing such a report. So we'll have a very robust process and database to work off.

James Birchenough: OK, thanks guys.

Jack Lief: Sure.

Operator: Our next question comes from Carol Werther of SSRP. Please go ahead.

Carol Werther: Thank you. What scope of these additional trials? Are they going to be larger than what you did previously? And how can the process be speeded up?

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Jack Lief: Yes so as Christy mentioned, most of the work is pretty clinical. And you know we're in the process of finalizing the protocols and initiating studies. You know we hope as we progress we may identify opportunities to accelerate the timeline to file even quicker than the end of next year. But we'll see how that works out. Christy, do you have anything to add to that?

Christy Anderson: Sure I mean in making the estimate of timing we've included a lot of time for you know setting up contracts with various CROs, a lot of time for creating the documents. If we can accelerate the process of contracts and make our internal processes for creating the documents more efficient we can significantly contract the period of time that it'll take to make the submission.

Since we're only in the process now of identifying and contracting with CROs, we gave a pretty conservative estimate of how long these things will take. So within the next few weeks we'll have a much more accurate estimate of how long this whole process will take.

Jack Lief: But right now we feel very confident that we plan on re-filing at the end of 2011.

Carol Werther: So the duration of the trials is pretty short then?

Jack Lief: Yes.

Carol Werther: And did the agency ask you to look at any other animal species?

Jack Lief: No.

Carol Werther: OK. And can you just give us an idea of how expensive do you think these trials are going to be?

Jack Lief: Sure. So you know at this time we can provide a preliminary estimate of the external costs of the outlying activities. We don't think the cost will exceed a few million dollars. We'll provide financial guidance for next year on our

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fourth quarter conference call that will include our estimate of Arena's portion of the cost. I recall that we shared our costs with (ASI). Our guidance remains that we expect to end this year, 2010, with approximately \$150 million in cash.

Carol Werther: Thank you.

Operator: Our next question comes from Thomas Wei of Jefferies & Company. Please go ahead.

Thomas Wei: Thanks. I just wanted to follow-up on (Jim)'s question on what exactly the FDA has agreed on in terms of the prolactin elevation. So did they – did they agree that you know this prolactin elevation that occurs within the early maturity of the rats is sufficient to prove that there might be a rat memory tumor effect that's not relevant to humans? Did they – did they agree with this bromocriptine example that you raised?

Jack Lief: Dominic?

Dominic Behan: I was simply using that as an example in the literature, short-term exposure to prolactin appears to be very important. With the agency, we discussed a range of experimentation that would be appropriate for them to see persistent increases in prolactin.

So again, we're you know finalizing the protocols in that regard. We think all these experiments can be fit within the 2011 time frame and we'll have more clarity as we move forward. But that's what we're comfortable with and with communicating currently. The good news is I think we got a significant level of clarity in terms of what we need to achieve here.

Thomas Wei: And with whatever timeframe it is that you do end up running this study for, should it be interpreted as a failed trial if you show a transient increase early on in the dosing period but at the last study follow-up there's no prolactin elevation? Would that basically not meet with the FDA as laying out for you?

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Phil Nadeau: Yes, I think you know in general the diagnoses are clear, but we have to make sure that these changes for you know can be accommodated in the FDA's eyes. And with this final blinded review should provide a – there are five independent you know highly trained pathologists who are reviewing these slides independently. And that will give us I think a very accurate final accounting.

Jack Lief: And the agency has been very helpful in approving our protocols for the re-adjudication and that sort of thing. So this is all pretty clear for us.

Thomas Wei: Thanks.

Jack Lief: Sure.

Operator: Our next question comes from Steve Byrne of Bank of America. Please go ahead.

Steve Byrne: I was wondering if you'd discussed the BLOOM-DM data with the FDA and specifically whether or not they had any comments about the (inaudible) cases in the Lorcaserin treated patients.

Jack Lief: Yes, so I'll let Christy Anderson address that question.

Christy Anderson: We basically told the FDA that the BLOOM-DM data will be available to them in a study report very quickly. They told us at the (inaudible) review, the BLOOM-DM data when we provide the complete response. So they basically said it's a review issue.

We'll provide them the echo data in the same format that we provided with the other studies. The same analyses will be provided. In addition, the FDA asked that we provide the same integrated analyses that we provided in the (NDA) but that we include the BLOOM-DM data.

In addition, we will provide some more sophisticated integrated analyses where we basically pool the BLOOM, BLOSSOM and BLOOM-DM data and

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No. 14-55633

**UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT**

TODD SCHUENEMAN, on behalf of himself
and all others similarly situated,

Plaintiff-Appellant,

v.

ARENA PHARMACEUTICALS, INC., et al.,

Defendants-Appellees.

On Appeal from the United States District Court
for the Southern District of California
Hon. Cathy Ann Bencivengo
No. 3:10-cv-01959-CAB-BLM

**APPELLANT'S EXCERPTS OF RECORD
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ARENA PHARMACEUTICALS

Moderator: David Walsey
March 30, 2009
7:30 am CT

Operator: Good morning everyone, and welcome to Arena Pharmaceuticals' Lorcaserin BLOOM results conference call. This call is being recorded.

At this time for opening remarks and introductions, I would like to turn the call over to Arena's Senior Director of Corporate Communications, David Walsey. Mr. Walsey, please go ahead.

David Walsey: Thank you. Good morning everyone and thank you for joining our conference call today.

On today's call are Jack Lief, our CEO and President, Dominic Behan, our Senior Vice President and Chief Scientific Officer, Bill Shanahan, our Vice President and Chief Medical Officer, and (Kristy Anderson), our Vice President of Clinical Development.

Before we begin, I would like to point out that we will be making numerous forward-looking statements during this conference call. Such forward-looking statements include statements about our clinical trials and results, internal and partnered programs, drug candidate pipeline technologies, financial guidance, assumptions, strategy and other statements that are not historical facts. Such statements may include the words, plan, will, believe, expect, promise, potential, intent or similar words. You're cautioned to not place undue reliance on these forward-looking statements, which are only predications and reflect the company's beliefs, expectations

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and assumptions based on currently available operating, financial and competitive information and speak only as of the time they are made.

Risks and uncertainties that could cause actual results to differ materially from those described in our forward-looking statements include our ability to obtain funds, the timing, success and cost of our Lorcaserin program and other of our research and development programs, the results of clinical trials or pre-clinical studies may not be predictive of future results, the regulatory process of FDA approval, the timing and outcome of our partnership efforts, whether our assumptions prove to be correct and other risks are identified in our SEC reports.

For a discussion of these and other factors, please refer to the risk factors described in our annual report on Form 10-K for the year ended December 31, 2008 as well as other subsequent filings with the Securities and Exchange Commission. For forward-looking statements, we claim the protection of the Private Securities Litigation Reform Act of 1995.

I'd now like to turn the call over to Jack Lief.

Jack Lief: Thanks David. I'm extremely pleased to share with you the top line BLOOM data today. The press release has a lot of important information, and there are many positive findings. I'd like to focus on three points I think are important. After briefly reviewing these points, I'll turn the call over to Bill Shanahan, our Chief Medical Officer, to review some of the data. And then we will open the call to your questions.

First and foremost, the BLOOM trial met with high statistically – statistical significance all of the hierarchically ordered co-primary endpoints as well as the categorical efficacy benchmark in the FDA guidance.

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Second, BLOOM top line data showed Lorcaserin to be safe and very well tolerated. We met our pre-specified primary safety endpoint relating to cardiac safety. There was no evidence of a difference in the development of the valve disease in a large number of patients on Lorcaserin versus control over up to 2 years of continuous use. And, if the BLOOM results are confirmed in BLOSSOM, I think Lorcaserin is an approvable drug.

The third point I'd like to make is that the data shows Lorcaserin has the potential to become the first in a new class of weight management therapeutics that selectively target the serotonin 2C receptor. Obesity is a serious, widespread disease. And there is an urgent need for new treatment options appropriate for the majority of patients. The two currently approved drugs for chronic weight management have limitations, and patients need help managing their weight. Doctors and their patients need new options. And, to my knowledge, Lorcaserin is the only single agent in phase III development for weight management.

I'd now like to turn the call over to Bill.

Bill Shanahan: Thanks Jack. As a reminder, the BLOOM study evaluated 10 milligrams of Lorcaserin dosed twice daily in 3182 patients at approximately 100 sites in the United States over a 2-year period in obese patients with or without co-morbid conditions and overweight patients with at least one co-morbid condition.

I'd like to elaborate on Jack's three points noting the efficacy, tolerability and novelty of Lorcaserin. I'd first emphasize that we met all three parts of the hierarchical primary efficacy endpoints. All endpoints were evaluated using an ITT LOCF analysis, intent to treat, last observation carried forward.

In addition, the 5% categorical result achieved in BLOOM satisfied the efficacy benchmark for this criterion in the most recent FDA draft guidance. The FDA guidance provides that, in general, a

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product can be considered effective for weight management if, after 1 year, it achieves either of two endpoints, one of which is a categorical endpoint. That categorical endpoint is as follows. The proportion of subjects who lose greater than or equal to 5% of baseline body weight in the active product group is at least 35%, is approximately double the proportion in the placebo treated group, and the difference between groups is statistically significant.

The BLOOM results met this test. At week 52, almost half of Lorcaserin patients, 47.5% lost greater than or equal to 5% of their body weight from baseline compared to 20.3% in the placebo group. This is a medically important amount of weight loss.

The results relating to the other hierarchical endpoints, which were also met, were as follows. Twenty-two point six percent of Lorcaserin patients lost greater than or equal to 10% of their body weight from baseline compared to 7.7% in the placebo group. And, on average, patients taking Lorcaserin lost 12.7 pounds or 5.8% of their body weight compared to 4.7 pounds or 2.2% of body weight for patients taking placebo. Also notable is that Lorcaserin patients completing 52 weeks of treatment, according to the protocol, lost 17.9 pounds or 8.2% of their body weight compared to 7.3 pounds or 3.4% for placebo.

In addition to meeting the study's primary efficacy endpoints, treatment with Lorcaserin was associated with rapid weight loss. Statistically significant weight loss was observed by week two, the first post-baseline measurement.

Further, given the important role obesity plays in the development of co-morbidities, it is relevant that Lorcaserin also had a statistically significant effect on several key secondary endpoints, including improvements in total cholesterol, LDL cholesterol, triglycerides and blood pressure.

We were also pleased to note that at 2 years, patients continuing on Lorcaserin were better able to maintain more of their week 52 weight loss from year 1 than Lorcaserin patients re-randomized

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to placebo in year 2. Tolerability, no doubt, played a role in patients willing to stay on the study drug for as long as 2 years.

This takes us to our second point, Lorcaserin has the potential to be the best tolerated, weight management therapeutic. Weight management is often very difficult for patients. A well tolerated drug has the potential to make patient compliance easier and help patients better manage their weight. As expected, based on earlier data and Lorcaserin's selective mechanism, the top line data has not indicated any significant safety concerns. Adverse events of depression, anxiety and suicidal ideation were infrequent and reported at a similar rate in each treatment group. Serious adverse events occurred with similar frequency in each group throughout the trial without apparent relationship to Lorcaserin, and no seizures were recorded.

Importantly, the week 52 completion rate was 10% higher for patients on Lorcaserin compared to those on placebo. Discontinuations for adverse events and other reasons were similar. Completion rates for year 2 were similar across the treatment groups, as were discontinuations for adverse events.

Also very important from the safety perspective was that Lorcaserin met the primary safety endpoint of no significant differences in rates of valvulopathy at 12 months. In reviewing the echocardiographic data, there was no suggestion of a drug effect on the development of valve disease in a large number of patients continuously receiving Lorcaserin for up to 2 years. No perspective valvulopathy trial has ever studied this many patients for this period of time, particularly under such well controlled circumstances.

Assuming similar results in BLOSSOM, the integrated dataset from the (two) trials will be more than sufficiently large to rule out a 1.5 fold or greater risk of valvulopathy with 80% power, as requested by the FDA.

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I'd like to expand on the third point before turning the call back to Jack. Lorcaserin has the potential to become the first in a novel class of effective and very well tolerated weight management therapeutics that selectively target the serotonin 2C receptor. The medically important weight loss achieved, coupled with the tolerability profile shown in the trial differentiates Lorcaserin from other approved drugs or agents in clinical trials. I believe the BLOSSOM data will support our findings to date and allow us to submit a robust database to the FDA for its evaluation. Our submission will include phase III data from about 7200 patients studied for up to 2 years.

With that, I'll now turn the call back over to Jack.

Jack Lief: Thank you Bill. In summary, the BLOOM trial met the primary efficacy and safety endpoints as well as the categorical efficacy benchmark in the FDA guidance in a very well tolerated manner. If the BLOSSOM data are consistent with BLOOM, I believe Lorcaserin has the potential to become a first in a new class of effective and very well tolerated weight management therapeutics.

I would now like to turn the call over to your – to questions. Lori?

Operator: Certainly. If you would like to signal for a question at this time, please do so by pressing star 1 on your touch-tone telephone. And if you are on a speakerphone, please be sure your line is not muted so that your signal will reach us. Again, that is star 1 for questions.

And our first question is from Thomas Wei with Piper Jaffray.

Thomas Wei: Thanks. Just a couple of questions. One is – one is just maybe some perspective here to give – to give investors some comfort around what the commercial implications are of having an average weight loss of 3.6%.

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Jack Lief: So what we know is that patients stayed in our study very nicely on Lorcaserin. There was a huge excess of patients that wanted to stay in the study who were on Lorcaserin versus just on placebo. We did show that the weight management was better even the second year of patients staying on Lorcaserin versus placebo. We did show that there was no difference in valvulopathy in that second year between those patients. Again, this is – this is top line data, and you know you just have to wait until we get all of the data. We just got the data in this weekend, and we're really – we're really excited. We're really happy to share that – what we have with you.

Alan Carr: OK. One – can you – can you – I guess to follow on this a little bit more, can you tell me a bit more about what you think the FDA is looking for in the year 2 data?

Jack Lief: Well you know clearly the purpose of year 2 is to answer the question, "What happens after year 1?" What we know is that in year 2 patients continue to stay on Lorcaserin. There's a relatively low dropout rate. In fact, more than 3/4 of the patients that started year 2 on Lorcaserin finished year 2 on Lorcaserin. So that, I think, speaks for itself.

We also know that there's no increase in any heart valve disease. And we're not aware of any excess in other areas as well. So we're really thrilled that we have such a effective as well as safe compound. And obviously when we have more data, we plan on sharing that data. We hope to present a full dataset relatively soon, as soon as we published and present at a medically associated meeting. Bill?

Bill Shanahan: I would just add that with the most recent guidance, only 1 year of study is required. So, again, we're focusing on the 52-week endpoint, however, we believe that the data generated in year 2 adds significantly to our safety knowledge about the drug, and also that it may allow us to discuss weight maintenance in the – in the label. But we will have to talk to the FDA about this.

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Jack Lief: We don't believe that there's any numerical disadvantage in any of these important risk factors.

And, as you'll see when the full dataset is present, our drug will be very safe, well tolerated. I think there's a lot of information in the press release. I think over the 2 year period of time, as I said, more people lose more weight in a safer fashion on Lorcaserin. The heart valves, there's a slight increase in placebo versus drug. So clearly there is – there is no single there. I think the information we have from Dr. (Neil Weisman) is also consistent with that. And so I'm really happy that we have such a safe drug without the (CNS) or cardiovascular side effects that have plagued other drugs potentially in the past ...

Bret Holley: OK, thank you.

Jack Lief: ... ((inaudible)). My pleasure. We'll take the next question. Let's try and limit the questions to two per person.

Operator: And our next question is from Jason Zhang with BMO Capital Market. Please go ahead.

Jason Zhang: Yes, thanks for taking my questions. Two, so I will stick to that. Number one is a discontinuation. So for the Lorcaserin group you have 55 completed that suggest a 45% discontinuation, much better than the placebo. This is still pretty high, actually higher than I guess the Accomplia trial. So how do you – you know what do you think this is – this is reflecting? The real world situation? And do you worry about the high discontinuation rate in the trial? That's number one.

Number two, with the data now in hand, what's your plan for partnership discussion? Can you give us any you know heads up? And any philosophical change in terms of that? Or are you still going to try to find a partner as soon as possible?

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time. We had the statisticians working overtime to give us the top line data. And, as I said, we just got it this weekend. We've been able to review it. We're thrilled with the results that there's no doubt that we've met the FDA guidance in terms of both safety and efficacy. And we look forward to sharing even more information with you you know as it becomes available.

Jim Birchenough: But in terms of the question of whether the BLOSSOM data is showing the same pooled weight loss as BLOOM, can you comment on that?

Jack Lief: Bill, you want to comment on that?

Bill Shanahan: I think the only thing I'd like to comment on is that – is that you have to remember that you know that BLOOM is a very large trial and it's likely to be representative of the data you will see in subsequent trials. We primarily look at safety, and that's what – you know and again we're getting support for the excellent safety profile of the drug.

Jim Birchenough: And just – I just want to clarify, it's not really a question, but the, for valvulopathy, the 12-month assessment was the specified primary? And there is a numerical imbalance between Lorcaserin and placebo, but you're not giving (up) the confidence (then well) at this time, am I getting that right?

Jack Lief: That's absolutely not correct. You know your perception is we've reported the absolute numbers in terms of the rates of valvulopathy in our study, in the press release. Keep in mind that there were more patients on Lorcaserin that finished the study than on placebo. So the absolute numbers would be reflective in the larger number of patients that finished the study. And you can see how the rates of valvulopathy changed at each of the 6 month time points that patients came into the study such that we're confident that the FDA is not going to have a problem with valvulopathy for Lorcaserin. There's no evidence at all of any signal whatsoever for cardiovascular risk in valvulopathy.

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Arena Pharmaceuticals Announces First Quarter 2009 Financial Results

SAN DIEGO, May 11, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) today reported financial results for the first quarter ended March 31, 2009.

Arena reported a net loss allocable to common stockholders in the first quarter of 2009 of \$50.6 million, or \$0.68 per share, compared to a net loss allocable to common stockholders in the first quarter of 2008 of \$55.0 million, or \$0.75 per share.

"Receiving the positive lorcaserin BLOOM results was a significant milestone for Arena, and we are focusing our financial, management and development resources on completing the lorcaserin BLOSSOM trial on schedule and submitting our New Drug Application for lorcaserin by the end of the year," stated Jack Lief, Arena's President and Chief Executive Officer. "Given the challenging economic environment, we made the difficult decision to reduce the number of employees and limit our research programs to provide additional financial flexibility for this primary objective."

"As previously announced, during the first year of the BLOOM trial, 47.5% of lorcaserin patients lost 5% or more of their body weight from baseline, compared to 20.3% in the placebo group, exceeding the efficacy benchmark in the most recent FDA draft guidance," stated William R. Shanahan, M.D., Arena's Vice President and Chief Medical Officer. "Patients on lorcaserin rapidly lost a medically important amount of weight in a well-tolerated manner, with about one-third losing at least 5% of their body weight in only eight weeks. Lorcaserin helped nearly half of the patients to lose at least 5% of their body weight, and nearly a quarter to lose 10% or more of their body weight. We look forward to presenting these and additional data at the upcoming American Diabetes Association meeting in June."

As expected, research and development expenses, which totaled \$42.6 million in the first quarter of 2009, declined from \$47.4 million in the first quarter of 2008. This decrease in research and development expenses is primarily attributable to decreased clinical trial costs due to the completion of clinical and preclinical studies as Arena prioritized its spending towards the completion of trials for lorcaserin. Research and development expenses are expected to continue to significantly decline throughout the year as the lorcaserin pivotal Phase 3 studies complete. Research and development expenses included \$0.9 million in non-cash, share-based compensation expense in the quarter ended March 31, 2009, compared to \$1.0 million in the quarter ended March 31, 2008. General and administrative expenses totaled \$7.6 million in the first quarter of 2009, compared to \$8.9 million in the first quarter of 2008. This decrease in general and administrative expenses is primarily attributable to decreased patent costs. General and administrative expenses in the first quarter of 2009 included \$1.1 million in non-cash, share-based compensation expense, compared to \$1.4 million in the first quarter of 2008.

At March 31, 2009, cash, cash equivalents and short-term investments totaled \$70.3 million and approximately 74.3 million shares of common stock were outstanding.

In April 2009, Arena received aggregate net proceeds of \$14.6 million from the sale of approximately 5.7 million shares under a \$50.0 million equity financing commitment entered into in March 2009 with Azimuth Opportunity Ltd., or Azimuth.

Arena's First Quarter and Recent Developments

- Abstract accepted for presentation of data from BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management), the first of two pivotal trials evaluating the safety and efficacy of lorcaserin for weight management, at the 69th Scientific Sessions of the American Diabetes Association scheduled for June 5-9, 2009 in New Orleans, Louisiana.
- Announced positive top-line results from BLOOM. Lorcaserin was highly efficacious, achieving statistical significance ($p < 0.0001$ vs. placebo) on all three co-primary efficacy endpoints ($>5\%$ categorical, absolute, and $>10\%$ categorical weight loss). The BLOOM results also

satisfy the efficacy benchmark in the most recent US Food and Drug Administration, or FDA, draft guidance for the development of drugs for weight management. Treatment with lorcaserin was generally very well tolerated. Lorcaserin treatment for up to two years was not associated with evidence of heart valve damage; rates for the development of echocardiographic FDA-defined valvulopathy were similar to placebo throughout the study. Arena is on track to report results from the second pivotal trial, BLOSSOM (Behavioral modification and Lorcaserin Second Study for Obesity Management), by the end of September 2009.

- Committed to a reduction in Arena's US workforce of approximately 31%, or a total of approximately 130 employees, which is expected to be substantially completed by June 22, 2009. As a result of this workforce reduction, Arena expects to incur cash charges, primarily in the second quarter of 2009, of approximately \$3.0 million in connection with one-time employee termination costs, including severance and other benefits. This workforce reduction is expected to result in annual operating cost savings of approximately \$25.0 million.
- Received aggregate net proceeds of \$14.6 million under a \$50.0 million equity financing commitment entered into in March 2009 with Azimuth. During the 18-month term of the equity financing commitment, Arena may sell newly issued registered shares of its common stock to Azimuth at a pre-negotiated discount to the market price.
- Received net proceeds of \$14.6 million as reimbursement for improvements made to one of Arena's facilities.
- Announced the completion of a positive randomized, double-blind, placebo-controlled Phase 1 program and the initiation of a Phase 2 clinical trial of a second generation oral niacin receptor agonist intended for the treatment of atherosclerosis in Arena's partnership with Merck.

Scheduled Earnings Call

Arena will host both a conference call and webcast to discuss the first quarter 2009 financial results and to provide a business and financial update today, Monday, May 11, 2009, at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). Jack Lief, President and Chief Executive Officer and Robert E. Hoffman, Vice President, Finance and Chief Financial Officer will host the conference call.

The conference call may be accessed by dialing 877.857.6151 for domestic callers and 719.325.4806 for international callers. Please specify to the operator that you would like to join the "Arena Pharmaceuticals First Quarter 2009 Earnings Call." The conference call will be webcast live under the investor relations section of Arena's website at www.arenapharm.com, and will be archived there for 30 days following the call. Please connect to Arena's website several minutes prior to the start of the broadcast to ensure adequate time for any software download that may be necessary.

Upcoming Corporate Presentations

Arena is planning to present at upcoming investment and industry conferences, including:

- The 34th Annual Deutsche Bank Health Care Conference, May 18-19, 2009, Boston, Massachusetts
- The 8th Annual Needham Life Sciences Conference, June 10-11, 2009, New

York, New York

About Arena Pharmaceuticals

Arena is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing oral drugs in four major therapeutic areas: cardiovascular, central nervous system, inflammatory and metabolic diseases. Arena's most advanced drug candidate, lorcaserin, is being investigated in a Phase 3 clinical trial program for weight management. Arena's broad pipeline of novel compounds target G protein-coupled receptors, an important class of validated drug targets, and includes compounds being evaluated independently and with partners, including Merck & Co., Inc., and Ortho-McNeil-Janssen Pharmaceuticals, Inc.

Arena Pharmaceuticals® and Arena® are registered service marks of the company. "APD" is an abbreviation for Arena Pharmaceuticals Development.

Forward-Looking Statements

Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include statements about the significance of the BLOOM results; future research and development focus and plans; future activities, results and announcements relating to lorcaserin, including with regard to the BLOSSOM trial and the submission of a New Drug Application for lorcaserin; the development, therapeutic indication, tolerability, safety, selectivity, efficacy and potential of lorcaserin; the protocol, design, scope, and other aspects of the lorcaserin trials; the potential of lorcaserin to meet the FDA's requirements for approval; the impact of weight loss on health; the significance of the review of echocardiographic data and lorcaserin's effect on the development of FDA-defined valvulopathy; the decline of Arena's research and development expenses; the planned reduction of Arena's workforce, including the expected size, timing, related charges and savings, and other expected impact of such reduction; Arena's ability to raise additional funds, including through its agreement with Azimuth; and about Arena's strategy, internal and partnered programs, and ability to develop compounds and commercialize drugs. For such statements, Arena claims the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from Arena's expectations. Factors that could cause actual results to differ materially from the forward-looking statements include, but are not limited to, Arena's ability to obtain additional funds, the timing, success and cost of Arena's lorcaserin program and other of its research and development programs, the charges related to the recent reduction in Arena's workforce may be greater than anticipated, Arena may not realize the savings expected from this reduction, results of clinical trials or preclinical studies may not be predictive of future results, clinical trials and studies may not proceed at the time or in the manner Arena expects or at all, Arena's ability to partner lorcaserin or other of its compounds or programs, the timing and ability of Arena to receive regulatory approval for its drug candidates, Arena's ability to obtain and defend its patents, and the timing and receipt of payments and fees, if any, from Arena's collaborators. Additional factors that could cause actual results to differ materially from those stated or implied by Arena's forward-looking statements are disclosed in Arena's filings with the Securities and Exchange Commission. These forward-looking statements represent Arena's judgment as of the time of this release. Arena disclaims any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

<p>Contacts: Jack Lief President and Chief Executive Officer Cindy McGee Senior Communications Associate</p>	<p>Mary Claire Duch WeissComm Partners Media Relations 212.301.7228</p>
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Arena Pharmaceuticals, Inc.
858.453.7200, ext. 1479

Arena Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations
(In thousands, except per share amounts)

	Three months ended March 31,	
	2009	2008
	(unaudited)	
Revenues		
Manufacturing services	\$1,418	\$2,019
Collaborative agreements	1,240	590

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Total revenues	2,658	2,609
Operating Expenses		
Cost of manufacturing services	1,354	2,330
Research and development	42,620	47,368
General and administrative	7,642	8,861
Amortization of acquired technology and other intangibles	566	581
Total operating expenses	52,182	59,140
Interest and other income (expense), net	(1,090)	2,066
Net loss	(50,614)	(54,465)
Dividends on redeemable convertible preferred stock	-	(540)
Net loss allocable to common stockholders	\$(50,614)	\$(55,005)
Net loss per share allocable to common stockholders, basic and diluted	\$(0.68)	\$(0.75)
Shares used in calculating net loss per share allocable to common stockholders, basic and diluted	74,189	73,605

Arena Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheet Data
(In thousands)

	March 31, 2009 (unaudited)	December 31, 2008 (Note)
Assets		
Cash, cash equivalents and short-term investments	\$70,257	\$110,129
Accounts receivable	1,795	1,823
Other current assets	3,898	5,031
Land, property and equipment, net	99,028	102,740
Acquired technology and other non-current assets	20,533	21,608
Total assets	\$195,511	\$241,331
Liabilities and Stockholders' Equity		
Accounts payable, accrued liabilities and warrant liability	\$39,315	\$46,789
Total deferred revenues	4,049	4,049
Total lease financing obligations and other long-term liabilities	87,155	72,861
Total stockholders' equity	64,992	117,632
Total liabilities and stockholders' equity	\$195,511	\$241,331

Note: The Condensed Consolidated Balance Sheet Data has been derived from the audited financial statements as of that date.

SOURCE Arena Pharmaceuticals, Inc.

<http://www.arenapharm.com>

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EXHIBIT AB



Arena Pharmaceuticals Announces Lorcaserin Data Demonstrating Highly Significant Categorical and Absolute Weight Loss and Improvements in Secondary Endpoints Associated with Cardiovascular Risk

-- Late-Breaking Data from Pivotal BLOOM Trial Presented at the American Diabetes Association's 69th Scientific Sessions Expand on Previously Announced Positive Top-Line Results -

NEW ORLEANS, June 6, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) announced today a late-breaking poster presentation of positive results from BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management), the first of two pivotal trials evaluating the safety and efficacy of lorcaserin for weight management, at the American Diabetes Association's 69th Scientific Sessions. Lorcaserin patients achieved highly significant categorical and absolute weight loss in Year 1, and continued treatment with lorcaserin in Year 2 helped significantly more patients maintain their weight loss as compared to those on placebo. Treatment with lorcaserin also resulted in highly significant improvements as compared to placebo in multiple secondary endpoints associated with cardiovascular risk. Lorcaserin did not result in increased risk of depression and was not associated with the development of cardiac valvular insufficiency.

Previously announced BLOOM data demonstrated that lorcaserin was highly efficacious, achieving statistical significance on all three co-primary efficacy endpoints, and was very well tolerated. The BLOOM results also satisfy the efficacy requirement in the most recent US Food and Drug Administration, or FDA, draft guidance for the development of drugs for weight management.

"These data provide reason for new optimism for the millions of people who struggle with managing their weight and are in need of novel, well tolerated treatments to help improve their overall health," said Steven R. Smith, M.D., Co-Principal Investigator and Professor and Assistant Director for Clinical Research at the Pennington Biomedical Research Center. "Lorcaserin's positive impact on multiple secondary measures has important implications for improving co-morbidities associated with excess weight and further demonstrates the medically significant benefits of 5% or more weight loss, a mark two-thirds of the lorcaserin patients who completed the BLOOM trial achieved."

"Given the positive lorcaserin BLOOM results, we are focused on partnering efforts and realizing lorcaserin's significant commercial potential," stated Jack Lief, Arena's President and Chief Executive Officer.

Per Protocol Efficacy

In addition to supporting the previously announced results on all three co-primary endpoints on an intent-to-treat, last observation carried forward (ITT-LOCF) basis, the data presented today demonstrated strong efficacy in patients who completed one year of treatment according to the trial's protocol. In the per protocol population, nearly two-thirds (66.4%) of lorcaserin patients lost at least 5% of their weight compared to 32.1% of patients on placebo ($p < 0.0001$), and over one-third (36.2%) of lorcaserin patients lost at least 10% of their weight compared to 13.6% for placebo ($p < 0.0001$). The average weight loss in this population was 17.9 pounds in the lorcaserin group, compared to 7.4 pounds in the placebo group. Patients randomized to remain on lorcaserin for Year 2 maintained a significantly greater amount of weight loss compared to the lorcaserin patients who switched to placebo at Week 52 in both the ITT-LOCF and per protocol populations.

Secondary Endpoint Analysis

New data demonstrate that treatment with lorcaserin over one year was associated with highly significant improvements compared to placebo in multiple secondary endpoints associated with cardiovascular risk, including:

- Blood Pressure: systolic blood pressure, diastolic blood pressure and heart rate
- Lipids: total cholesterol, LDL cholesterol and triglycerides
- Glycemic Parameters: fasting glucose, fasting insulin and insulin resistance

-- Inflammatory Markers of Cardiovascular Risk: high-sensitivity CRP and fibrinogen

Quality of Life, as assessed by the Impact of Weight Questionnaire - Lite, also improved to a significantly greater extent in the lorcaserin group than the placebo group at Week 52.

"We are pleased to present the BLOOM data in a scientific forum. In this trial, lorcaserin helped patients rapidly lose weight and keep it off in a well-tolerated manner," said William R. Shanahan, M.D., Arena's Vice President and Chief Medical Officer. "We believe that lorcaserin's overall safety profile along with the significant improvements seen in important secondary endpoints associated with cardiovascular risk will be supportive of the approval process. We look forward to announcing our BLOSSOM data in September and completing our NDA submission by the end of the year."

Safety and Tolerability Profile

Lorcaserin was very well tolerated. Discontinuation rates for adverse events were similar in the lorcaserin and placebo groups for Year 1 and Year 2 (7.1% vs. 6.7% and 3.0% vs. 3.0%, respectively).

In addition to the previously announced tolerability data, today's presentation also reported that lorcaserin demonstrated no increase in depression or suicidal ideation compared to placebo. Depression adverse events were measured using a Standard MedDRA Query for adverse event terms related to depression (e.g. depression, depressed mood, crying, decreased interest, etc.). Overall, the rate of depression-related events was low and rates were comparable in patients who took lorcaserin and placebo. Suicidal ideation was prospectively evaluated by administration of the Beck Depression Inventory-II. Overall, the rate of suicidal ideation was low and similar numbers of patients on lorcaserin and placebo reported suicidal thoughts during Year 1 and Year 2.

Cardiovascular Safety

Using an LOCF analysis for each year, the assessment of echocardiograms performed at baseline and after patients completed 6, 12, 18 and 24 months of dosing indicated that lorcaserin was not associated with valvular insufficiency: during two years of use, rates of change in individual regurgitant scores and the development of FDA-defined valvulopathy (moderate or greater mitral insufficiency and/or mild or greater aortic insufficiency) were similar between treatment groups.

Lorcaserin met the primary safety endpoint of no significant difference in rates of valvulopathy at 12 months. Rates of valvulopathy at 6, 12, 18 and 24 months for lorcaserin versus placebo were 2.1% vs. 1.9% ($p=0.88$), 2.7% vs. 2.3% ($p=0.70$), 2.9% vs. 3.1% ($p=0.86$) and 2.6% vs. 2.7% ($p=1.00$). At 18 and 24 months, rates of valvulopathy for lorcaserin patients crossing over to placebo were 3.6% and 1.9%, respectively.

In addition, similar numbers of mitral insufficiency shifts and aortic insufficiency shifts in Year 1 and Year 2 were reported for patients on lorcaserin and placebo.

The FDA previously requested that Arena rule out a 1.5-fold or greater risk of valvulopathy with 80% power. Assuming similar results in Arena's final pivotal trial, BLOSSOM (Behavioral modification and Lorcaserin Second Study for Obesity Management), the integrated data set from the two trials will be more than sufficiently large to meet this requirement.

BLOOM Trial Design

BLOOM, the first of three lorcaserin Phase 3 trials, is a double-blind, randomized, placebo-controlled trial involving 3,182 patients in approximately 100 sites in the US. The trial evaluated 10 mg of lorcaserin dosed twice daily versus placebo over a two-year treatment period in obese patients (Body Mass Index, or BMI, 30 to 45) with or without co-morbid conditions and overweight patients (BMI 27 to less than 30) with at least one co-morbid condition. The trial did not include any dose titration or run-in period. Patients were randomized in a 1:1 ratio to lorcaserin or placebo at baseline. At Week 52, 856 patients taking lorcaserin were re-randomized in a 2:1 ratio to continue lorcaserin or to switch to placebo, and 697 patients on placebo were continued on placebo. Patients received echocardiograms at screening, and at 6, 12, 18 and 24 months after initiating dosing in the trial; patients with FDA-defined valvulopathy were excluded from enrolling in the trial.

Phase 3 Program Overview

The Phase 3 program consists of three trials, BLOOM, BLOSSOM and BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus), and is planned to enroll a total of approximately 7,800 patients. BLOOM and BLOSSOM comprise the Phase 3 pivotal registration program. BLOSSOM has enrolled 4,008 patients and is evaluating 10 mg of lorcaserin dosed once or twice daily versus placebo over a one-year treatment period in obese patients with or without co-morbid conditions and overweight patients with at least one co-morbid condition at about 100 sites in the US.

BLOOM-DM is expected to complete enrollment around the end of June and is evaluating 10 mg of lorcaserin dosed once or twice daily versus placebo over a one-year treatment period in obese and overweight patients with type 2 diabetes at about 60 sites in the US. Approximately 600 patients are expected to be enrolled in BLOOM-DM, which is planned as a supplement to the lorcaserin NDA.

A standardized program of moderate diet and exercise guidance is included in the Phase 3 program. The program's hierarchically ordered co-primary efficacy endpoints are: the proportion of patients achieving 5% or greater weight loss after 12 months, the difference in mean weight loss compared to placebo after 12 months, and the proportion of patients achieving 10% or greater weight loss after 12 months. Arena is also studying several key secondary endpoints, including changes in serum lipids, markers of inflammation and insulin resistance, and in the BLOOM-DM trial, other indicators of glycemic control. In BLOSSOM and BLOOM-DM all patients will receive echocardiograms at baseline, at month 6, and at the end of the study to assess heart valve function over time. In contrast to the BLOOM trial, however, there are no echocardiographic exclusion criteria for entry into these trials and there is no monitoring by an independent board.

About Lorcaserin

Lorcaserin is a novel single agent that represents the first in a new class of selective serotonin 2C receptor agonists. The serotonin 2C receptor is located in areas of the brain involved in the control of appetite and metabolism, such as the hypothalamus. Stimulation of this receptor is strongly associated with feeding behavior and satiety. Lorcaserin is currently being evaluated in a Phase 3 program expected to enroll approximately 7,800 patients and potentially represents a targeted treatment option for the millions of patients who need to better manage their weight. Arena has patents that cover lorcaserin in the US and other jurisdictions, which in most cases are capable of continuing into 2023 without taking into account any patent term extensions or other exclusivity Arena might obtain.

About Obesity

The National Institutes of Health reported in 2007 that about 65% of US adults are overweight or obese. Medical and related costs of obesity to the US are \$123 billion per year according to a 2005 report by the International Diabetes Federation. Studies have shown that weight loss of 5% to 10% is medically significant and results in meaningful improvements in cardiovascular risk factors and a significant reduction in the incidence of type 2 diabetes. Diet and exercise should form the basis of healthy weight loss, but pharmaceutical treatment options for obesity are currently limited for the many patients that require additional help in achieving and maintaining medically important weight loss.

About the FDA Draft Guidance

The FDA draft guidance document for developing products for weight management dated February 2007 provides recommendations regarding the development of drugs for the indication of weight management. It contains two alternate efficacy benchmarks, only one of which needs to be met for approval. The guidance provides that, in general, a product can be considered effective for weight management if after one year of treatment either of the following occurs: (1) the difference in mean weight loss between the active-product and placebo-treated groups is at least 5% and the difference is statistically significant, or (2) the proportion of subjects who lose greater than or equal to 5% of baseline body weight in the active-product group is at least 35%, is approximately double the proportion in the placebo-treated group, and the difference between groups is statistically significant.

About Arena Pharmaceuticals

Arena is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing oral drugs in four major therapeutic areas: cardiovascular, central nervous system, inflammatory and metabolic diseases. Arena's most advanced drug candidate, lorcaserin, is being investigated in a Phase 3 clinical trial program for weight management. Arena's broad pipeline of novel compounds target G protein-coupled receptors, an important class of validated drug targets, and includes compounds being evaluated independently and with partners, including Merck & Co., Inc., and Ortho-McNeil-Janssen Pharmaceuticals, Inc.

Arena Pharmaceuticals(R) and Arena(R) are registered service marks of the company. "APD" is an abbreviation for Arena Pharmaceuticals Development.

Forward-Looking Statements

Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include statements about the BLOOM results; the development, advancement, therapeutic indication, tolerability, safety, selectivity and efficacy of lorcaserin; the FDA's guidance, process and requirements; the potential of the lorcaserin Phase 3 program and its results to meet the FDA's approval requirements, including with regard to assessing the risk of developing valvulopathy; the approval of lorcaserin for marketing; lorcaserin's partnering, commercial and other

potential; the protocol, design, scope, enrollment and other aspects of the lorcaserin trials; future activities, results and announcements relating to lorcaserin, including the BLOSSOM results, the submission of an NDA for lorcaserin and the submission of the BLOOM-DM results as a supplement to the NDA; the potential of lorcaserin in managing weight, improving health and generating patient interest; the impact of weight loss on health, including improving co-morbidities and providing other medically significant benefits; lorcaserin's patent coverage; and Arena's focus, strategy, internal and partnered programs, and ability to develop compounds and commercialize drugs. For such statements, Arena claims the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from Arena's expectations. Factors that could cause actual results to differ materially from the forward-looking statements include, but are not limited to, Arena's ability to obtain additional funds; the timing, success and cost of Arena's lorcaserin program and other of its research and development programs; results of clinical trials or preclinical studies may not be predictive of future results; clinical trials and studies may not proceed at the time or in the manner Arena expects or at all; Arena's ability to partner lorcaserin or other of its compounds or programs; the timing and ability of Arena to receive regulatory approval for its drug candidates; Arena's ability to obtain and defend its patents; and the timing and receipt of payments and fees, if any, from Arena's collaborators. Additional factors that could cause actual results to differ materially from those stated or implied by Arena's forward-looking statements are disclosed in Arena's filings with the Securities and Exchange Commission. These forward-looking statements represent Arena's judgment as of the time of this release. Arena disclaims any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2009

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 000-31161

ARENA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or
organization)

23-2908305

(I.R.S. Employer Identification No.)

6166 Nancy Ridge Drive, San Diego, CA
(Address of principal executive offices)

92121
(Zip Code)

858.453.7200

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company.

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐

Smaller reporting company ☐

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

☐ Yes ☒ No

The number of shares of common stock outstanding as of the close of business on August 5, 2009:

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identified in our SEC reports, including this Quarterly Report. In addition, past financial or operating performance is not necessarily a reliable indicator of future performance, and you should not use our historical performance to anticipate results or future period trends. We can give no assurances that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our results of operations and financial condition. Except as required by law, we undertake no obligation to update publicly or revise our forward-looking statements.

OVERVIEW AND RECENT DEVELOPMENTS

We are a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing oral drugs in four major therapeutic areas: cardiovascular, central nervous system, inflammatory and metabolic diseases. Our most advanced drug candidate, lorcaserin hydrochloride, or lorcaserin, is being investigated in a Phase 3 clinical trial program for weight management. We have a broad pipeline of novel compounds targeting G protein-coupled receptors, or GPCRs, an important class of validated drug targets, which includes compounds being evaluated independently and with partners, including Merck & Co., Inc., or Merck, and Ortho-McNeil-Janssen Pharmaceuticals, Inc., or Ortho-McNeil-Janssen. We incorporated on April 14, 1997 in the state of Delaware and commenced operations in July 1997.

Our recent developments include:

- Completed dosing in all clinical trials expected to be included in the planned New Drug Application, or NDA, submission for lorcaserin. We plan to report results from BLOSSOM (Behavioral modification and Lorcaserin Second Study for Obesity Management), the second of two pivotal trials evaluating the safety and efficacy of lorcaserin for weight management, in September 2009.
- Completed enrollment in BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus), a one-year study evaluating lorcaserin in obese and overweight patients with type 2 diabetes. Results from BLOOM-DM will be submitted as a supplement to the lorcaserin NDA filing.
- Announced a late-breaking poster presentation of positive results from BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management), the first of two pivotal trials evaluating the safety and efficacy of lorcaserin for weight management, at the 69th Scientific Sessions of the American Diabetes Association. Lorcaserin patients achieved highly significant categorical and absolute weight loss in Year 1, and continued treatment with lorcaserin in Year 2 helped significantly more patients maintain their weight loss as compared to those on placebo. 66.4% of lorcaserin patients who completed one year of treatment according to the trial's protocol lost at least 5% of their weight and the average weight loss in this responder population was 26 pounds. Treatment with lorcaserin also resulted in highly significant improvements as compared to placebo in multiple secondary endpoints associated with cardiovascular risk. Lorcaserin was very well tolerated, did not result in increased risk of depression and was not associated with development of cardiac valvular insufficiency.
- Ortho-McNeil-Janssen completed a Phase 1 clinical trial evaluating the safety, tolerability, pharmacokinetics and pharmacodynamics of a single ascending dose of APD597 for the treatment of type 2 diabetes in healthy volunteers. Ortho-McNeil-Janssen has initiated another clinical trial evaluating multiple ascending doses of APD597.
- Completed a public offering of 12.5 million shares of our common stock, resulting in net proceeds of approximately \$49.7 million.
- Received net proceeds of \$95.6 million from a \$100.0 million secured loan provided by Deerfield Management. The outstanding principal accrues interest until maturity in June 2013 at a rate of 7.75% per annum. In connection with the loan, we issued Deerfield warrants for 28,000,000 shares of our common stock at an exercise price of \$5.42 per share. On or before June 17, 2011, Deerfield may make a one-time election to loan us up to an additional \$20.0 million under the same terms, with the additional loan also maturing in June 2013. For each additional \$1.0 million in funding, we will issue Deerfield warrants for 280,000 shares of our common stock at an exercise price of \$5.42 per share. We repaid Deerfield the first scheduled principal repayment of \$10.0 million upon completion of our public offering in July.

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- Received aggregate net proceeds of \$14.7 million from the sale of approximately 5.7 million shares of common stock under a \$50.0 million equity financing commitment with Azimuth Opportunity Ltd, or Azimuth. During the 18-month term of the equity financing commitment, we may sell newly issued registered shares of our common stock to Azimuth at a pre-negotiated discount to the market price.
- Completed a reduction of our US workforce of approximately 31%, or a total of approximately 130 employees.

RESULTS OF OPERATIONS

We are providing the following summary of our revenues, research and development expenses and general and administrative expenses to supplement the more detailed discussion below. The following tables are stated in millions.

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The determination of the grant-date fair value of share-based awards using the Black-Scholes option pricing model is based on the exercise price of the award and the fair market value of our stock price on the date of grant, as well as assumptions for expected volatility, the expected life of options granted and the risk-free interest rate. Changes in the assumptions can have a material impact on the compensation expense we recognize. Expected volatility for awards granted after adoption of SFAS No. 123R is based on a combination of 75% historical volatility of our common stock and 25% market-based implied volatilities from traded options on our common stock, with historical volatility being more heavily weighted due to the low volume of traded options on our common stock. The expected life of options granted under SFAS No. 123R is determined based on historical experience of similar awards, giving consideration to the contractual terms of the share-based awards, vesting schedules and post-vesting cancellations. The risk-free interest rates are based on the US Treasury yield curve, with a remaining term approximately equal to the expected term used in the option pricing model.

As compensation expense recognized is based on awards ultimately expected to vest, it is reduced for estimated forfeitures. SFAS No. 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. If actual forfeitures vary from estimates, we will recognize the difference in compensation expense in the period the actual forfeitures occur or when options vest.

Accounting for lease financing obligations. We have accounted for our sale and leaseback transactions in accordance with SFAS Nos. 66 and 98. Our option to repurchase these properties in the future is considered continued involvement under SFAS No. 66 and, therefore, we have applied the financing method under SFAS No. 98. Under the financing method, the book value of the properties and related accumulated depreciation remain on our balance sheet and no sale is recognized. Instead, the sales price of the properties is recorded as a financing obligation, and a portion of each lease payment is recorded as interest expense. We estimated the borrowing rate that we use to impute interest expense on our lease payments.

The above listing is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by GAAP. See our audited consolidated financial statements and notes thereto included in our 2008 Annual Report, which contain additional accounting policies and other disclosures required by GAAP.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

There have been no material changes from the information we included in this section of our annual report on Form 10-K for the year ended December 31, 2008.

Item 4. Controls and Procedures.

Based on an evaluation carried out as of the end of the period covered by this quarterly report, under the supervision and with the participation of our management, including our Chief Executive Officer and Vice President, Finance and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures, our Chief Executive Officer and Vice President, Finance and Chief Financial Officer have concluded that, as of the end of such period, our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934) were effective. There was no change in our internal control over financial reporting that occurred during the quarter covered by this quarterly report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION**Item 1A. Risk Factors.****RISK FACTORS**

Investment in our stock involves a high degree of risk. You should consider carefully the risks described below, together with other information in this quarterly report on Form 10-Q and our other public filings, before making investment decisions regarding our stock. If any of the following events actually occur, our business, operating results, prospects or financial condition could be materially and adversely affected. This could cause the trading price of our common stock to decline and you may lose all or part of your investment.

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Moreover, the risks described below are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business, operating results, prospects or financial condition.

The risk factors set forth below with an asterisk () before the title are new risk factors or risk factors containing substantive changes, including any material changes, from the risk factors previously disclosed in Item 1A to Part I of our annual report on Form 10-K for the year ended December 31, 2008, as filed with the Securities and Exchange Commission.*

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Table of Contents***Risks Relating to Our Business***

***We will need additional funds to conduct our planned research and development efforts, we may not be able to obtain such funds and may never become profitable.**

We have accumulated a large deficit since inception that has primarily resulted from the significant research and development expenditures we have made in seeking to identify and validate new drug targets and develop compounds that could become marketed drugs. We expect that our losses will continue to be substantial for at least the next several years and that our operating expenses will also continue to be substantial, even if we or our collaborators are successful in advancing our compounds or partnered compounds.

We do not have any commercially available drugs, and we have substantially less money than we need to develop our compounds into marketed drugs. It takes many years and potentially hundreds of millions of dollars to successfully develop a preclinical or early clinical compound into a marketed drug, and our efforts may not result in any marketed drugs.

We will need additional funds or a partner to bring our most advanced drug candidate, lorcaserin, to market, if ever, and we may not be able to secure adequate funding or find an acceptable partner at all or on terms you or we believe are favorable. We also believe that due to global economic challenges, and as our cash balances decline, it may be difficult for us to obtain additional financing or enter into strategic relationships on terms acceptable to us, if at all. If additional funding is not available, we will have to eliminate or further postpone or scale back some or all of our research or development programs or delay the development of one or more of such programs, including our lorcaserin program.

The current global economic environment poses severe challenges to our business strategy, which relies on access to capital from the markets and our collaborators, and creates other financial risks for us.

The global economy, including credit markets and the financial services industry, has been experiencing a period of substantial turmoil and uncertainty. These conditions have generally made equity and debt financing more difficult to obtain, and may negatively impact our ability to complete financing transactions. The duration and severity of these conditions is uncertain, as is the extent to which they may adversely affect our business and the business of current and prospective collaborators and vendors. If the global economy does not improve or worsens, we may be unable to secure additional funding to sustain our operations or to find suitable partners to advance our internal programs, even if we receive positive results from our research and development or business development efforts.

We maintain a portfolio of investments in marketable debt securities which are recorded at fair value. Although we have established investment guidelines relative to diversification and maturity with the objectives of maintaining safety of principal and liquidity, credit rating agencies may reduce the credit quality of our individual holdings which could adversely affect their value. Lower credit quality and other market events, such as changes in interest rates and further deterioration in the credit markets, may have an adverse effect on the fair value of our investment holdings and cash position.

We are focusing our activities and resources on the development of lorcaserin and depend on its success.

We are focusing our near-term research and development activities and resources on lorcaserin, and we believe a significant portion of the value of our company relates to our ability to develop this drug candidate. The development of lorcaserin is subject to many risks, including the risks discussed in other risk factors. If the results of clinical trials and preclinical studies of lorcaserin, the regulatory decisions affecting lorcaserin, the anticipated or actual timing and plan for commercializing lorcaserin, or, ultimately, the market acceptance of lorcaserin do not meet our, your, analysts' or others' expectations, the market price of our common stock could decline significantly.

***Our stock price could decline significantly based on the results and timing of clinical trials and preclinical studies of, and decisions affecting, our most advanced drug candidates.**

We announce results of clinical trials and preclinical studies from time to time. For example, we announced the results from our Phase 3 BLOOM pivotal trial for lorcaserin in March 2009 and expect to announce the results of our Phase 3 BLOSSOM pivotal trial for lorcaserin by the end of September 2009.

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The results and timing of clinical trials and preclinical studies can affect our stock price. Preclinical studies include experiments performed in test tubes, in animals, or in cells or tissues from humans or animals. These studies include all drug studies except those conducted in human subjects, and may occur before or after initiation of clinical trials for a particular compound. Results of clinical trials and preclinical studies of lorcaserin or our other drug candidates may not be viewed favorably by us or third parties, including investors, analysts, potential collaborators, the academic and medical community, and regulators. The same may be true of how we design the development programs of our most advanced drug candidates and regulatory decisions (including by us or regulatory authorities) affecting those development programs. Biotechnology company stock prices have declined significantly when such results and decisions were unfavorable or perceived negatively or when a drug candidate did not otherwise meet expectations.

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We have drug programs that are currently in clinical trials. In addition to successfully completing clinical trials, to conduct long-term clinical trials and gain regulatory approval to commercialize drug candidates, regulatory authorities require that all drug candidates complete short- and long-term preclinical toxicity and carcinogenicity studies. These preclinical, animal studies are required to help us and regulatory authorities assess the potential risk that drug candidates may be toxic or cause cancer in humans. The results of clinical trials and preclinical studies are uncertain and subject to different interpretations, and the design of these trials and studies (which may change significantly and be more expensive than anticipated depending on results and regulatory decisions) may also be viewed negatively by us, regulatory authorities or other third parties and adversely impact the development and opportunities for regulatory approval and commercialization of our and our partnered drug candidates. We may not be successful in advancing our programs on our projected timetable, if at all. Failure to initiate or delays in the development programs for any of our drug candidates, or unfavorable results or decisions or negative perceptions regarding any of such programs, could cause our stock price to decline significantly. This is particularly the case with respect to lorcaserin.

***We have significant indebtedness and debt service obligations as a result of our \$100 million secured loan, which may adversely affect our cash flow, cash position and stock price.**

We substantially increased our total debt and debt service obligations when we received a \$100.0 million secured loan on July 6, 2009. This loan matures on June 17, 2013, and the outstanding principal accrues interest at a rate of 7.75% per annum, payable quarterly in arrears. The schedule of our required principal repayments is as follows: \$10.0 million in July 2010, \$20.0 million in July 2011, \$30.0 million in July 2012, and the remainder at maturity. We may be required to make the scheduled repayments earlier in connection with certain equity issuances. For example, we were required to make the first scheduled repayment of \$10.0 million in connection with the closing of our July 2009 public offering. In addition, we are required to make mandatory prepayments of the loan upon certain changes of control and in the event we issue equity securities (other than certain exempted issuances) at a price of less than \$2.00 per share.

On or before June 17, 2011, the lender may elect to provide us with an additional loan in a principal amount of up to \$20.0 million under the same terms as the \$100.0 million loan, with the additional loan also maturing on June 17, 2013.

In the future, if we are unable to generate cash from operations sufficient to meet these debt obligations, we will need to obtain additional funds from other sources, which may include one or more financings. However, we may be unable to obtain sufficient additional funds when we need them, on favorable terms or at all. The sale of equity or convertible debt securities in the future may be dilutive to our stockholders, and debt-financing arrangements may require us to enter into covenants that would restrict certain business activities or our ability to incur further indebtedness, and may contain other terms that are not favorable to our stockholders or us.

Also, if we are unable to generate cash from operations or obtain additional funds from other sources sufficient to meet these debt obligations, or we need to use existing cash to fund these debt obligations, we may have to delay or curtail some or all of our research, development and commercialization programs or sell or license some or all of our assets. Our indebtedness could have significant additional negative consequences, including, without limitation:

- increasing our vulnerability to general adverse economic conditions;
- limiting our ability to obtain additional funds; and
- placing us at a possible competitive disadvantage to less leveraged competitors and competitors that have better access to capital resources.

If an event of default occurs under our loan documents, including in certain circumstances the warrants issued in connection with the loan transaction, the lender may declare the outstanding principal balance and accrued but unpaid interest owed to it immediately due and payable, which would have a material adverse effect on our financial position. We may not have sufficient cash to satisfy this obligation. Also, if a default occurs under our \$100.0 million loan, and we are unable to repay the lender, the lender could seek to enforce its rights under its security interest in substantially all of our assets. If this were to happen, we may lose some or all of our assets in order to satisfy our debt, which could cause our business to fail.

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***If we do not partner one or more unpartnered programs or raise additional funds, we may have to further curtail our activities.**

In light of our financial resources, we decided to focus our near-term research and development efforts on our lorcaserin Phase 3 program and select earlier-stage preclinical and research programs. We also decreased the number of our US employees in June 2009 by approximately 31% in a workforce reduction. While we believe this strategy will conserve resources, our ability to advance our drug candidate pipeline outside of lorcaserin will be limited. Without additional capital or funding from partners, we will need to significantly curtail some of our planned activities and expenditures. Any such further reductions may adversely impact our lorcaserin development and commercialization timeline or narrow or slow the development of our pipeline, which we believe would reduce our

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opportunities for success. Our decision to limit near-term development of drug candidates other than lorcaserin will likely extend the time it will take us to reach the market in these other therapeutic areas and may allow competing products to reach the market before our drug candidates.

Our development of lorcaserin may be adversely impacted by cardiovascular side effects previously associated with fenfluramine and dexfenfluramine.

We have developed lorcaserin to more selectively stimulate the serotonin 2C receptor because we believe this may avoid the cardiovascular side effects associated with fenfluramine and dexfenfluramine (often used in combination with phentermine, the combination of which was commonly referred to as "fen-phen"). These two drugs were serotonin-releasing agents and non-selective serotonin receptor agonists, and were withdrawn from the market in 1997 after reported incidences of heart valve disease and pulmonary hypertension associated with their usage. We may not be correct in our belief that selectively stimulating the serotonin 2C receptor will avoid these undesired side effects or lorcaserin's selectivity profile may not be adequate to avoid these side effects. Moreover, the potential relationship between the activity of lorcaserin and the activity of fenfluramine and dexfenfluramine may result in increased US Food and Drug Administration, or FDA, regulatory scrutiny of the safety of lorcaserin and may raise potential adverse publicity in the marketplace, which could affect clinical enrollment or sales if lorcaserin is approved for commercialization.

***The development programs for our drug candidates are expensive, time consuming, uncertain and susceptible to change, interruption, delay or termination.**

Drug development programs are very expensive, time consuming and difficult to design and implement. Our drug candidates are in various stages of research and development and are prone to the risks of failure inherent in drug development. Clinical trials and preclinical studies are needed to demonstrate that drug candidates are safe and effective to the satisfaction of the FDA and similar non-US regulatory authorities. These trials are expensive and uncertain processes that take years to complete. Failure can occur at any stage of the process, and successful early clinical or preclinical trials do not ensure that later trials or studies will be successful. In addition, the commencement or completion of our planned clinical trials could be substantially delayed or prevented by several factors, including:

- limited number of, and competition for, suitable patients required for enrollment in our clinical trials;
- limited number of, and competition for, suitable sites to conduct our clinical trials;
- delay or failure to obtain FDA approval or agreement to commence a clinical trial;
- delay or failure to obtain sufficient supplies of our drug candidates for our clinical trials;
- delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or investigators; and
- delay or failure to obtain institutional review board, or IRB, approval to conduct a clinical trial at a prospective site.

Even if the results of our development programs are favorable, the development programs of our most advanced drug candidates, including those being developed by our collaborators, may take significantly longer than expected to complete. In addition, the FDA, other regulatory authorities, our collaborators, or we may suspend, delay or terminate our development programs at any time for various reasons, including:

- lack of effectiveness of any drug candidate during clinical trials;
- side effects experienced by study participants or other safety issues;
- slower than expected rates of patient recruitment and enrollment or lower than expected patient retention rates;
- delays or inability to manufacture or obtain sufficient quantities of materials for use in clinical trials;
- inadequacy of or changes in our manufacturing process or compound formulation;
- delays in obtaining regulatory approvals to commence a study, or "clinical holds," or delays requiring suspension or termination of a study by a regulatory authority, such as the FDA, after a study is commenced;

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- changes in applicable regulatory policies and regulations;
- delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites;
- uncertainty regarding proper dosing;
- unfavorable results from ongoing clinical trials and preclinical studies;

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- failure of our clinical research organizations to comply with all regulatory and contractual requirements or otherwise perform their services in a timely or acceptable manner;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to design appropriate clinical trial protocols;
- insufficient data to support regulatory approval;
- termination of clinical trials by one or more clinical trial sites;
- inability or unwillingness of medical investigators to follow our clinical protocols;
- difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data; or
- lack of sufficient funding to continue clinical trials and preclinical studies.

There is typically a high rate of attrition from the failure of drug candidates proceeding through clinical trials, and many companies have experienced significant setbacks in advanced development programs even after promising results in earlier studies or trials. For example, because our drug candidate for insomnia, APD125, did not meet the primary or secondary endpoints of a Phase 2b clinical trial, we are not planning any further clinical development of APD125. We have experienced setbacks in other development programs and may experience additional setbacks in the future. If we or our collaborators abandon or are delayed in our development efforts related to lorcaserin or any other drug candidate, we may not be able to generate sufficient revenues to continue our operations at the current level or become profitable, our reputation in the industry and in the investment community would likely be significantly damaged, additional funding may not be available to us or may not be available on terms you or we believe are favorable, and our stock price would likely decrease significantly.

***Our drug candidates are subject to extensive regulation, and we may not receive required regulatory approvals, or timely approvals, for any of our drug candidates.**

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, marketing and distribution, and other possible activities relating to our drug candidates are, and any resulting drugs will be, subject to extensive regulation by the FDA and other regulatory agencies in the United States. Neither our collaborators nor we are permitted to market our drug candidates in the United States until we receive regulatory approval from the FDA. Neither our collaborators nor we have received marketing approval for any of our drug candidates. Specific preclinical data, chemistry, manufacturing and controls data, a proposed clinical trial protocol and other information must be submitted to the FDA as part of an investigational new drug, or IND, application, and clinical trials may commence only after the IND application becomes effective. To market a new drug in the United States, we must submit to the FDA and obtain FDA approval of a New Drug Application, or NDA. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls to demonstrate the safety and effectiveness of the drug candidate.

Obtaining approval of an NDA can be a lengthy, expensive and uncertain process. As part of the Prescription Drug User Fee Act, or PDUFA, the FDA has a goal to review and act on a percentage of all submissions in a given time frame. The general review goal for a drug application is 10 months for a standard application and six months for priority review. The FDA has missed a portion of their PDUFA goals, and it is unknown whether the review of an NDA filing for lorcaserin, or for any of our other drug candidates, will be completed within the FDA review goals or will be delayed. Moreover, the duration of the FDA's review may depend on the number and type of other NDAs that are filed with the FDA around the same time period. For example, we believe that at least two companies are planning to file an NDA for a drug candidate for weight management at around the time we expect the FDA will review our NDA for lorcaserin, which may impact the review of our NDA. Furthermore, any drug that acts on the central nervous system, or CNS, such as lorcaserin, has the potential to be scheduled as a controlled substance by the Drug Enforcement Administration of the United States Department of Justice, or DEA. DEA scheduling is an independent process that can delay drug launch beyond an NDA approval date.

In addition, failure to comply with FDA and other applicable regulatory requirements may, either before or

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after product approval, if any, subject our company to administrative or judicially imposed sanctions, including:

- Form 483 notices and Warning Letters;
- civil and criminal penalties;
- injunctions;
- withdrawal of approved products;

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- product seizure or detention;
- product recalls;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements; and
- refusal to approve pending NDAs or supplements to approved NDAs.

Regulatory approval of an NDA or NDA supplement is not guaranteed. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional preclinical studies and clinical trials. The number of preclinical studies and clinical trials that will be required for FDA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to target and the regulations applicable to any particular drug candidate. The FDA can delay, limit or deny approval of a drug candidate for many reasons, including:

- a drug candidate may not be deemed adequately safe and effective;
- FDA officials may not find the data from preclinical studies and clinical trials sufficient;
- the FDA may not approve the manufacturing processes or facilities;
- the FDA may change its approval policies or adopt new regulations; or
- the FDA may not accept our NDA submission (which is expected to be electronic) due to, among other reasons, the formatting of the submission.

We do not expect any drugs resulting from our research and development efforts to be commercially available until at least late 2010. We have not previously filed NDAs with the FDA, either by paper or electronically. This lack of corporate experience may impede our ability to successfully complete these trials and obtain FDA approval in a timely manner, if at all, for our drug candidates for which development and commercialization is our responsibility. Even if we believe that data collected from our preclinical studies and clinical trials of our drug candidates are promising and that our information and procedures regarding chemistry, manufacturing and controls are sufficient, our data may not be sufficient to support approval by the FDA or any other United States or foreign regulatory authority. In addition, we believe that the regulatory review of NDAs for drug candidates intended for widespread use by a large proportion of the general population is becoming increasingly focused on safety. In this regard, it is possible that some of our drug candidates, including lorcaserin, will be subject to increased scrutiny to show adequate safety than would drug candidates for more acute or life-threatening diseases such as cancer. Even if approved, drug candidates may not be approved for all indications requested and such approval may be subject to limitations on the indicated uses for which the drug may be marketed. Our business and reputation may be harmed by any failure or significant delay in receiving regulatory approval for the sale of any drugs resulting from our drug candidates. As a result, we cannot predict when or whether regulatory approval will be obtained for any drug we develop.

To market any drugs outside of the United States, we and our collaborators must comply with numerous and varying regulatory requirements of other countries. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks associated with FDA approval as well as additional, presently unanticipated, risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects associated with regulatory approval in the United States, including the risk that our drug candidates may not be approved for all indications requested and that such approval may be subject to limitations on the indicated uses for which the drug may be marketed.

***The results of preclinical studies and completed clinical trials are not necessarily predictive of future results, and our current drug candidates may not have favorable results in later studies or trials.**

Preclinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of a drug candidate, but rather to test safety, to study pharmacokinetics and pharmacodynamics, and to understand

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the drug candidate's side effects at various doses and schedules. To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our drug candidates, except lorcaserin. Favorable results in our early studies or trials may not be repeated in later studies or trials, including continuing preclinical studies and large-scale clinical trials, and our drug candidates in later-stage trials may fail to show desired safety and efficacy despite having progressed through earlier-stage trials. In the case of lorcaserin, results in one pivotal trial (BLOOM) may not be confirmed in another pivotal trial (BLOSSOM). Unfavorable results from ongoing preclinical studies or clinical trials could result in delays, modifications or abandonment of ongoing or future clinical trials, or abandonment of a clinical program. Preclinical and clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be

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New Data From Arena Pharmaceuticals' Pivotal BLOSSOM Trial of Lorcaserin Demonstrate Improvements in Patients' Body Composition, Cardiovascular Risk Factors and Quality of Life

- Late-Breaking Data Presented at the 27th Annual Scientific Meeting of The Obesity Society Expand on Previously Announced Highly Significant Top-Line Weight Loss Results -

WASHINGTON, Oct 27, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) reported today data from the pivotal BLOSSOM (Behavioral modification and LORcaserin Second Study for Obesity Management) Phase 3 trial that demonstrate improvements in patients' body composition, cardiovascular risk factors and quality of life. These findings add to the previously announced top-line BLOSSOM data that showed highly significant weight loss with lorcaserin over one year of treatment in 4,008 patients.

The late-breaking data were presented by Lee Kaplan, M.D., Ph.D., Associate Professor of Medicine at Harvard Medical School and Director of the Massachusetts General Hospital Weight Center, at Obesity 2009, the 27th Annual Scientific Meeting of The Obesity Society.

"Safety is of paramount importance in treating patients who are overweight or have obesity," said Dr. Kaplan. "We need new therapies that help patients reduce their weight and improve cardiovascular factors such as high blood pressure and cholesterol, while avoiding cardiac toxicity and symptoms of depression. Lorcaserin works by selectively affecting a unique and important pathway, which allows for significant weight loss and improvements in these important risk factors, along with an excellent safety and tolerability profile."

William R. Shanahan, M.D., Arena's Vice President and Chief Medical Officer, stated, "Treatment with lorcaserin offers patients the opportunity to achieve sustainable weight loss in a well-tolerated manner, resulting in improved cardiometabolic health and quality of life. In order to improve overall health, it's important to see these measurements moving in the right direction as patients reduce their weight. Based on lorcaserin's safety and efficacy profile, we expect primary care physicians to find lorcaserin an attractive first-line therapy for weight management."

Specifically, the new data demonstrate that treatment with lorcaserin over one year was associated with highly significant improvements or favorable trends compared to placebo in multiple secondary endpoints evaluated in the trial:

Body Composition

Using Intent-to-Treat Last Observation Carried Forward (ITT-LOCF) analysis, lorcaserin patients achieved highly significant improvements in Body Mass Index (BMI), waist circumference and hip circumference. Changes from baseline for patients who took lorcaserin twice daily, lorcaserin once daily or placebo, respectively, were as follows: BMI (kg/m squared), (-2.1, -1.7, -1.0); waist circumference (cm), (-6.2, -5.6, -4.2); and hip circumference (cm), (-5.3, -5.0, -3.3), ($p < 0.0001$) compared to placebo for all measurements. In addition, lorcaserin patients lost significantly more body fat than the placebo patients.

Cardiovascular Risk Factors

Using ITT-LOCF analysis, lorcaserin helped improve patients' cardiovascular risk factors. Patients dosed with 10 mg of lorcaserin once or twice daily achieved statistical significance ($p < 0.05$) versus placebo at Week 52 for percent change in HDL cholesterol and triglycerides and achieved favorable trends in total cholesterol and LDL cholesterol. Lorcaserin did not increase blood pressure or heart rate at any time point. Changes from baseline for patients who took lorcaserin twice daily, lorcaserin once daily or placebo, respectively, were as follows: diastolic blood pressure (mmHg), (-1.9, -1.0, -1.9); systolic blood pressure (mmHg), (-2.0, -1.1, -1.2); and heart rate (bpm), (-2.3, -1.1, -1.6).

Quality of Life

Lorcaserin did not increase depression or suicidal ideation compared to placebo. Adverse events related to depression and their rates for patients who took lorcaserin twice daily, lorcaserin once daily or placebo, respectively, were as follows:

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depression (1.9%, 1.1%, 1.8%); depressed mood (0.6%, 0.9%, 0.9%); and depressive symptoms (<0.1%, 0%, 0%).

Quality of Life, as assessed by the Impact of Weight on Quality of Life-Lite (IWQOL-Lite) questionnaire, improved to a significantly greater extent in the lorcaserin twice daily ($p<0.0001$) and lorcaserin once daily ($p<0.01$) groups as compared to placebo at Week 52. All measurements, including physical function, self esteem, sexual life, public distress and work, improved in a dose-dependent fashion.

"Our team at Arena has worked diligently to discover and develop a novel treatment for weight management that delivers the combination of efficacy, safety and tolerability. Lorcaserin patients in the pivotal program achieved meaningful weight loss and improvements in important secondary endpoints," said Jack Lief, Arena's President and Chief Executive Officer. "The Obesity Society meeting provides us with an outstanding opportunity to discuss lorcaserin's profile with the enthusiastic physicians who are in need of promising, new treatment options."

Safety and Tolerability Profile

Lorcaserin was very well tolerated. Adverse events that exceeded placebo by greater than 3% and their rates for patients who took lorcaserin twice daily, lorcaserin once daily or placebo, respectively, were as follows: headache (15.6%, 15.6%, 9.2%); nausea (9.1%, 7.6%, 5.3%); dizziness (8.7%, 6.2%, 3.9%); fatigue (8.4%, 6.6%, 4.1%); and dry mouth (5.4%, 3.4%, 2.3%). Serious adverse events occurred infrequently and their rates for patients who took lorcaserin twice daily, lorcaserin once daily or placebo, respectively, were as follows: 3.1%, 3.4% and 2.2%.

Cardiovascular Safety

The assessment of echocardiograms performed at baseline and after patients completed 6 and 12 months of dosing indicated that lorcaserin did not increase echocardiographic heart valve regurgitation. Lorcaserin met the primary safety endpoint that evaluated the rates of new FDA-defined valvulopathy in BLOSSOM at Week 52: lorcaserin 10 mg twice daily (2.0%), 10 mg once daily (1.4%) and placebo (2.0%). The integrated BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management) and BLOSSOM echocardiography data set rules out a risk of valvulopathy in lorcaserin patients according to criteria requested by the FDA.

New data demonstrate that similar numbers of mitral insufficiency and aortic insufficiency shifts were reported for patients on lorcaserin and placebo. In patients with pre-existing FDA-defined valvulopathy at baseline, changes in valvular regurgitant scores did not differ between the placebo and lorcaserin groups. The majority of patients experienced either no change or an improvement in valvular regurgitation.

Previously Announced Efficacy Data

The previously announced BLOSSOM data demonstrated that lorcaserin was highly efficacious, achieving statistical significance on all three co-primary efficacy endpoints, and was very well tolerated. Lorcaserin patients achieved highly significant categorical and absolute weight loss over 52 weeks of treatment. About two-thirds (63.2%) of lorcaserin patients dosed twice daily who completed the trial according to the protocol lost at least 5% of their weight, compared to 34.9% of patients on placebo, and more than one-third (35.1%) of these lorcaserin patients lost at least 10% of their weight, compared to 16.1% for placebo. The average weight loss for lorcaserin patients dosed twice daily was 17.0 pounds, compared to 8.7 pounds for placebo. The top quartile of lorcaserin patients who completed the trial according to protocol and had their Week 52 weight recorded lost an average of 35.1 pounds.

Patient Disposition

BLOSSOM evaluated 4,008 patients with an average BMI of 35.9 and baseline weight of 220 pounds. The Week 52 completion rate was higher for patients on lorcaserin 10 mg twice daily (57.2%) and 10 mg once daily (59.0%) compared to patients on placebo (52.0%). Discontinuations for adverse events were low and as follows: lorcaserin 10 mg twice daily (7.2%), 10 mg once daily (6.2%) and placebo (4.6%).

BLOSSOM Trial Design

BLOSSOM is a double-blind, randomized, placebo-controlled trial in approximately 100 sites in the US. The trial evaluated 10 mg of lorcaserin dosed once or twice daily versus placebo over a one-year treatment period in obese patients (BMI 30 to 45) with or without co-morbid conditions and overweight patients (BMI 27 to less than 30) with at least one co-morbid condition. The trial did not include dose titration or a run-in period. Patients were randomized at baseline in a 2:2:1 ratio to lorcaserin 10 mg twice daily, placebo or lorcaserin 10 mg once daily. Patients received echocardiograms at baseline, month 6 and at the end of the trial to assess heart valve function over time. In contrast to the BLOOM trial, there were no echocardiographic exclusion criteria for entry into BLOSSOM and there was no oversight or interim data review monitoring by an independent safety monitoring board.

Phase 3 Program Overview

The lorcaserin Phase 3 program consists of three trials: BLOOM, BLOSSOM and BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus). Enrollment in the lorcaserin Phase 3 program is complete with approximately 7,800 patients. Positive results from BLOOM were presented at the 69th Scientific Sessions of the American Diabetes Association in June 2009. BLOOM and BLOSSOM comprise the Phase 3 pivotal registration program and will be the basis for the lorcaserin NDA submission. BLOOM-DM, which is planned as a supplement to the NDA, is evaluating 10 mg of lorcaserin dosed once or twice daily versus placebo over a one-year treatment period in obese and overweight patients with type 2 diabetes at about 60 sites in the US.

A standardized program of moderate diet and exercise guidance is included in the Phase 3 program. The program's hierarchically ordered co-primary efficacy endpoints are: the proportion of patients achieving 5% or greater weight loss after 12 months, the difference in mean weight loss compared to placebo after 12 months, and the proportion of patients achieving 10% or greater weight loss after 12 months. Arena is also studying several key secondary endpoints, including changes in serum lipids, markers of inflammation and insulin resistance, and in the BLOOM-DM trial, other indicators of glycemic control.

About Lorcaserin

Lorcaserin is a novel single agent that represents the first in a new class of selective serotonin 2C receptor agonists. The serotonin 2C receptor is expressed in the brain, including the hypothalamus, an area involved in the control of appetite and metabolism. Stimulation of this receptor is strongly associated with feeding behavior and satiety. Arena has patents that cover lorcaserin in the US and other jurisdictions, which in most cases are capable of continuing into 2023 without taking into account any patent term extensions or other exclusivity Arena might obtain.

About Weight Management

The National Institutes of Health reported in 2007 that about 65% of US adults are overweight or obese. A 2009 publication in *Health Affairs* estimated the annual medical burden of obesity in the US to be \$147 billion in 2008. Studies have shown that weight loss of 5% to 10% is medically significant and results in meaningful improvements in cardiovascular risk factors and a significant reduction in the incidence of type 2 diabetes in patients with glucose intolerance.

About Arena Pharmaceuticals

Arena is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing oral drugs in four major therapeutic areas: cardiovascular, central nervous system, inflammatory and metabolic diseases. Arena's most advanced drug candidate, lorcaserin, is being investigated in a Phase 3 clinical trial program for weight management. Arena has a broad pipeline of novel compounds targeting G protein-coupled receptors, an important class of validated drug targets, which includes compounds being evaluated independently and with partners, including Merck & Co., Inc., and Ortho-McNeil-Janssen Pharmaceuticals, Inc.

Arena Pharmaceuticals(R) and Arena(R) are registered service marks of the company. "APD" is an abbreviation for Arena Pharmaceuticals Development.

Forward-Looking Statements

Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include statements about the development, advancement, therapeutic indication and use, tolerability, safety, selectivity, efficacy, and regulatory approval of lorcaserin; the protocol, design, scope, enrollment and other aspects of the lorcaserin trials; lorcaserin's commercial and other potential, including in managing weight, meeting patients' and physicians' needs, changing treatment, improving health and quality of life and generating interest; significance of the lorcaserin trial results and the completion of the lorcaserin Phase 3 pivotal registration program; the FDA's approval process and requirements; the risk of developing valvulopathy; the potential of the lorcaserin Phase 3 program and its results to satisfy the FDA's approval requirements; future activities, results and announcements relating to lorcaserin, including submitting an NDA for lorcaserin, submitting the BLOOM-DM results as a supplement to the NDA, and commercializing lorcaserin; the impact of weight loss on health; lorcaserin's patent coverage; and Arena's strategy, internal and partnered programs, and ability to develop compounds and commercialize drugs. For such statements, Arena claims the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from Arena's expectations. Factors that could cause actual results to differ materially from the forward-looking statements include, but are not limited to, the timing, success and cost of Arena's lorcaserin program and other of its research and development programs; results of clinical trials or preclinical studies may not be predictive of future results; clinical trials and studies may not proceed at the time or in the manner Arena expects or at all; Arena's ability to partner or commercialize lorcaserin or other of its compounds or programs; the timing and ability of Arena to receive regulatory approval for its drug candidates; Arena's ability to obtain additional funds; Arena's ability to obtain and defend its patents; and the timing and receipt of payments and fees, if any, from Arena's collaborators. Additional

factors that could cause actual results to differ materially from those stated or implied by Arena's forward-looking statements are disclosed in Arena's filings with the Securities and Exchange Commission. These forward-looking statements represent Arena's judgment as of the time of this release. Arena disclaims any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
 Washington, D.C. 20549

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☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2009

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 000-31161

ARENA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
 (State or other jurisdiction of
 incorporation or organization)

23-2908305
 (I.R.S. Employer Identification No.)

6166 Nancy Ridge Drive, San Diego, CA
 (Address of principal executive offices)

92121
 (Zip Code)

858.453.7200
 (Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company.

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐ (Do not check if a smaller reporting company)

Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

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Our recent developments include:

- Announced positive, highly significant top-line results from the BLOSSOM (Behavioral modification and Lorcaserin Second Study for Obesity Management) Phase 3 trial. Lorcaserin patients achieved highly significant categorical and absolute weight loss over 52 weeks of treatment. About two-thirds (63.2%) of lorcaserin patients dosed twice daily who

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completed the trial according to protocol lost at least 5% of their weight, compared to 34.9% of patients on placebo, and more than one-third (35.1%) of these lorcaserin patients lost at least 10% of their weight, compared to 16.1% for placebo. The average weight loss for lorcaserin patients dosed twice daily was 17.0 pounds, compared to 8.7 pounds for placebo. The top quartile of lorcaserin patients who completed the trial according to protocol and had their Week 52 weight recorded lost an average of 35.1 pounds. Lorcaserin was very well tolerated and no excess depression or suicidal ideation was observed with lorcaserin treatment. The incidence of new FDA-defined valvulopathy from the integrated echocardiographic data set from BLOSSOM and BLOOM did not differ from placebo.

- Announced a late-breaking oral presentation from the pivotal BLOSSOM trial and additional positive data from the pivotal BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management) Phase 3 trial at the 27th Annual Scientific Meeting of The Obesity Society. The new BLOSSOM data demonstrate improvements in patients' body composition, cardiovascular risk factors and quality of life. The new BLOOM data demonstrate that lorcaserin significantly improved markers of cardiovascular risk and glycemic parameters and was not associated with depression or suicidal ideation. Lorcaserin patients who completed the BLOOM trial according to protocol lost 31% of their excess body weight, compared to 12% for the placebo group.
- Completed dosing in all lorcaserin clinical trials we expect to be included in the NDA we plan to submit to the FDA by the end of 2009.
- Completed a public offering of 12.5 million shares of common stock, resulting in net proceeds to us of \$49.7 million.
- Received net proceeds of \$95.6 million from a \$100.0 million loan provided by Deerfield Management. The outstanding principal accrues interest until maturity in June 2013 at a rate of 7.75% per annum. In connection with the loan, we issued Deerfield warrants for 28 million shares of our common stock at an exercise price of \$5.42 per share. On or before June 17, 2011, Deerfield may make a one-time election to provide us with up to an additional \$20.0 million under similar terms, with the additional loan also maturing in June 2013. For each additional \$1.0 million in funding, we will issue Deerfield additional warrants for 280,000 shares of our common stock at an exercise price of \$5.42 per share. We repaid Deerfield the first scheduled principal repayment of \$10.0 million upon completion of our public offering in July.

RESULTS OF OPERATIONS

We are providing the following summary of our revenues, research and development expenses and general and administrative expenses to supplement the more detailed discussion below. The following tables are stated in millions.

Revenues

<u>Source of revenue</u>	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2009</u>	<u>2008</u>	<u>2009</u>	<u>2008</u>
Manufacturing services agreement	\$ 1.7	\$ 1.5	\$ 4.7	\$ 5.5
Collaborative agreements	0.9	0.4	3.0	1.6
Total revenues	<u>\$ 2.6</u>	<u>\$ 1.9</u>	<u>\$ 7.7</u>	<u>\$ 7.1</u>

Research and development expenses

<u>Type of expense</u>	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2009</u>	<u>2008</u>	<u>2009</u>	<u>2008</u>
External clinical and preclinical study fees and expenses	\$ 7.7	\$ 27.9	\$ 39.8	\$ 90.9
Salary and other personnel costs (excluding non-cash share-based compensation)	7.7	10.3	27.3	31.3
Facility and equipment costs	3.8	4.1	11.7	12.0
Other	1.1	1.7	3.6	5.2
Non-cash share-based compensation	1.0	1.1	2.9	3.3
Research supplies	0.8	2.4	3.7	8.3
Total research and development expenses	<u>\$ 22.1</u>	<u>\$ 47.5</u>	<u>\$ 89.0</u>	<u>\$ 151.0</u>

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Share-based compensation. We recognize compensation expense for all share-based awards based on the grant-date fair value, using the Black-Scholes option pricing model. The determination of the grant-date fair value of share-based awards using the Black-Scholes option pricing model is based on the exercise price of the award and the fair market value of our stock price on the date of grant, as well as assumptions for expected volatility, expected life of options granted and risk-free interest rate. Changes in the assumptions can have a material impact on the compensation expense we recognize. Expected volatility is based on a combination of 75% historical volatility of our common stock and 25% market-based implied volatilities from traded options on our common stock, with historical volatility being more heavily weighted due to the low volume of traded options on our common stock. The expected life of options granted is determined based on historical experience of similar awards, giving consideration to the contractual terms of the share-based awards, vesting schedules and post-vesting cancellations. The risk-free interest rates are based on the US Treasury yield curve, with a remaining term approximately equal to the expected term used in the option pricing model.

As compensation expense recognized is based on awards ultimately expected to vest, it is reduced for estimated forfeitures. We estimate forfeitures at the time of grant and revise such estimates, if necessary, in subsequent periods if actual forfeitures differ from those estimates. If actual forfeitures vary from estimates, we recognize the difference in compensation expense in the period the actual forfeitures occur or when options vest.

Accounting for lease financing obligations. We account for our sale and leaseback transactions using the financing method because our options to repurchase these properties in the future is considered continued involvement requiring such method. Under the financing method, the book value of the properties and related accumulated depreciation remain on our balance sheet and no sale is recognized. Instead, the sales price of the properties is recorded as a financing obligation, and a portion of each lease payment is recorded as interest expense. We estimated the borrowing rate that we use to impute interest expense on our lease payments.

The above listing is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by GAAP. See our audited consolidated financial statements and notes thereto included in our 2008 Annual Report, which contain additional accounting policies and other disclosures required by GAAP.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

There have been no material changes from the information we included in this section of our annual report on Form 10-K for the year ended December 31, 2008.

Item 4. Controls and Procedures.

Based on an evaluation carried out as of the end of the period covered by this quarterly report, under the supervision and with the participation of our management, including our Chief Executive Officer and Vice President, Finance and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures, our Chief Executive Officer and Vice President, Finance and Chief Financial Officer have concluded that, as of the end of such period, our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934) were effective. There was no change in our internal control over financial reporting that occurred during the quarter covered by this quarterly report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION**Item 1A. Risk Factors.****RISK FACTORS**

Investment in our stock involves a high degree of risk. You should consider carefully the risks described below, together with other information in this quarterly report on Form 10-Q and our other public filings, before making investment decisions regarding our stock. If any of the following events actually occur, our business, operating results, prospects or financial condition could be materially and adversely affected. This could cause the trading price of our common stock to decline and you may lose all or part of your investment. Moreover, the risks described below are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business, operating results, prospects or financial condition.

The risk factors set forth below with an asterisk () before the title are new risk factors or risk factors containing substantive*

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changes, including any material changes, from the risk factors previously disclosed in Item 1A to Part I of our annual report on Form 10-K for the year ended December 31, 2008, as filed with the Securities and Exchange Commission.

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***We will need additional funds to conduct our planned research and development efforts, we may not be able to obtain such funds and may never become profitable.**

We have accumulated a large deficit since inception that has primarily resulted from the significant research and development expenditures we have made in seeking to identify and validate new drug targets and develop compounds that could become marketed drugs. We expect that our losses will continue to be substantial for at least the short term and that our operating expenses will also continue to be substantial, even if we or our collaborators are successful in advancing our compounds or partnered compounds.

We do not have any commercially available drugs, and we have substantially less money than we need to develop our compounds into marketed drugs. It takes many years and potentially hundreds of millions of dollars to successfully develop a preclinical or early clinical compound into a marketed drug, and our efforts may not result in any marketed drugs.

We will need additional funds or a partner to bring our most advanced drug candidate, lorcaserin, to market, if ever, and we may not be able to secure adequate funding or find an acceptable partner at all or on terms you or we believe are favorable. We also believe that due to global economic challenges, and as our cash balances decline, it may be difficult for us to obtain additional financing or enter into strategic relationships on terms acceptable to us, if at all. If additional funding is not available, we will have to eliminate or further postpone or scale back some or all of our research or development programs or delay the development of one or more of such programs, including our lorcaserin program.

The current global economic environment poses severe challenges to our business strategy, which relies on access to capital from the markets and our collaborators, and creates other financial risks for us.

The global economy, including credit markets and the financial services industry, has been experiencing a period of substantial turmoil and uncertainty. These conditions have generally made equity and debt financing more difficult to obtain, and may negatively impact our ability to complete financing transactions. The duration and severity of these conditions is uncertain, as is the extent to which they may adversely affect our business and the business of current and prospective collaborators and vendors. If the global economy does not improve or worsens, we may be unable to secure additional funding to sustain our operations or to find suitable partners to advance our internal programs, even if we receive positive results from our research and development or business development efforts.

We maintain a portfolio of investments in marketable debt securities which are recorded at fair value. Although we have established investment guidelines relative to diversification and maturity with the objectives of maintaining safety of principal and liquidity, credit rating agencies may reduce the credit quality of our individual holdings which could adversely affect their value. Lower credit quality and other market events, such as changes in interest rates and further deterioration in the credit markets, may have an adverse effect on the fair value of our investment holdings and cash position.

We are focusing our activities and resources on the development of lorcaserin and depend on its success.

We are focusing our near-term research and development activities and resources on lorcaserin, and we believe a significant portion of the value of our company relates to our ability to develop this drug candidate. The development of lorcaserin is subject to many risks, including the risks discussed in other risk factors. If the results of clinical trials and preclinical studies of lorcaserin, the regulatory decisions affecting lorcaserin, the anticipated or actual timing and plan for commercializing lorcaserin, or, ultimately, the market acceptance of lorcaserin do not meet our, your, analysts' or others' expectations, the market price of our common stock could decline significantly.

***Our stock price could decline significantly based on the results and timing of clinical trials and preclinical studies of, and decisions affecting, our most advanced drug candidates.**

The results and timing of clinical trials and preclinical studies can affect our stock price. Preclinical studies include experiments performed in test tubes, in animals, or in cells or tissues from humans or animals. These studies include all drug studies except those conducted in human subjects, and may occur before or after initiation of clinical trials for a particular compound. Results of clinical trials and preclinical studies of lorcaserin or our other drug candidates may not be viewed favorably by us or third parties, including investors, analysts, potential collaborators, the academic and medical communities, and regulators. The same may be true of how we design the development programs of our most advanced drug candidates and regulatory decisions (including by us or regulatory authorities) affecting those development programs. Biotechnology company stock prices have declined significantly when such results and decisions were unfavorable or perceived negatively

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or when a drug candidate did not otherwise meet expectations.

We have drug programs that are currently in clinical trials. In addition to successfully completing clinical trials, to conduct long-term clinical trials and gain regulatory approval to commercialize drug candidates, regulatory authorities require that all drug candidates complete short- and long-term preclinical toxicity and carcinogenicity studies. These preclinical, animal studies are required to help

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us and regulatory authorities assess the potential risk that drug candidates may be toxic or cause cancer in humans. The results of clinical trials and preclinical studies are uncertain and subject to different interpretations, and the design of these trials and studies (which may change significantly and be more expensive than anticipated depending on results and regulatory decisions) may also be viewed negatively by us, regulatory authorities or other third parties and adversely impact the development and opportunities for regulatory approval and commercialization of our and our partnered drug candidates. We may not be successful in advancing our programs on our projected timetable, if at all. Failure to initiate or delays in the development programs for any of our drug candidates, or unfavorable results or decisions or negative perceptions regarding any of such programs, could cause our stock price to decline significantly. This is particularly the case with respect to lorcaserin.

***We have significant indebtedness and debt service obligations as a result of our \$100 million secured loan, which may adversely affect our cash flow, cash position and stock price.**

We substantially increased our total debt and debt service obligations when we received a \$100.0 million loan from Deerfield on July 6, 2009. This loan matures on June 17, 2013, and the outstanding principal accrues interest at a rate of 7.75% per annum on the stated principal balance, payable quarterly in arrears. The schedule of our required principal repayments is as follows: \$10.0 million in July 2010, \$20.0 million in July 2011, \$30.0 million in July 2012, and \$40 million at maturity. We may be required to make the scheduled repayments earlier in connection with certain equity issuances. For example, we were required to make the first scheduled repayment of \$10.0 million in connection with the closing of our July 2009 public offering. In addition, we are required to make mandatory prepayments of the loan upon certain changes of control and in the event we issue equity securities (other than certain exempted issuances) at a price of less than \$2.00 per share.

On or before June 17, 2011, the lenders may elect to provide us with an additional loan in a principal amount of up to \$20.0 million under similar terms as the \$100.0 million loan, with the additional loan also maturing on June 17, 2013.

In the future, if we are unable to generate cash from operations sufficient to meet these debt obligations, we will need to obtain additional funds from other sources, which may include one or more financings. However, we may be unable to obtain sufficient additional funds when we need them, on favorable terms or at all. The sale of equity or convertible debt securities in the future may be dilutive to our stockholders, and debt-financing arrangements may require us to enter into covenants that would restrict certain business activities or our ability to incur further indebtedness, and may contain other terms that are not favorable to our stockholders or us.

Also, if we are unable to generate cash from operations or obtain additional funds from other sources sufficient to meet these debt obligations, or we need to use existing cash to fund these debt obligations, we may have to delay or curtail some or all of our research, development and commercialization programs or sell or license some or all of our assets. Our indebtedness could have significant additional negative consequences, including, without limitation:

- increasing our vulnerability to general adverse economic conditions;
- limiting our ability to obtain additional funds; and
- placing us at a possible competitive disadvantage to less leveraged competitors and competitors that have better access to capital resources.

If an event of default occurs under our loan documents, including in certain circumstances the warrants issued in connection with the loan transaction, the lenders may declare the outstanding principal balance and accrued but unpaid interest owed to them immediately due and payable, which would have a material adverse effect on our financial position. We may not have sufficient cash to satisfy this obligation. Also, if a default occurs under our \$100.0 million loan, and we are unable to repay the lenders, the lenders could seek to enforce their rights under their security interests in substantially all of our assets. If this were to happen, we may lose some or all of our assets in order to satisfy our debt, which could cause our business to fail.

***If we do not partner one or more unpartnered programs or raise additional funds, we may have to further curtail our activities.**

In light of our financial resources, we decreased the number of our US employees in June 2009 by approximately 31% in a workforce reduction. We also are focusing our near-term research and development efforts on our lorcaserin Phase 3 program and select earlier-stage preclinical and research programs. While we believe this strategy will conserve resources, our ability to advance our drug candidate pipeline outside of lorcaserin will be limited. Without additional capital or funding from partners, we will need to significantly curtail some of our planned activities and expenditures. Any such further reductions may adversely impact our lorcaserin development and commercialization timeline or narrow or slow the development of our

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pipeline, which we believe would reduce our opportunities for success. Our decision to limit near-term development of drug candidates other than lorcaserin will likely extend the time it will take us to reach the market in these other therapeutic areas and may allow competing products to reach the market before our drug candidates.

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We have developed lorcaserin to more selectively stimulate the serotonin 2C receptor because we believe this may avoid the cardiovascular side effects associated with fenfluramine and dexfenfluramine (often used in combination with phentermine, the combination of which was commonly referred to as "fen-phen"). These two drugs were serotonin-releasing agents and non-selective serotonin receptor agonists, and were withdrawn from the market in 1997 after reported incidences of heart valve disease and pulmonary hypertension associated with their usage. We may not be correct in our belief that selectively stimulating the serotonin 2C receptor will avoid these undesired side effects or lorcaserin's selectivity profile may not be adequate to avoid these side effects. Moreover, the potential relationship between the activity of lorcaserin and the activity of fenfluramine and dexfenfluramine may result in increased US Food and Drug Administration, or FDA, regulatory scrutiny of the safety of lorcaserin and may raise potential adverse publicity in the marketplace, which could affect clinical enrollment or sales if lorcaserin is approved for commercialization. We have completed two large pivotal lorcaserin trials of one and two years' duration, both of which showed no apparent effects on heart valves or pulmonary artery pressures, but these results will need to be reviewed by the FDA.

***The development programs for our drug candidates are expensive, time consuming, uncertain and susceptible to change, interruption, delay or termination.**

Drug development programs are very expensive, time consuming and difficult to design and implement. Our drug candidates are in various stages of research and development and are prone to the risks of failure inherent in drug development. Clinical trials and preclinical studies are needed to demonstrate that drug candidates are safe and effective to the satisfaction of the FDA and similar non-US regulatory authorities. These trials are expensive and uncertain processes that take years to complete. Failure can occur at any stage of the process, and successful early clinical or preclinical trials do not ensure that later trials or studies will be successful. In addition, the commencement or completion of our planned clinical trials could be substantially delayed or prevented by several factors, including:

- limited number of, and competition for, suitable patients required for enrollment in our clinical trials;
- limited number of, and competition for, suitable sites to conduct our clinical trials;
- delay or failure to obtain FDA approval or agreement to commence a clinical trial;
- delay or failure to obtain sufficient supplies of our drug candidates for our clinical trials;
- delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or investigators; and
- delay or failure to obtain institutional review board, or IRB, approval to conduct a clinical trial at a prospective site.

Even if the results of our development programs are favorable, the development programs of our most advanced drug candidates, including those being developed by our collaborators, may take significantly longer than expected to complete. In addition, the FDA, other regulatory authorities, our collaborators, or we may suspend, delay or terminate our development programs at any time for various reasons, including:

- lack of effectiveness of any drug candidate during clinical trials;
- side effects experienced by study participants or other safety issues;
- slower than expected rates of patient recruitment and enrollment or lower than expected patient retention rates;
- delays or inability to manufacture or obtain sufficient quantities of materials for use in clinical trials;
- inadequacy of or changes in our manufacturing process or compound formulation;
- delays in obtaining regulatory approvals to commence a study, or "clinical holds," or delays requiring suspension or termination of a study by a regulatory authority, such as the FDA, after a study is commenced;
- changes in applicable regulatory policies and regulations;
- delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites;

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- uncertainty regarding proper dosing;
- unfavorable results from ongoing clinical trials and preclinical studies;
- failure of our clinical research organizations to comply with all regulatory and contractual requirements or otherwise perform their services in a timely or acceptable manner;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to design appropriate clinical trial protocols;
- insufficient data to support regulatory approval;
- termination of clinical trials by one or more clinical trial sites;
- inability or unwillingness of medical investigators to follow our clinical protocols;
- difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data; or
- lack of sufficient funding to continue clinical trials and preclinical studies.

There is typically a high rate of attrition from the failure of drug candidates proceeding through clinical trials, and many companies have experienced significant setbacks in advanced development programs even after promising results in earlier studies or trials. For example, because our drug candidate for insomnia, APD125, did not meet the primary or secondary endpoints of a Phase 2b clinical trial, we are not planning any further clinical development of APD125. We have experienced setbacks in other development programs and may experience additional setbacks in the future. If we or our collaborators abandon or are delayed in our development efforts related to lorcaserin or any other drug candidate, we may not be able to generate sufficient revenues to continue our operations at the current level or become profitable, our reputation in the industry and in the investment community would likely be significantly damaged, additional funding may not be available to us or may not be available on terms you or we believe are favorable, and our stock price would likely decrease significantly.

***Our drug candidates are subject to extensive regulation, and we may not receive required regulatory approvals, or timely approvals, for any of our drug candidates.**

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, marketing and distribution, and other possible activities relating to our drug candidates are, and any resulting drugs will be, subject to extensive regulation by the FDA and other regulatory agencies in the United States. Neither our collaborators nor we are permitted to market our drug candidates in the United States until we receive regulatory approval from the FDA. Neither our collaborators nor we have received marketing approval for any of our drug candidates. Specific preclinical data, chemistry, manufacturing and controls data, a proposed clinical trial protocol and other information must be submitted to the FDA as part of an investigational new drug, or IND, application, and clinical trials may commence only after the IND application becomes effective. To market a new drug in the United States, we must submit to the FDA and obtain FDA approval of a New Drug Application, or NDA. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls to demonstrate the safety and effectiveness of the drug candidate.

Obtaining approval of an NDA can be a lengthy, expensive and uncertain process. As part of the Prescription Drug User Fee Act, or PDUFA, the FDA has a goal to review and act on a percentage of all submissions in a given time frame. The general review goal for a drug application is 10 months for a standard application and six months for priority review. The FDA has missed a portion of their PDUFA goals, and it is unknown whether the review of an NDA filing for lorcaserin, or for any of our other drug candidates, will be completed within the FDA review goals or will be delayed. Moreover, the duration of the FDA's review may depend on the number and type of other NDAs that are filed with the FDA around the same time period. For example, we believe that at least two companies are planning to file an NDA for a drug candidate for weight management at around the time we expect the FDA will review our NDA for lorcaserin, which may impact the review of our NDA. Furthermore, any drug that acts on the central nervous system, or CNS, such as lorcaserin, has the potential to be scheduled as a controlled substance by the Drug Enforcement Administration of the US Department of Justice, or DEA. DEA scheduling is an independent process that can delay drug launch beyond an NDA approval date.

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In addition, failure to comply with FDA and other applicable regulatory requirements may, either before or after product approval, if any, subject our company to administrative or judicially imposed sanctions, including:

- Form 483 notices and Warning Letters;
- civil and criminal penalties;
- injunctions;
- withdrawal of approved products;
- product seizure or detention;
- product recalls;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements; and
- refusal to approve pending NDAs or supplements to approved NDAs.

Regulatory approval of an NDA or NDA supplement is not guaranteed. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional preclinical studies and clinical trials. The number of preclinical studies and clinical trials that will be required for FDA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to target and the regulations applicable to any particular drug candidate. The FDA can delay, limit or deny approval of a drug candidate for many reasons, including:

- a drug candidate may not be deemed adequately safe and effective;
- FDA officials may not find the data from preclinical studies and clinical trials sufficient;
- the FDA may not approve the manufacturing processes or facilities;
- the FDA may change its approval policies or adopt new regulations; or
- the FDA may not accept our NDA submission (which is expected to be electronic) due to, among other reasons, the formatting of the submission.

We do not expect any drugs resulting from our research and development efforts to be commercially available until at least late 2010. We have not previously filed NDAs with the FDA, either by paper or electronically. This lack of corporate experience may impede our ability to successfully complete these trials and obtain FDA approval in a timely manner, if at all, for our drug candidates for which development and commercialization is our responsibility. Even if we believe that data collected from our preclinical studies and clinical trials of our drug candidates are promising and that our information and procedures regarding chemistry, manufacturing and controls are sufficient, our data may not be sufficient to support approval by the FDA or any other United States or foreign regulatory authority. In addition, we believe that the regulatory review of NDAs for drug candidates intended for widespread use by a large proportion of the general population is becoming increasingly focused on safety. In this regard, it is possible that some of our drug candidates, including lorcaserin, will be subject to increased scrutiny to show adequate safety than would drug candidates for more acute or life-threatening diseases such as cancer. Even if approved, drug candidates may not be approved for all indications requested and such approval may be subject to limitations on the indicated uses for which the drug may be marketed. Our business and reputation may be harmed by any failure or significant delay in receiving regulatory approval for the sale of any drugs resulting from our drug candidates. As a result, we cannot predict when or whether regulatory approval will be obtained for any drug we develop.

To market any drugs outside of the United States, we and our collaborators must comply with numerous and varying regulatory requirements of other countries. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks associated with FDA approval as well as additional, presently unanticipated, risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects associated with regulatory approval in the United States, including the risk that our drug candidates may not be approved for all indications requested and that such approval may be subject to limitations on the indicated uses for which the drug may be marketed.

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***The results of preclinical studies and completed clinical trials are not necessarily predictive of future results, and our current drug candidates may not have favorable results in later studies or trials.**

Preclinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of a drug candidate, but rather to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the drug candidate's side effects at various doses and schedules. To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our drug candidates, except lorcaserin. Favorable results in our early studies or trials may not be repeated in later studies or trials, including continuing preclinical studies and large-scale clinical trials, and our drug candidates in later-stage trials may fail to show desired safety and efficacy despite having progressed through earlier-stage trials. Unfavorable results from ongoing preclinical studies or clinical trials could result in delays, modifications or abandonment of ongoing or future clinical trials, or abandonment of a clinical program. Preclinical and clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated or terminated, or a clinical program to be abandoned. In addition, we may report top-line data from time to time, which is based on a preliminary analysis of key efficacy and safety data, and is subject to change following a more comprehensive review of the data related to the applicable clinical trial.

Many of our research and development programs are in early stages of development, and may not result in the commencement of clinical trials.

Many of our research and development programs are in the discovery or preclinical stage of development. The process of discovering compounds with therapeutic potential is expensive, time consuming and unpredictable. Similarly, the process of conducting preclinical studies of compounds that we discover requires the commitment of a substantial amount of our technical and financial resources and personnel. We may not discover additional compounds with therapeutic potential, and any of the compounds for which we are conducting preclinical studies may not result in the commencement of clinical trials. We cannot be certain that results sufficiently favorable to justify commencement of Phase 1 clinical trials will be obtained in these preclinical investigations. Even if such favorable preclinical results are obtained, our financial resources may not allow us to commence Phase 1 clinical trials. If we are unable to identify and develop new drug candidates, we may not be able to maintain a clinical development pipeline or generate revenues.

***Our revenues, for at least the short term, depend upon the actions of our collaborators and our ability to enter into new collaborations.**

We expect that, for at least the short term, our ability to generate significant revenues will depend upon the success of our existing collaborations and our ability to enter into new collaborations. Future revenues from our collaborations with Merck and Ortho-McNeil-Janssen will depend on, in addition to patent reimbursements, milestone and royalty payments, if any. Thus, we will receive little additional revenues from our existing collaborators if our own or our collaborators' research, development or, ultimately, marketing efforts are unsuccessful.

Typically, our collaborators (and not us) control the development of partnered compounds into drugs after we have met early preclinical scientific milestones. In addition, we may not have complete access to information about the results and status of our collaborators' clinical trials and regulatory programs and strategies. We are not entitled to the more significant milestone payments under our agreements until our collaborators have advanced compounds in clinical testing. Our partners may not devote adequate resources to the development of our compounds and may not develop or implement a successful clinical or regulatory strategy. We cannot guarantee that any development, approval or sales milestones in our existing or future collaborations will be achieved in the future, or that we will receive any payments for the achievement of any milestones. In addition, our existing collaborations, including our collaborations with Merck and Ortho-McNeil-Janssen, may be terminated early in certain circumstances, in which case we may not receive future milestone or royalty payments or patent reimbursements.

Moreover, our ability to enter into new collaborations depends on the outcomes of our preclinical and clinical testing. We do not control these outcomes. In addition, even if our testing is successful, pharmaceutical companies may not partner with us on terms that we believe are acceptable until we have advanced our drug candidates into the clinic and, possibly, through later-stage clinical trials, if at all.

***We may participate in new partnerships and other strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.**

From time to time we consider strategic transactions, such as out-licensing or in-licensing of compounds or technologies, acquisitions of companies and asset purchases. Additional potential transactions we may consider include a variety of

EXHIBIT AG



New England Journal of Medicine Publishes Results of Two-Year BLOOM Trial Showing Lorcaserin Caused Significant Weight Loss and Improved Maintenance of Weight Loss

Lorcaserin Also Improved Values for Biomarkers That May be Predictors of Future Cardiovascular Events

SAN DIEGO and WOODCLIFF LAKE, N.J., July 14, 2010 /PRNewswire via COMTEX News Network/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) and Eisai Inc. today announced that results from the two-year BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management) trial will be published in the July 15, 2010, issue of the *New England Journal of Medicine*. The data presented in the article show that lorcaserin used in conjunction with behavioral modification caused significantly greater weight loss and improved maintenance of weight loss compared to placebo. Lorcaserin also improved values for biomarkers that may be predictive of future cardiovascular events, including lipid levels, insulin resistance, levels of inflammatory markers and blood pressure.

Steven R. Smith, M.D., Scientific Director of the Florida Hospital Translational Research Institute for Metabolism and Diabetes, was the lead author of the article. Neil J. Weissman, M.D., President of MedStar Health Research Institute and Professor of Medicine, Georgetown University, oversaw the echocardiographic safety evaluations that were performed in the study. Drs. Smith and Weissman served as BLOOM's co-principal investigators.

"There is a significant and growing need for effective treatment options that can help patients reduce their weight in a well-tolerated and safe manner," said Dr. Smith. "Lorcaserin patients who completed Year 1 of the BLOOM trial lost an average of 8.2% of their baseline weight and improved their cardiovascular risk factors."

"We have reached another major milestone for Arena with publication of the BLOOM results in the *New England Journal of Medicine*," said Jack Lief, Arena's President and Chief Executive Officer. "We look forward to continued execution of our plans for lorcaserin and interaction with the FDA as it conducts its review of the NDA."

At the end of Year 1 of the BLOOM trial, using Intent-to-Treat with Last Observation Carried Forward analysis (ITT-LOCF), the proportion of patients achieving at least 5% body weight loss in the lorcaserin group (47.5%) was more than twice that achieved by the placebo group (20.3%). Nearly three times as many patients achieved at least 10% weight loss in the lorcaserin group (22.6%) than in the placebo group (7.7%). Lorcaserin patients who completed the first year of the trial according to the protocol lost an average of 8.2% of their baseline weight, or approximately 18 pounds, at the end of Year 1 as compared to approximately 7 pounds in the placebo group. In Year 2, patients who continued to take lorcaserin were significantly better able to maintain their Year 1 weight loss than those who were switched to placebo.

In Year 1, lorcaserin caused significant decreases in waist circumference, BMI, glycemic parameters, high-sensitivity C-reactive protein, and fibrinogen levels compared to placebo. Total cholesterol, LDL cholesterol and triglyceride levels at Year 1 were significantly lower in the lorcaserin group than in the placebo group. Lorcaserin did not increase heart rate or blood pressure; rather, heart rate, systolic blood pressure and diastolic blood pressure decreased slightly but significantly with lorcaserin treatment compared to placebo. Quality of life, measured by the Impact of Weight on Quality of Life-Lite questionnaire, improved in both treatment groups, with a greater improvement in the lorcaserin group than in the placebo group.

At the end of Year 1, 55.4% of patients in the lorcaserin group and 45.1% of patients in the placebo group remained enrolled in the study, and 7.1% and 6.7% of patients, respectively, discontinued the study due to an adverse event. Among the most frequent adverse events reported with lorcaserin were headache (18.0% vs. 11.0%, lorcaserin vs. placebo); dizziness (8.2% vs. 3.8%); and nausea (7.5% vs. 5.4%). The rates of serious adverse events were similar in both treatment groups. The rates of depression and the incidence of anxiety and suicidal thoughts were low in both treatment groups. Lorcaserin caused no significant increase compared to placebo in the incidence of new cardiac valvulopathy.

BLOOM Trial Design

BLOOM, the first of three lorcaserin Phase 3 trials, is a double-blind, randomized, placebo-controlled trial involving 3,182 patients in 98 sites in the United States. The trial evaluated 10 mg of lorcaserin dosed twice daily versus placebo over a two-

year treatment period in obese patients (Body Mass Index, BMI 30 to 45) with or without co-morbid conditions and overweight patients (BMI 27 to less than 30) with at least one co-morbid condition, such as hypertension, cardiovascular diseases or glucose intolerance. All patients received diet and exercise counseling, and the trial did not include any dose titration or run-in period. Patients were randomized in a 1:1 ratio to lorcaserin or placebo at baseline. At Week 52, 856 patients taking lorcaserin were re-randomized in a 2:1 ratio to continue lorcaserin or switch to placebo, and 697 patients on placebo were continued on placebo. Patients underwent echocardiography at screening, and at 6, 12, 18 and 24 months after initiating dosing in the trial; patients with FDA-defined valvulopathy were excluded from enrolling in the trial.

About Lorcaserin

Lorcaserin is a new chemical entity that is believed to act as a selective serotonin 2C receptor agonist. The serotonin 2C receptor is expressed in the brain, including the hypothalamus, an area involved in the control of appetite and metabolism. Stimulation of the serotonin 2C receptor in the hypothalamus is associated with feeding behavior and satiety. Arena has patents that cover lorcaserin in the United States and other jurisdictions, which in most cases are capable of continuing into 2023 without taking into account any patent term extensions or other exclusivity Arena might obtain.

About Arena Pharmaceuticals

Arena is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing oral drugs that target G protein-coupled receptors, an important class of validated drug targets, in four major therapeutic areas: cardiovascular, central nervous system, inflammatory and metabolic diseases. Arena's most advanced drug candidate, lorcaserin, is intended for weight management and has completed a pivotal Phase 3 clinical trial program. Arena has filed an NDA for lorcaserin with the FDA, and the FDA has assigned a PDUFA date of October 22, 2010, for review of the application. Arena Pharmaceuticals GmbH, a wholly owned subsidiary of Arena Pharmaceuticals, Inc., has granted Eisai Inc. exclusive rights to market and distribute lorcaserin in the United States.

Arena Pharmaceuticals(R) and Arena(R) are registered service marks of the company.

About Eisai Inc.

Eisai Inc. was established in 1995 and is ranked among the top-20 U.S. pharmaceutical companies (based on retail sales). The company began marketing its first product in the United States in 1997 and has rapidly grown to become a fully integrated pharmaceutical business with fiscal year 2009 (year ended March 31, 2010) sales of approximately \$3.9 billion. Eisai's areas of commercial focus include neurology, gastrointestinal disorders and oncology/critical care. The company serves as the U.S. pharmaceutical operation of Eisai Co., Ltd.

Eisai has a global product creation organization that includes U.S.-based R&D facilities in Maryland, Massachusetts, New Jersey, North Carolina and Pennsylvania as well as manufacturing facilities in Maryland and North Carolina. The company's areas of R&D focus include neuroscience; oncology; vascular, inflammatory and immunological reaction; and antibody-based programs. For more information about Eisai, please visit www.eisai.com.

Forward-Looking Statements

Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include statements about the advancement, therapeutic indication and use, safety, efficacy, tolerability and potential of lorcaserin; significance of biomarkers; the need for obesity treatments; interactions with the FDA; regulatory review and potential regulatory approval and commercialization of lorcaserin; lorcaserin's patent coverage; and Arena's focus, goals, strategy, research and development programs, and ability to develop compounds, commercialize drugs and execute on its plans. For such statements, Arena claims the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from Arena's expectations. Factors that could cause actual results to differ materially from the forward-looking statements include, but are not limited to, risks related to the implementation and continuation of the marketing and supply agreement with Eisai and dependence on Eisai for commercialization of lorcaserin in the United States; regulatory authorities or advisors may not find data from Arena's clinical trials and other studies sufficient for regulatory approval; the timing and ability of Arena to receive regulatory approval for its drug candidates; the ability to enter into agreements to develop or commercialize lorcaserin and other of Arena's compounds or programs; Arena's ability to commercialize lorcaserin outside of the United States with another company or independently; the timing, success and cost of the lorcaserin program and other of Arena's research and development programs; results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results; clinical trials and other studies may not proceed at the time or in the manner Arena or others expect or at all; Arena's ability to obtain adequate funds; Arena's ability to obtain and defend its patents; and the timing and receipt of payments and fees, if any, from Eisai and Arena's collaborators. Additional factors that could cause actual results to differ materially from those stated or implied by Arena's forward-looking statements are disclosed in Arena's filings with the Securities and Exchange Commission. These forward-looking statements represent Arena's judgment as of the time of this release. Arena disclaims any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

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MANAGEMENT DISCUSSION SECTION

Operator: Good day, everyone, and welcome to the Arena Pharmaceuticals Second Quarter 2009 Financial Results Conference. As a reminder, today's call is being recorded.

At this time for opening remarks and introductions, I would like to turn the conference over to Arena's Vice President, Finance and Chief Financial Officer, Mr. Robert Hoffman. Mr. Hoffman, please go ahead, sir.

Robert E. Hoffman, Vice President of Finance and Chief Financial Officer

Thank you, Sara. Good afternoon, and welcome to Arena Pharmaceuticals' second quarter 2009 financial results conference call. I'm Robert Hoffman, Arena's Vice President of Finance and Chief Financial Officer. Joining me on the call today is Jack Lief, our President and Chief Executive Officer. Also available to help address any questions after our prepared remarks are Dominic Behan, our Senior Vice President and Chief Scientific Officer; Bill Shanahan, our Vice President and Chief Medical Officer; and Christie Anderson, our Vice President of Clinical Development. After Jack provides an introduction, I'll review our financial results for the second quarter of 2009.

Before we begin, I'd like to point out that we'll be making numerous forward-looking statements during this conference call. Such forward-looking statements include statements about our clinical trials and results, internal and partnered programs, drug candidate pipeline, technologies, financial guidance, assumptions, strategy, plans, and other statements that are not historical facts.

Such statements may include the words, may, plan, will, believe, expect, potential, intend or similar words. You are cautioned not to place undue reliance on these forward-looking statements, which are only predictions and reflect the company's beliefs, expectations, and assumptions based on currently available operating, financial and competitive information and speak only as of the time they are made.

Risks and uncertainties that could cause actual results to differ materially from those described in our forward-looking statements include the timing, success and cost of clinical trials, preclinical studies and research activities, the regulatory process, the timing and outcome of our partnership efforts, our ability to obtain additional funds from collaborators and investors, whether our assumptions prove to be correct, and other risks identified in our SEC reports.

For a discussion of these and other factors, please refer to the risk factors described in our filings with the Securities and Exchange Commission. For forward-looking statements, we claim the protection of the Private Securities Litigation Reform Act of 1995.

Now I'd like to turn the call over to our President and CEO, Jack Lief.

Jack Lief, Co-Founder, Chairman, President and Chief Executive Officer

Good afternoon, everyone, and welcome to our second quarter 2009 conference call. On today's call, I will first discuss the following important topics: one, the current status of our lorcaserin program; two, the increased recognition of the health and financial impacts of obesity; and three, the potential commercial opportunities for lorcaserin. I will then turn it over to Robert to review our financials before returning to provide a further business update and review upcoming milestones. We will then open the call to your questions.

Let me begin by telling you that our lorcaserin program remains on track. I'm pleased to announce that dosing is now complete in all lorcaserin registration studies that will be included in the New

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Drug Application or NDA submission. We have received results from the abuse potential study, which were favorable, and we plan to publish the data in a peer review journal. Based on the results of this study, we and our expert consultants believe that lorcaserin has a very low abuse potential. We look forward to announcing data from the BLOSSOM trial next month followed by presentations of our BLOOM and BLOSSOM results at the Annual Scientific Meeting of the Obesity Society in late October. And late this year we expect to file lorcaserin's NDA.

Also of note, BLOOM-DM, our one-year study evaluating lorcaserin in patients with type-2 diabetes, completed enrolment last month. As previously stated, BLOOM-DM will be filed as a supplement to the lorcaserin NDA.

In support of our focus on lorcaserin, we've recently been able to execute two significant financial transactions to put us in a stronger financial position. This is important as it provides us with negotiating power and flexibility in partnership discussions for lorcaserin as well as our earlier stage drug candidates.

Moving to the second topic that I'd like to address, recently published research on the costs of obesity highlights the impact of this health crisis above and beyond the medical consequences. Furthermore, these data reinforce the importance of an agent like lorcaserin, which could help patients manage their weight and possibly reduce long-term health consequences of obesity.

According to a study published last week, in the journal "Health Affairs", obesity costs Americans \$147 billion per year, a number that has recently doubled since 1998. And, obesity now makes up about 10% of the total cost of health care. Importantly, the majority of these costs are related to treatment of medical conditions resulting from obesity, not from the treatment of obesity itself. Rather than preventing and treating obesity, we've been treating and paying for the co-morbid conditions caused by excess weight. Fortunately, awareness of the health and financial implications of excess body weight is resulting in a call to action among the government, employers and insurers.

Former President Bill Clinton and U.S. Department of Health and Human Services Secretary, Kathleen Sebelius spoke at last week's Weight of the Nation, the CDC's inaugural conference on obesity prevention and control. Secretary Sebelius said that they expect a significant amount of the \$1 billion appropriated by Congress for disease prevention, as part of the stimulus plan, to go to a CDC planned initiative to fight obesity.

Former President Bill Clinton added that obesity is the number one health problem. Last week's conference and publication underscore the magnitude and significance of the obesity crisis. We believe that lorcaserin's complete efficacy, safety, and tolerability profile will position the drug candidate as an ideal new option to help manage excess body weight and its associated risks.

At the ADA Meeting in June, we had the opportunity to present efficacy and safety data from the BLOOM trial. Two thirds of lorcaserin patients who completed one year of treatment according to the trial's protocol lost at least 5% of their weight and the average weight loss in this responder population was 26 pounds.

As a reminder, lorcaserin's tolerability profile allows patients to begin therapy on the full dose and achieve rapid weight loss without a titration period. By week four of the BLOOM trial, using ITT [intent-to-treat] analysis, 11% of lorcaserin patients lost at least 5% of their body weight, nearly three times as many as on placebo. In addition, cardiovascular metabolic risk factors improved for lorcaserin patients versus those on placebo as measured by blood pressure, heart rate, cholesterol, CRP and insulin resistance.

Lorcaserin also helped patients maintain weight loss. During the second year of the trial, patients who continue to take lorcaserin kept more weight off than those who switched to placebo. In year

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two of the BLOOM study, lorcaserin helped over two thirds of patients maintain their 5% of greater weight loss.

Lorcaserin was very well-tolerated, as reflected by the low incidence of withdrawals due to adverse events. Transient headache was the only adverse event that exceeded placebo by greater than 5%.

Looking forward, we expect the BLOSSOM trial to confirm BLOOM results. If it does, we believe that lorcaserin will have a safety and efficacy profile that is consistent with the FDA approvability criteria. This compelling safety and efficacy profile will differentiate lorcaserin from currently available therapies and others in late-stage development.

Lorcaserin could represent the first in a new class of effective and well tolerated weight management therapeutics and hopefully will be an important new option for physicians and patients currently struggling to manage weight. We think that lorcaserin's overall profile will provide physicians with a confidence to use it as a first line therapy for the majority of their patients.

Before I turn the call over the Robert to discuss the financials, I'd like to reiterate that we believe lorcaserin has the potential to substantially impact obesity, a significant problem in a large number of patients as illustrated by my earlier remarks. We're confident that this potential will translate into an attractive market opportunity. Robert?

Robert E. Hoffman, Vice President, Finance and Chief Financial Officer

Thank you, Jack. First I'll review our financial results for the second quarter and first six months of 2009, then I'll review our financial guidance for 2009.

In the second quarter of 2009, we recorded revenues of approximately \$2.4 million compared to second quarter 2008 revenues of approximately \$2.6 million. Second quarter 2009 revenues included 1.5 million in manufacturing services revenue under our manufacturing services agreement with Siegfried; and 0.9 million for patent activities from our collaborations with Merck and Ortho-McNeil-Janssen.

In the first six months of 2009 we recorded revenues of approximately \$5.1 million compared to first six months 2008 revenues of \$5.3 million. Revenues in the first six months of 2009 included \$2.9 million in manufacturing services revenue under our manufacturing services agreement with Siegfried and 2.2 million for patent activities from our collaborations with Merck and Ortho-McNeil-Janssen.

As expected, Research and Development expenses decreased significantly in the second quarter of 2009 as compared to 2008. In the second quarter of 2009, Research and Development expenses were approximately \$24.2 million compared to approximately \$56.2 million in the second quarter of 2008. This \$32 million, or 57%, decrease was primarily attributable to a decrease in clinical study fees and expenses of approximately \$27.1 million due to completing our BLOOM trial and nearing the completion of our BLOSSOM trial as well as the completion of clinical trials in our other programs as we prioritized our spending towards completing lorcaserin activities that support filing an NDA for lorcaserin.

Research and Development expenses also decreased significantly in the first six months of 2009 as compared to 2008. In the first six months of 2009, Research and Development expenses were approximately \$66.8 million as compared to approximately \$103.6 million in the first six months of 2008. This \$36.8 million decrease was primarily attributable to decreases of \$30.8 million in external clinical and preclinical study fees and expenses, which was primarily due to completing our BLOOM trial and nearing the completion of our BLOSSOM trial. Research and Development

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QUESTION AND ANSWER SECTION

Operator: Thank you, Mr. Lief. [Operator Instructions]. And we'll take our first question with Thomas Wei at Piper Jaffray.

<Q – Thomas Wei>: Thanks. I had a question on the BLOSSOM data; just as we've seen some variability from trial to trial with other weight-loss development programs in terms of efficacy, I just wanted to understand to what degree there are differences that you can tell in patient demographics, or maybe the entry criteria, the use of [inaudible] dietary modification in BLOSSOM that might make the data look different from the BLOOM study?

<A – Jack Lief>: I'll let Bill Shanahan, our Chief Medical Officer answer that question regarding what differences we expect from BLOSSOM versus BLOOM.

<A – William Shanahan, Jr.>: Yes. We expect very little difference. As you know, the BLOOM trial was a very large trial, 3,200 patients in approximately 100 centers and we have very similar inclusion/exclusion criteria in the two trials. So that's what we're basing it on; we expect the data to be very similar. And there is – you can see those kinds of comparisons like with the Ramona Vam data previously.

<Q – Thomas Wei>: And when you look at the efficacy data on a blinded basis, does it look similar in terms of the number of patients who are getting a greater than 5% weight loss? Does it look like the BLOOM data?

<A – Jack Lief>: Bill?

<A – William Shanahan, Jr.>: We're not going to comment specifically on that. I mean, again, we just expect very comparable results when we unblind the study.

<Q – Thomas Wei>: And one last question; just as you've had a chance now with the BLOOM data to go out and re-approach some of your prospective partners, curious how they've looked at the data, especially on the efficacy side and the magnitude of the weight loss?

<A – Jack Lief>: So, we do talk to partners. And I think it would be inappropriate to comment on their comments right now, other than to mention that there is a lot of diligence that is going on.

<Q – Thomas Wei>: Okay. Thanks.

<A – Jack Lief>: Sure.

Operator: We'll take our next question from Alan Carr at Needham & Company.

<Q – Alan Carr>: Hi, good afternoon, everyone.

<A – Jack Lief>: Hi, Alan.

<Q – Alan Carr>: Are there any other gating studies, pre-clinical or clinical, that are still needed at the FDA? Is that last abuse potential trial – is that the last of them?

<A – Jack Lief>: Christie, do you want to comment on that?

<A – Christen Anderson>: Sure. Yes, the abuse liability study pretty much finished up the package that we are planning to submit to the FDA as our initial NDA submission. So we will have no additional studies that we'll be submitting in the initial NDA once we complete that study report.

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Arena Pharmaceuticals Announces Second Quarter 2009 Financial Results and Recent Developments

SAN DIEGO, Aug. 3, 2009, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) today reported financial results for the second quarter ended June 30, 2009.

Arena reported a lower net loss allocable to common stockholders in the second quarter of 2009 of \$38.0 million, or \$0.48 per share, compared to a net loss allocable to common stockholders in the second quarter of 2008 of \$65.8 million, or \$0.89 per share, and a net loss allocable to common stockholders in the first half of 2009 of \$88.6 million, or \$1.16 per share, compared to a net loss allocable to common stockholders in the first half of 2008 of \$120.8 million, or \$1.64 per share.

"We are on track to announce results from the BLOSSOM trial in September, which we expect will be the final piece of lorcaserin's NDA that we plan to submit by the end of this year," stated Jack Lief, Arena's President and Chief Executive Officer. "Based on its emerging efficacy, safety and tolerability profile, lorcaserin has the potential to be an important new treatment option for patients needing to better manage their weight and improve their overall health. Our improved financial position strengthens our ability to obtain marketing approval for lorcaserin and our position in partnership discussions."

As expected, research and development expenses declined significantly to \$24.2 million in the second quarter of 2009 from \$56.2 million in the second quarter of 2008. Research and development expenses declined to \$66.8 million in the first half of 2009 from \$103.6 million in the first half of 2008. This decrease primarily resulted from decreased clinical trial costs due to the completion of clinical and preclinical studies as Arena prioritized its spending towards activities that support filing a New Drug Application, or NDA, for lorcaserin. Arena expects its research and development expenses to continue to decline this year as dosing in BLOSSOM (Behavioral modification and LOrcaserin Second Study for Obesity Management), the second of two pivotal trials evaluating the safety and efficacy of lorcaserin for weight management, is now complete and Arena realizes expected cost savings from its recently completed workforce reduction and other cost-containment efforts. Research and development expenses in the first half of 2009 included \$1.8 million in non-cash, share-based compensation expense, compared to \$2.2 million in the first half of 2008. General and administrative expenses totaled \$5.7 million in the second quarter of 2009, compared to \$7.2 million in the second quarter of 2008, and \$13.3 million in the first half of 2009, compared to \$16.0 million in the first half of 2008. This decrease is primarily attributable to lower patent and other legal fees. General and administrative expenses in the first half of 2009 included \$1.6 million in non-cash, share-based compensation expense, compared to \$2.1 million in the first half of 2008.

At June 30, 2009, cash, cash equivalents and short-term investments totaled \$39.6 million and approximately 80.1 million shares of common stock were outstanding. In July 2009, Arena received net proceeds of approximately \$95.6 million from a \$100.0 million secured loan and approximately \$49.7 million from a public offering of 12.5 million shares of its common stock.

Arena's Recent and Second Quarter Developments

- Completed dosing in all lorcaserin clinical trials expected to be included in the planned NDA submission. Arena plans to report results from BLOSSOM in September 2009.
- Completed enrollment in BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus), a one-year study evaluating lorcaserin in obese and overweight patients with type 2 diabetes. Results from BLOOM-DM will be submitted as a supplement to the lorcaserin NDA filing.
- Announced a late-breaking poster presentation of positive results from BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management), the first of two pivotal trials evaluating the safety and efficacy of lorcaserin for weight management, at the 69th Scientific Sessions of the American Diabetes Association. Lorcaserin patients achieved highly significant categorical and absolute weight loss in Year 1, and continued treatment with lorcaserin in Year 2 helped

significantly more patients maintain their weight loss as compared to those on placebo. 66.4% of lorcaserin patients who completed one year of treatment according to the trial's protocol lost at least 5% of their weight and the average weight loss in this responder population was 26 pounds. Treatment with lorcaserin also resulted in highly significant improvements as compared to placebo in multiple secondary endpoints associated with cardiovascular risk. Lorcaserin was very well tolerated, did not result in increased risk of depression and was not associated with development of cardiac valvular insufficiency.

- Ortho-McNeil-Janssen completed a Phase 1 clinical trial evaluating the safety, tolerability, pharmacokinetics and pharmacodynamics of a single ascending dose of APD597 in healthy volunteers. Ortho-McNeil-Janssen has initiated another clinical trial evaluating multiple ascending doses of APD597.
- Completed a public offering of 12.5 million shares of common stock, resulting in net proceeds to Arena of approximately \$49.7 million.
- Received net proceeds of \$95.6 million from a \$100.0 million secured loan provided by Deerfield Management. The outstanding principal accrues interest until maturity in June 2013 at a rate of 7.75% per annum. In connection with the loan, Arena issued Deerfield warrants for 28 million shares of its common stock at an exercise price of \$5.42 per share. On or before June 17, 2011, Deerfield may make a one-time election to provide Arena with up to an additional \$20.0 million under the same terms, with the additional loan also maturing in June 2013. For each additional \$1.0 million in funding, Arena will issue Deerfield additional warrants for 280,000 shares of its common stock at an exercise price of \$5.42 per share. Arena repaid Deerfield the first scheduled principal repayment of \$10.0 million upon completion of its public offering in July.
- Received aggregate net proceeds of \$14.7 million from the sale of approximately 5.7 million shares of common stock under a \$50.0 million equity financing commitment with Azimuth Opportunity Ltd. During the 18-month term of the equity financing commitment, Arena may sell newly issued registered shares of its common stock to Azimuth at a pre-negotiated discount to the market price.
- Completed a reduction in Arena's US workforce of approximately 31%, or a total of approximately 130 employees.

2009 Financial Guidance

Arena reported that it expects to end 2009 with \$120 million to \$130 million in cash, cash equivalents and short-term investments, reflecting net proceeds from its secured loan with Deerfield and public offering of 12.5 million shares of common stock, both completed in July 2009. Arena reiterated the other components of its full year 2009 financial guidance, including external clinical and preclinical study fees and expenses of approximately \$42 million to \$46 million, internal research and development expenses of approximately \$62 million to \$66 million (including non-cash expenses of approximately \$12 million), general and administrative expenses of approximately \$24 million to \$26 million (including non-cash expenses of approximately \$3 million), and capital expenditures of approximately \$5 million.

Scheduled Earnings Call

Arena will host both a conference call and webcast to discuss the second quarter 2009 financial results and to provide a business and financial update today, Monday, August 3, 2009, at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). Jack Lief, President and Chief Executive Officer, and Robert E. Hoffman, Vice President, Finance and Chief Financial Officer, will host the conference call.

The conference call may be accessed by dialing 877.397.0235 for domestic callers and 719.325.4881 for international callers. Please specify to the operator that you would like to join the "Arena Pharmaceuticals' Second Quarter 2009 Earnings Call." The conference call will be webcast live under the investor relations section of Arena's website at www.arenapharm.com, and will be archived there for 30 days following the call. Please connect to Arena's website several minutes prior to the start of the broadcast to ensure adequate time for any software download that may be necessary.

Upcoming Corporate Presentations

Arena plans to present at upcoming investment and industry conferences, including:

- BMO Capital Markets 9th Annual Focus on Healthcare Conference, August 5, 2009, New York, New York
- Rodman & Renshaw Annual Global Investment Conference, September 9-11, 2009, New York, New York
- NewsMakers in the Biotech Industry, September 16, 2009, New York, New York
- UBS Global Life Sciences Conference, September 21-23, 2009, New York, New York

About Arena Pharmaceuticals

Arena is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing oral drugs in four major therapeutic areas: cardiovascular, central nervous system, inflammatory and metabolic diseases. Arena's most advanced drug candidate, lorcaserin, is being investigated in a Phase 3 clinical trial program for weight management. Arena has a broad pipeline of novel compounds targeting G protein-coupled receptors, an important class of validated drug targets, which includes compounds being evaluated independently and with partners, including Merck & Co., Inc., and Ortho-McNeil-Janssen Pharmaceuticals, Inc.

Arena Pharmaceuticals(R) and Arena(R) are registered service marks of the company. "APD" is an abbreviation for Arena Pharmaceuticals Development.

Forward-Looking Statements

Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include statements about future activities, results and announcements relating to lorcaserin, including the BLOSSOM results, the submission of a lorcaserin NDA, the content of such NDA, and the submission of the BLOOM-DM results as a supplement to the NDA; the development, advancement, therapeutic indication, tolerability, safety, selectivity and efficacy of lorcaserin; the protocol, design, scope, enrollment and other aspects of the lorcaserin trials; the potential of lorcaserin in managing weight, improving health and generating commercial and other interest; Arena's financial position and its impact on Arena's abilities; the approval of lorcaserin for marketing; partnering discussions; financial guidance; the decline of Arena's research and development expenses; cost savings from Arena's reduction in force and other cost-containment efforts; dosing in lorcaserin clinical trials expected to be included in the planned NDA submission; Arena's agreements with Azimuth and Deerfield and rights and future activities thereunder; and Arena's strategy, internal and partnered programs, and ability to develop compounds and commercialize drugs. For such statements, Arena claims the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from Arena's expectations. Factors that could cause actual results to differ materially from the forward-looking statements include, but are not limited to, the timing, success and cost of Arena's lorcaserin program and other of its research and development programs; results of clinical trials or preclinical studies may not be predictive of future results; clinical trials and studies may not proceed at the time or in the manner Arena expects or at all; Arena's ability to partner lorcaserin or other of its compounds or programs; the timing and ability of Arena to receive regulatory approval for its drug candidates; Arena's ability to obtain additional funds; Arena's ability to obtain and defend its patents; and the timing and receipt of payments and fees, if any, from Arena's collaborators. Additional factors that could cause actual results to differ materially from those stated or implied by Arena's forward-looking statements are disclosed in Arena's filings with the Securities and Exchange Commission. These forward-looking statements represent Arena's judgment as of the time of this release. Arena disclaims any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

Arena Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations
(In thousands, except per share amounts)

Three months ended		Six months ended	
June 30,		June 30,	
-----		-----	
2009	2008	2009	2008
----	----	----	----
(unaudited)		(unaudited)	

Revenues				
Manufacturing services	\$1,508	\$2,000	\$2,926	\$4,019
Collaborative agreements	920	645	2,160	1,235
	-----	-----	-----	-----
Total revenues	2,428	2,645	5,086	5,254
Operating Expenses				
Cost of manufacturing services	1,643	2,290	2,997	4,620
Research and development	24,205	56,206	66,825	103,574
General and administrative	5,660	7,153	13,302	16,014
Restructuring charges	3,324	-	3,324	-
Amortization of acquired technology & other intangibles	573	588	1,139	1,169
	-----	-----	-----	-----
Total operating expenses	35,405	66,237	87,587	125,377
Interest and other income (expense), net	(5,006)	(1,677)	(6,096)	389
	-----	-----	-----	-----
Net loss	(37,983)	(65,269)	(88,597)	(119,734)
Dividends on redeemable convertible preferred stock	-	(546)	-	(1,086)
	-----	-----	-----	-----
Net loss allocable to common stockholders	\$(37,983)	\$(65,815)	\$(88,597)	\$(120,820)
	=====	=====	=====	=====
Net loss per share allocable to common stockholders, basic & diluted	\$(0.48)	\$(0.89)	\$(1.16)	\$(1.64)
	=====	=====	=====	=====
Shares used in calculating net loss per share allocable to common stockholders, basic & diluted	79,212	73,815	76,701	73,710
	=====	=====	=====	=====

Arena Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheet Data
(In thousands)

	June 30, 2009	December 31, 2008
	----- (unaudited)	----- (Note)
Assets		
Cash, cash equivalents & short-term investments	\$39,599	\$110,129
Accounts receivable	1,663	1,823
Other current assets	4,666	5,031
Land, property & equipment, net	97,082	102,740
Acquired technology & other non-current assets	20,515	21,608
	-----	-----
Total assets	\$163,525	\$241,331
	=====	=====
Liabilities and Stockholders' Equity		
Accounts payable, accrued liabilities & warrant liability	\$26,762	\$46,789
Total deferred revenues	4,049	4,049
Total lease financing obligations & other		

long-term liabilities	87,776	72,861
Total stockholders' equity	44,938	117,632
	-----	-----
Total liabilities & stockholders' equity	\$163,525	\$241,331
	=====	=====

Note: The Condensed Consolidated Balance Sheet Data has been derived from the audited financial statements as of that date.

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EXHIBIT AK



Arena Pharmaceuticals Announces Fourth Quarter and Full Year 2009 Financial Results

SAN DIEGO, March 12, 2010 /PRNewswire via COMTEX News Network/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) today reported financial results for the fourth quarter and full year ended December 31, 2009.

Arena reported a lower net loss allocable to common stockholders in the fourth quarter of 2009 of \$29.8 million, or \$0.32 per share, compared to a net loss allocable to common stockholders in the fourth quarter of 2008 of \$62.5 million, or \$0.84 per share, and a net loss allocable to common stockholders in the full year ended December 31, 2009 of \$153.2 million, or \$1.82 per share, compared to a net loss allocable to common stockholders in the full year ended December 31, 2008 of \$239.5 million, or \$3.24 per share.

"We are pleased with the timely execution and significant progress made in our lorcaserin program," stated Jack Lief, Arena's President and Chief Executive Officer. "As we continue efforts to reach a commercial agreement for lorcaserin, we are building a strong foundation for a successful launch upon potential approval."

As expected, research and development expenses declined significantly to \$21.2 million in the fourth quarter of 2009 from \$53.3 million in the fourth quarter of 2008. Research and development expenses declined to \$110.2 million in the full year ended December 31, 2009 from \$204.4 million in the full year ended December 31, 2008. This decrease is due primarily to the completion of the BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management) and BLOSSOM (Behavioral modification and Lorcaserin Second Study for Obesity Management) Phase 3 clinical trials evaluating the safety and efficacy of lorcaserin for weight management, and prioritizing spending towards activities that supported the December 2009 submission of a New Drug Application, or NDA, for lorcaserin. Arena expects its research and development expenses to continue to decline in 2010 due to the completion of the BLOOM and BLOSSOM clinical trials, expected cost savings related to the second-quarter 2009 workforce reduction and other cost-containment measures. Research and development expenses for all of 2009 included \$4.1 million in non-cash, share-based compensation expense, compared to \$5.0 million in 2008. General and administrative expenses totaled \$6.5 million in the fourth quarter of 2009, compared to \$8.6 million in the fourth quarter of 2008, and \$25.2 million in full year ended December 31, 2009, compared to \$30.5 million in the full year ended December 31, 2008. General and administrative expenses in the full year ended December 31, 2009 included \$2.8 million in non-cash, share-based compensation expense, compared to \$3.5 million in 2008.

Total interest and other expense increased to \$14.8 million in the full year ended December 31, 2009 from \$1.6 million in 2008, due to a \$13.3 million increase in interest expense primarily related to the loan Arena received in July 2009.

At December 31, 2009, cash, cash equivalents and short-term investments totaled \$115.4 million and approximately 92.8 million shares of common stock were outstanding. On March 9, 2010, Arena received net proceeds of approximately \$24.2 million from the sale of approximately 8.3 million shares under an equity financing commitment it entered into with Azimuth Opportunity Ltd., or Azimuth, in March 2009.

Arena's Recent Developments

Lorcaserin

- Filed an NDA for lorcaserin and the US Food and Drug Administration, or FDA, has assigned a Prescription Drug User Fee Act, or PDUFA, date of October 22, 2010 for review of the application. The NDA is based on a data package from lorcaserin's development program that includes 18 clinical trials totaling 8,576 patients. The pivotal Phase 3 clinical trial program, BLOOM and BLOSSOM, evaluated nearly 7,200 patients treated for up to two years. In both trials, lorcaserin produced statistically significant weight loss with excellent safety and tolerability.
- Presented favorable data from a clinical trial evaluating the abuse potential of lorcaserin in a poster session at the 48th Annual Meeting of the American College of Neuropsychopharmacology. Investigational drugs that act through mechanisms in the brain are generally required to undergo an evaluation to determine abuse potential. The clinical trial compared the relative abuse potential of lorcaserin against three comparators: placebo, zolpidem, a schedule IV controlled substance, and ketamine, a schedule III controlled substance. Data from the trial demonstrate that the risk for abuse associated with lorcaserin is very low and less than that of zolpidem or ketamine.
- Presented results from the BLOSSOM trial and additional positive data from the BLOOM trial at the 27th Annual Scientific

- Meeting of The Obesity Society. The BLOSSOM data demonstrate improvements in patients' body composition, cardiovascular risk factors and quality of life. The BLOOM data demonstrate that lorcaserin significantly improved markers of cardiovascular risk and glycemic parameters and was not associated with depression or suicidal ideation. Lorcaserin patients who completed Year 1 of the BLOOM trial according to protocol lost 31% of their excess body weight.
- Announced positive top-line results from the BLOSSOM trial. Lorcaserin patients achieved statistically significant categorical and absolute weight loss over one year of treatment. About two-thirds (63.2%) of lorcaserin patients who received lorcaserin 10 mg twice daily and completed the trial according to the protocol lost at least 5% of their weight and more than one-third (35.1%) of these lorcaserin patients lost at least 10% of their weight. The average weight loss for these lorcaserin patients was 17.0 pounds, and the top quartile lost an average of 35.1 pounds. Lorcaserin was very well tolerated and adverse events of depression, anxiety and suicidal ideation were infrequent and were reported at a similar rate in each treatment group. The incidence of new FDA-defined valvulopathy from the integrated echocardiographic data set from BLOOM and BLOSSOM was similar to that of placebo.
 - Completed enrollment in BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus), a one-year trial evaluating lorcaserin in obese and overweight patients with type 2 diabetes. Arena plans to file the results of BLOOM-DM as a supplement to the lorcaserin NDA.
 - Presented positive results from the BLOOM trial at the 69th Scientific Sessions of the American Diabetes Association. Lorcaserin patients achieved statistically significant categorical and absolute weight loss in Year 1, and over two-thirds (67.9%) of lorcaserin patients that achieved 5% or greater weight loss in Year 1 and continued treatment with lorcaserin in Year 2 maintained 5% or greater weight loss. About two-thirds (66.4%) of lorcaserin patients who completed one year of treatment according to the trial's protocol lost at least 5% of their weight and the average weight loss in this responder population was 26 pounds. More than one-third (36.2%) of lorcaserin patients who completed one year of treatment according to the trial's protocol lost at least 10% of their weight. Treatment with lorcaserin also resulted in statistically significant improvements as compared to placebo in multiple secondary endpoints associated with cardiovascular risk. Lorcaserin was very well tolerated, did not result in increased risk of depression or suicidal ideation compared to placebo and was not associated with development of cardiac valvular insufficiency.

Other Developments

- Received aggregate net proceeds of \$24.2 million from the sale of approximately 8.3 million shares of common stock in March 2010, and aggregate net proceeds of \$14.7 million from the sale of approximately 5.7 million shares of common stock in April 2009, both under Arena's equity financing commitment with Azimuth.
- Through an affiliate, Merck and Co., Inc., or Merck, discontinued development of MK-1903, an investigational niacin receptor agonist to treat atherosclerosis being developed under its research and development collaboration with Arena, and notified Arena of its decision to discontinue the collaboration.
- Completed a public offering in July 2009 of 12.5 million shares of common stock, resulting in net proceeds to Arena of \$49.7 million.
- Completed a reduction in Arena's US workforce of approximately 31%, or a total of approximately 130 employees.
- Received net proceeds of \$95.6 million from a \$100.0 million loan provided by Deerfield Management, or Deerfield. The outstanding principal accrues interest until maturity in June 2013 at a rate of 7.75% per annum. In connection with the loan, Arena issued Deerfield warrants for 28,000,000 shares of its common stock at an exercise price of \$5.42 per share. On or before June 17, 2011, Deerfield may make a one-time election to provide Arena with up to an additional \$20.0 million under similar terms, with the additional loan also maturing in June 2013. For each additional \$1.0 million in funding, Arena will issue Deerfield additional warrants for 280,000 shares of its common stock at an exercise price of \$5.42 per share. Arena repaid Deerfield the first scheduled principal repayment of \$10.0 million upon completion of the public offering in July 2009.
- Ortho-McNeil-Janssen Pharmaceuticals, Inc., or Ortho-McNeil-Janssen, completed a Phase 1 clinical trial in healthy volunteers evaluating the safety, tolerability, pharmacokinetics and pharmacodynamics of single ascending doses of APD597, a novel oral drug candidate that targets GPR119 for the treatment of type 2 diabetes. Ortho-McNeil-Janssen has initiated another clinical trial evaluating multiple ascending doses of APD597.
- Received net proceeds of \$14.6 million as reimbursement for improvements made to one of Arena's facilities.

Outlook for 2010

Arena expects to use cash, cash equivalents and short-term investments of approximately \$97 to \$107 million for its operating activities and interest expense in 2010, and approximately \$7 million for capital expenditures primarily for the manufacturing facility in Switzerland. This assumes that Arena, and not another pharmaceutical company, pays for the lorcaserin pre-commercial launch activities.

"Our primary objectives in 2010 are getting lorcaserin approved by the FDA and optimizing the value of lorcaserin in a commercial agreement," stated Mr. Lief. "We are active in several areas to meet these objectives and to ensure the success of the anticipated lorcaserin launch. We are manufacturing lorcaserin at our Swiss facility and completing the build-out of our commercial supply chain. We are taking important steps to more fully understand the weight management market to be in a position to increase market awareness of the potential medical benefits of adding pharmacotherapy to a weight loss program. We are also engaged in other commercial-readiness activities. Our intention remains to establish an agreement with a pharmaceutical company to commercialize lorcaserin, and we believe that these foundation-building efforts are prudent to

prepare for lorcaserin's anticipated entry into a large and currently underdeveloped market."

Scheduled Earnings Call

Arena will host both a conference call and webcast to discuss the fourth quarter and full year 2009 financial results and to provide a business and financial update today, Friday, March 12, 2010, at 8:30 a.m. Eastern Time (5:30 a.m. Pacific Time). Jack Lief, President and Chief Executive Officer, and Robert E. Hoffman, Vice President, Finance and Chief Financial Officer, will host the conference call.

The conference call may be accessed by dialing 877.643.7155 for domestic callers and 914.495.8552 for international callers. Please specify to the operator that you would like to join the "Arena Pharmaceuticals' Fourth Quarter and Full Year 2009 Financial Results Call." The conference call will be webcast live under the investor relations section of Arena's website at www.arenapharm.com, and will be archived there for 30 days following the call. Please connect to Arena's website several minutes prior to the start of the broadcast to ensure adequate time for any software download that may be necessary.

Upcoming Corporate Presentations

Arena is planning to present at upcoming investment and industry conferences, including:

- Barclays Capital 2010 Global Healthcare Conference, March 23-24, 2010, Miami, Florida
- Deutsche Bank 35th Annual Health Care Conference, May 3-5, 2010, Boston, Massachusetts
- The Ninth Annual JMP Securities Research Conference, May 10-12, 2010, San Francisco, California
- Jefferies 2010 Global Life Sciences Conference, June 8-11, 2010, New York, New York

About Arena Pharmaceuticals

Arena is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing oral drugs that target G protein-coupled receptors, an important class of validated drug targets, in four major therapeutic areas: cardiovascular, central nervous system, inflammatory and metabolic diseases. Arena's most advanced drug candidate, lorcaserin, is intended for weight management, including weight loss and maintenance of weight loss, and has completed a pivotal Phase 3 clinical trial program. Arena has filed an NDA for lorcaserin, and the FDA has assigned a PDUFA date of October 22, 2010 for the review of the application.

Arena Pharmaceuticals(R) and Arena(R) are registered service marks of the company.

Forward-Looking Statements

Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include statements about the development, advancement, therapeutic indication and use, tolerability, safety, selectivity, efficacy and regulatory review and approval of lorcaserin; the potential timing for the FDA to complete its review of the lorcaserin NDA; future activities and events relating to lorcaserin, including entering into a potential commercial agreement for lorcaserin, the commercialization of lorcaserin, current and expected efforts related to such commercialization, and submitting the BLOOM-DM results as a supplement to the NDA; financial guidance, including expected cost savings and decline in research and development expenses; Arena's agreements with Deerfield and rights and future activities thereunder; and Arena's objectives, strategy, research and development programs, and ability to develop compounds and commercialize drugs. For such statements, Arena claims the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from Arena's expectations. Factors that could cause actual results to differ materially from the forward-looking statements include, but are not limited to, regulatory authorities may not find data from Arena's clinical trials and other studies sufficient for regulatory approval; the timing and ability of Arena to receive regulatory approval for its drug candidates; the timing, success and cost of Arena's lorcaserin program and other of its research and development programs; results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results; clinical trials and other studies may not proceed at the time or in the manner Arena expects or at all; Arena's ability to partner or commercialize lorcaserin or other of its compounds or programs; Arena's ability to obtain adequate funds; Arena's ability to obtain and defend its patents; and the timing and receipt of payments and fees, if any, from Arena's collaborators. Additional factors that could cause actual results to differ materially from those stated or implied by Arena's forward-looking statements are disclosed in Arena's filings with the Securities and Exchange Commission. These forward-looking statements represent Arena's judgment as of the time of this release. Arena disclaims any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

(In thousands, except per share amounts)

	Three months ended December 31,		Year ended December 31,	
	2009	2008	2009	2008
	(unaudited)		(Note)	
Revenues				
Manufacturing services	\$1,916	\$1,973	\$6,579	\$7,434
Collaborative agreements	766	725	3,808	2,375
	----	----	-----	-----
Total revenues	2,682	2,698	10,387	9,809
Operating Expenses				
Cost of manufacturing services	1,834	2,153	6,536	8,515
Research and development	21,187	53,325	110,159	204,374
General and administrative	6,522	8,597	25,247	30,535
Restructuring charges	-	-	3,324	-
Amortization of acquired technology & other intangibles	1,787	565	3,508	2,314
	-----	----	-----	-----
Total operating expenses	31,330	64,640	148,774	245,738
Interest and Other Income (Expense)				
Interest income	398	841	689	7,370
Interest expense	(7,727)	(1,256)	(18,718)	(5,454)
Gain from valuation of derivative liabilities	5,073	-	5,418	-
Warrant settlement expense	-	-	-	(2,236)
Loss on extinguishment of debt	-	-	(2,479)	-
Other	1,132	144	273	(1,324)
	-----	----	----	-----
Total interest and other expense, net	(1,124)	(271)	(14,817)	(1,644)
	-----	-----	-----	-----
Net loss	(29,772)	(62,213)	(153,204)	(237,573)
Dividends on redeemable convertible preferred stock	-	(268)	-	(1,912)
	----	----	----	-----
Net loss allocable to common stockholders	\$(29,772)	\$(62,481)	\$(153,204)	\$(239,485)
	=====	=====	=====	=====
Net loss per share allocable to common stockholders, basic & diluted	\$(0.32)	\$(0.84)	\$(1.82)	\$(3.24)
	=====	=====	=====	=====
Shares used in calculating net loss per share allocable to common stockholders, basic & diluted	92,719	74,016	84,341	73,841
	=====	=====	=====	=====

Note: The Condensed Consolidated Statements of Operations has been derived from the audited financial statements for the year ended December 31, 2008 and from the unaudited financial statements for the year ended December 31, 2009.

Arena Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheet Data
(In thousands)

	December 31, 2009	December 31, 2008
	(Note)	(Note)
Assets		
Cash, cash equivalents & short-term investments	\$115,449	\$110,129
Accounts receivable	1,415	1,823
Other current assets	4,409	5,031
Land, property & equipment, net	95,445	102,740
Acquired technology & other non-current assets	19,560	21,608
	-----	-----
Total assets	\$236,278	\$241,331
	=====	=====
Liabilities and Stockholders' Equity		
Accounts payable and accrued liabilities	\$15,884	\$46,789
Total deferred revenues	4,086	4,049
Total derivative liabilities	6,642	-
Total notes payable	57,049	8,567
Total lease financing obligations & other long-term liabilities	78,050	64,294
Total stockholders' equity	74,567	117,632
	-----	-----
Total liabilities & stockholders' equity	\$236,278	\$241,331
	=====	=====

Note: The Condensed Consolidated Balance Sheet Data has been derived from the audited financial statements as of December 31, 2008 and from the unaudited financial statements as of December 31, 2009.

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EXHIBIT AL



FDA Confirms September 16th Advisory Committee Meeting to Review Lorcaserin for Obesity and Weight Management

SAN DIEGO and WOODCLIFF LAKE, N.J., Aug. 6, 2010 /PRNewswire via COMTEX News Network/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) and Eisai Inc. announced today that the US Food and Drug Administration (FDA) has notified the company of the confirmed scheduling of an Endocrinologic and Metabolic Drugs Advisory Committee meeting on September 16, 2010, for the review of the lorcaserin New Drug Application (NDA). Lorcaserin, which Arena discovered and has developed for weight management, is intended for obese patients as well as overweight patients who have at least one weight-related comorbid condition.

"Our primary objective at this time is to obtain FDA approval of lorcaserin," said Jack Lief, Arena's President and Chief Executive Officer. "We have been preparing for this anticipated Advisory Committee meeting, and look forward to reviewing lorcaserin's profile with the panel members."

Arena submitted the lorcaserin NDA on December 22, 2009, and the FDA assigned a PDUFA date, the target date for the agency to complete its review of the application, of October 22, 2010.

Lorcaserin New Drug Application

The lorcaserin New Drug Application is based on a data package from lorcaserin's development program that includes 18 clinical trials totaling 8,576 patients. The pivotal Phase 3 clinical trial program, BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management) and BLOSSOM (Behavioral modification and Lorcaserin Second Study for Obesity Management), evaluated nearly 7,200 patients treated for up to two years. In both trials, lorcaserin was well tolerated and produced statistically significant weight loss.

About Lorcaserin

Lorcaserin is a new chemical entity that is believed to act as a selective serotonin 2C receptor agonist. The serotonin 2C receptor is expressed in the brain, including the hypothalamus, an area involved in the control of appetite and metabolism. Stimulation of the serotonin 2C receptor in the hypothalamus is associated with feeding behavior and satiety. Arena has patents that cover lorcaserin in the United States and other jurisdictions, which in most cases are capable of continuing into 2023 without taking into account any patent term extensions or other exclusivity Arena might obtain.

About Arena Pharmaceuticals

Arena is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing oral drugs that target G protein-coupled receptors, an important class of validated drug targets, in four major therapeutic areas: cardiovascular, central nervous system, inflammatory and metabolic diseases. Arena's most advanced drug candidate, lorcaserin, is intended for weight management and has completed a pivotal Phase 3 clinical trial program. Arena has filed an NDA for lorcaserin with the FDA, and the FDA has assigned a PDUFA date of October 22, 2010, for review of the application. Arena's wholly owned subsidiary, Arena Pharmaceuticals GmbH, has granted Eisai Inc. exclusive rights to market and distribute lorcaserin in the United States.

Arena Pharmaceuticals(R) and Arena(R) are registered service marks of the company.

About Eisai Inc.

Eisai Inc. was established in 1995 and is ranked among the top-20 U.S. pharmaceutical companies (based on retail sales). The company began marketing its first product in the United States in 1997 and has rapidly grown to become a fully integrated pharmaceutical business with fiscal year 2009 (year ended March 31, 2010) sales of approximately \$3.9 billion. Eisai's areas of commercial focus include neurology, gastrointestinal disorders and oncology/critical care. The company serves as the U.S. pharmaceutical operation of Eisai Co., Ltd.

Eisai has a global product creation organization that includes U.S.-based R&D facilities in Maryland, Massachusetts, New Jersey, North Carolina and Pennsylvania as well as manufacturing facilities in Maryland and North Carolina. The company's areas of R&D focus include neuroscience; oncology; vascular, inflammatory and immunological reaction; and antibody-based programs. For more information about Eisai, please visit www.eisai.com.

Forward-Looking Statements

Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include statements about the advancement, therapeutic indication and use, safety, efficacy, tolerability, and regulatory review and approval of lorcaserin; lorcaserin's patent coverage; activities related to September 16, 2010 FDA advisory committee meeting; and Arena's focus, objectives, goals, strategy, research and development programs, and ability to develop compounds and commercialize drugs. For such statements, Arena claims the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from Arena's expectations. Factors that could cause actual results to differ materially from the forward-looking statements include, but are not limited to, risks related to the implementation and continuation of the marketing and supply agreement with Eisai and dependence on Eisai for commercialization of lorcaserin in the United States; regulatory authorities or advisors may not find data from Arena's clinical trials and other studies sufficient for regulatory approval; the timing and ability of Arena to receive regulatory approval for its drug candidates; the ability to enter into agreements to develop or commercialize lorcaserin and other of Arena's compounds or programs; Arena's ability to commercialize lorcaserin outside of the United States with another company or independently; the timing, success and cost of the lorcaserin program and other of Arena's research and development programs; results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results; clinical trials and other studies may not proceed at the time or in the manner Arena or others expect or at all; Arena's ability to obtain adequate funds; Arena's ability to obtain and defend its patents; and the timing and receipt of payments and fees, if any, from Eisai and Arena's collaborators. Additional factors that could cause actual results to differ materially from those stated or implied by Arena's forward-looking statements are disclosed in Arena's filings with the Securities and Exchange Commission. These forward-looking statements represent Arena's judgment as of the time of this release. Arena disclaims any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

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EXHIBIT AM

Arena Pharmaceuticals, Inc.

Company ▲

ARNA

Ticker ▲

Q4 2008 Earnings Call

Event Type ▲

Mar. 12, 2009

Date ▲

MANAGEMENT DISCUSSION SECTION

Operator: Good day everyone and welcome to the Arena Pharmaceuticals Fourth Quarter and Full Year 2008 Financial Results Conference Call. This call is being recorded.

At this time for opening remarks and introductions I would like to turn the call over to Arena's Vice President, Finance and Chief Financial Officer, Mr. Robert Hoffman. Mr. Hoffman, please go ahead sir.

Robert E. Hoffman, Vice President, Finance and Chief Financial Officer

Thank you. Good afternoon, and welcome to Arena Pharmaceuticals fourth quarter 2008 earnings conference call. I am Robert Hoffman, Arena's Vice President, Finance and Chief Financial Officer. Joining me on the call is Jack Lief, our President and CEO, also in the room and available to help address any questions after prepared remarks are Dominic Behan, our Senior Vice President and Chief Scientific Officer, and Bill Shanahan, our Vice President and Chief Medical Officer.

After Jack gives the brief introduction to the call, I will review our financial results for the fourth quarter and full year ended December 31, 2008. I'll then again turn the call over to Jack for additional comments, with time at the end for questions and answers.

Before we begin, I'd like to point out that we'll be making numerous forward-looking statements during this conference call. Such forward-looking statements include statements about our clinical trials and results, internal and partnered programs, drug candidate pipeline, technologies, financial guidance, assumptions, strategy, plans and other statements that are not historical facts. Such statements may include the words, may, plan, will, believe, expect, potential, intend or similar words. You are cautioned not to place undue reliance on these forward-looking statements, which are only predictions and reflect the company's beliefs, expectations and assumptions based on currently available operating, financial and competitive information and speak only as of the time they are made.

Risks and uncertainties that could cause actual results to differ materially from those described in our forward-looking statements include the timing, success and cost of clinical trials, preclinical studies and research activities, the regulatory process, the timing and outcome of our partnership efforts, our ability to obtain additional funds from collaborators and investors, whether our assumptions prove to be correct and other risks identified in our SEC reports.

For a discussion of these and other factors, please refer to the risk factors described in our Annual Report on Form 10-K for the year ended December 31, 2007, as well as our other subsequent filings with the Securities and Exchange Commission. For forward-looking statements we claim the protection of the Private Securities Litigation Reform Act of 1995.

Now I would like to turn the call over to our President and CEO, Jack Lief.

Jack Lief, Co-Founder, Chairman, President and Chief Executive Officer

Thanks, Robert. Good afternoon everyone and thank you for joining our 2008 fourth quarter conference call. As most of you know, we expect to have results from BLOOM, a two-year pivotal trial in 3,181 patients evaluating lorcaserin for weight loss around the end of this month. Although the BLOOM data will remain blinded until shortly before the release date, as we have previously stated, we have been encouraged by the overall emerging profile of lorcaserin.

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BLOOM results will be a significant milestone for Arena and we expect it to be followed by two more significant lorcaserin milestones this year.

The first is the result of our second pivotal trial BLOSSOM in September. The BLOSSOM study is a 4,000 patient one-year trial. The next event is the submission of our NDA at the end of the year.

Important recent lorcaserin developments include the completion of dosing all patients in the BLOOM trial and the enrolment completion in the BLOSSOM trial last June. With respect to the non-pivotal BLOOM-DM trial, we expect that trial to complete enrolment with about 600 patients in the next few months.

Last year we also published lorcaserin Phase IIb clinical trial results in the December fourth issue of Obesity, the official peer reviewed journal of The Obesity Society. Other positive recent and 2008 developments include positive data from both our single and multiple ascending dose Phase I trial evaluating the safety, pharmacokinetics and pharmacodynamics of APD791.

You will recall APD791 is our internally discovered oral drug candidate intended for the treatment of arterial thrombosis and other relating conditions, the initiation and completion of our Phase I program for a second-generation oral niacin receptor agonist discovered by Arena and being developed by Merck under our collaboration.

We also announced last month that Merck has initiated a Phase II trial for this program. The initiation of a Phase I program for APD597, a novel GPR119 agonist discovered by Arena and being developed by Ortho-McNeil-Janssen under our collaboration. The advancement of APD597 followed an announcement last year reporting that clinical results of a less potent GPR119 agonist, APD668 suggest that agonists at this receptor improve glucose control in patients with type 2 diabetes.

But not every program was successful. We announced last year that our APD125 Phase II trial measuring subjective endpoints in patients with primary insomnia did not meet the trial's primary or secondary endpoints. Although treatment was well tolerated with no adverse safety findings, we're not planning further clinical development of APD125.

Looking now to the remainder of 2009, I expect Arena will have some significant positive developments, mostly centered on lorcaserin, which continues to be the focus of our resources in this currently difficult economic environment. As I previously mentioned, lorcaserin events expected this year include the BLOOM pivotal trial data results around the end of this month, the BLOSSOM pivotal trial data results around the end of September and the submission of the lorcaserin NDA before the end of this year.

We're also looking forward to exploring partnering opportunities as we evaluate the data from pivotal trials and share it with potential partners as maybe appropriate.

I'll now turn the call over to Robert to go through the financials before I provide some additional information on what you can expect from the BLOOM data announcement along with some additional comments on our other programs. Robert?

Robert E. Hoffman, Vice President, Finance and Chief Financial Officer

Thank you, Jack. In the fourth quarter of 2008 we recorded revenues of approximately 2.7 million compared to fourth quarter 2007 revenues of approximately 4.6 million. Fourth quarter 2008 revenues included \$2 million in manufacturing services revenue under our manufacturing service agreement with Siegfried and \$0.7 million for patent activities from our collaborations with Merck and Ortho-McNeil-Janssen and Johnson & Johnson company.

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<Q – Bret Holley>: Hi yes – hi thanks for taking the question. Jack, I was just curious about your comment about, you know, looking at multiple data points from pivotal trials. Am I reading too much into that in regards to the partnership process? I mean it sounds like if you are going to be looking at multiple datasets would certainly suggest that a partnership might be a timeline behind the BLOSSOM results minimally.

<A – Jack Lief>: Well, in partnering you never know for sure. If it was confusing, I apologize but the multiple data that I was referring to was on the valvulopathy. There are two studies that are needed to adequately address, fully address based on the way we powered the studies addressing the FDA guidance to rule out valvulopathy and obviously there will be a lot more information we don't – we haven't unblinded the studies yet. So we don't know the full results. But there will be a lot more information about that in a couple of weeks. So we've agreed with the agency that both the BLOOM and the BLOSSOM study will be able to be pooled for that valvulopathy issue. Did I answer your question, Bret?

<Q – Bret Holley>: Yes. No, I think you did kind of indirectly. So I guess the way you'd answer the question then is that you would have to see statistically proven lack of valvulopathies in your mind for a potential partner to be comfortable, is that what you're saying?

<A – Jack Lief>: No, obviously there are different criteria from different partners and we have some partners that are highly interested in talking and reviewing the data. But we'll see what the data looks like. We don't know what the BLOOM data looks like. We may be able to fully address any concerns just with the BLOOM data, but that's only if we are lucky and we powered the studies, over 7000 patients in the two studies such that we are well powered to address those issues in both of those studies rather than just one.

<Q – Bret Holley>: And I guess the last question I have is, is three to four months really enough time to file the NDA if you are going to get the database from BLOSSOM in September I mean given the huge number of patients you are actually dealing with here?

<A – Jack Lief>: Yes. So it is a lot of patients, on the other hand we've geared up for it. We're not waiting till the very last bit of information comes in. We expect most of the information for the NDA to be available long before September. We'll just need to finish that BLOSSOM study, get the data to write the integrated summary that will be included in the package. So we believe it's very doable and we have the expertise to do that.

<Q – Bret Holley>: Okay. Thank you.

<A – Jack Lief>: Pleasure.

Operator: And we'll take our next question from Phil Nadeau with Cowen & Company.

<Q – Phil Nadeau>: Good evening, thanks for taking my question. Jack, my first one is to you. In your prepared remarks you made the comment that you folks are getting increasingly confident on lorcaserin's potential based on the blinded data that you are seeing. I was wondering if you could elaborate on that comment. What in particular has given you confidence, and maybe even more importantly, what have you really learned since the R&D day if anything that has made your confidence increase?

<A – Jack Lief>: Well, the confidence is not just based on the blinded data, of course the confidence is based on the Phase II data, the Phase I data, the preclinical studies that we've done, all of the animal studies that have been completed, as well as how the studies are recruiting – have recruited the retention in those studies and that sort of thing.

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So since the December date of course we've finished the BLOOM study and so that gives us a lot more confidence that we are unlikely to find some surprises that we are not already aware of. Keep in mind the data is still blinded, so I don't know who is on drug and who is on placebo. So we might be surprised when we unblind the data, but it looks like we're seeing such things that we absolutely would expect to see.

<Q – Phil Nadeau>: Okay.

<A – Jack Lief>: Did I answer your question Phil?

<Q – Phil Nadeau>: Yes, I think you did. And my second question is on the FDA valvulopathy that we are going to see in the top line press release. As you suggested in the answer, I think to the last question, just BLOOM itself isn't really powered for FDA valvulopathy, it's more kind of the overall database is powered to show difference in FDA valvulopathy.

So can you give us some idea of how we should be thinking about how to interpret what you are going to show to us over the next few weeks? I understand that's a tough question because there is no data on which to speak directly to. But I'm sure you and your management team have in their minds some sort of goal post for what that data should look like to give you comfort, that there is not going to be a problem, if you could share those with us that would be great

<A – William Shanahan, Jr.>: Okay, this is Bill. I will make a comment. I think the important thing to remember is that this is a two-year trial and 3,200 subjects. So it's going to be very reflective. We would really expect this to represent the BLOSSOM data as well. So that's – what we see there, I think it's going to give you a lot of guidance towards what you'd expect with the BLOSSOM trial. And so I think, you'll be able to take a great deal of comfort in knowing what the total base will look like, total database based on the BLOOM results.

<A – Jack Lief>: You know keep in mind as Bill said, that while we believe that BLOOM will be reflective of the BLOOM and BLOSSOM aggregate data, because it's the longer of the two studies, I think we'll have a lot of comfort in the results associated with that. But from a statistical powering perspective, the studies were designed to rely on both of those studies for achieving our statistical power for safety.

<Q – Phil Nadeau>: Okay. And have you ever disclosed what the power of either the BLOOM trial is on valvulopathy or the power of the overall sample size on that standpoint?

<A – Jack Lief>: Yes, so we have not, but will have a lot more visibility on that at the end, around the end of the month when we do that. Keep in mind that some, a lot of studies on valvulopathy have picked it up in relatively short period of time. Animal studies for example you can see valvulopathy after a few months using a compound like pergolide that typically produces that. So given the lengthy study, we think that we'll have a lot of visibility on our safety associated with lorcaserin.

<Q – Phil Nadeau>: Okay. That's very helpful. Thanks.

Operator: Next question from Carol Werther with Summer Street Research Partner.

<Q – Carol Werther>: Oh, thank you. I was wondering, Jack, if you would just go over the efficacy endpoints again, and do you need to do the statistical significance on both endpoints?

<A – Jack Lief>: Yes, so the FDA has these – this categorical endpoint as well as the average mean endpoint. And the categorical endpoint they want to see the proportion of patients that lose at least 5% of their body weight to be roughly doubled or more – on drug versus placebo, and the drug group needs to be at least 35%. You'll recall that in the 2b study, we almost achieved that goal

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MANAGEMENT DISCUSSION SECTION

Operator: Good day, everyone, and welcome to Arena Pharmaceuticals Fourth Quarter and Full-Year 2009 Financial Results Conference Call. This call is being recorded.

At this time, for opening remarks and introductions, I would like to turn the call over to Arena's Vice President, Finance and Chief Financial Officer, Mr. Robert Hoffman. Mr. Hoffman, please go ahead, sir.

Robert E. Hoffman, Vice President, Finance and Chief Financial Officer

Thank you. Good morning and welcome to Arena Pharmaceuticals' fourth quarter and full-year 2009 financial results conference call. I am Robert Hoffman, Arena's Vice President, Finance and Chief Financial Officer. Joining me on the call today are Jack Lief, our President and Chief Executive Officer and Dominic Behan, our Senior Vice President and Chief Scientific Officer. Bill Shanahan and Christen Anderson are traveling and will not be available on today's call.

Before we begin, I'd like to point out that we'll be making numerous forward-looking statements during this conference call. Such forward-looking statements include statements about our internal and partnered programs, financial guidance, strategy and plans, drug development, approval and commercialization, and other statements are not historical facts.

Such statements include the words, plan, will, expect or similar words. You're cautioned to not place undue reliance on these forward-looking statements, which are only predictions and reflect the company's beliefs, expectations, and assumptions based on currently available information and speak only as of the time they are made.

Risks and uncertainties that could cause actual results to differ materially from those described in our forward-looking statements include the timing and outcome of regulatory process, the timing and outcome of our partnership efforts, the timing, success and clinical – and cost of clinical trials, preclinical studies and research activities, our ability to obtain additional funds from collaborators, investors, whether our assumptions and interpretations above prove to be correct, and other risks identified in our SEC reports.

For a discussion of these and other factors, please refer to the risk factors described in our filings with the Securities and Exchange Commission. For forward-looking statements, we claim the protection of the Private Securities Litigation Reform Act of 1995.

Now I'd like to turn the call over to our President and CEO, Jack Lief.

Jack Lief, Co-Founder, Chairman, President and Chief Executive Officer

Thanks, Robert. Good morning. 2009 was a year of substantial accomplishment for Arena, as we reached critical milestones. The most important milestone was our submission of the lorcaserin New Drug Application in December. A couple of weeks ago, we announced that the FDA accepted our NDA for filing and assigned October 22 as the PDUFA date. We are pleased to be on track, as we move through an exciting year for Arena.

We believe that lorcaserin, if approved, will be well positioned as a first-line single agent therapy to help patients achieve sustainable weight loss in a well-tolerated manner. As we continue our efforts to reach commercial agreement for lorcaserin, we are moving forward with several activities to build a strong foundation for timely launch, either through a pharmaceutical company or on our own.

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I'm about to outline these activities for you. Afterwards, Dominic will highlight our ongoing programs. Robert will then review the financials for 2009 and provide guidance for this year that includes our investment in the activities I'll speak to. It's important to be well financed as we move towards the approval of lorcaserin.

We want our commercial discussions with pharmaceutical companies focused on the market potential of lorcaserin and not on our financial profile. As announced earlier this week, we exercised rights under an equity line of credit to add \$24.2 million to our balance sheet. These funds will help us maintain a stronger position for commercial discussions, prepare for FDA approval and will provide flexibility to make investments as necessary to build a foundation for the lorcaserin launch.

Our primary objective this year is to obtain FDA approval for lorcaserin. With an October PDUFA date, we are preparing for an expected FDA Advisory Committee Meeting. Such meetings, if convened, generally are held approximately four to eight weeks prior to the PDUFA date with approximately two to three months notice. We don't have specific information at this time, but we'll update you as appropriate.

To ensure the success of lorcaserin launch, we're active in several areas that we've identified as important to both the pre-launch and launch phases. These activities are being undertaken to better assure a timely launch following approval. In some cases, we would expect the activities to be assumed by the pharmaceutical company responsible for marketing and distributing lorcaserin.

The first area involves manufacturing. As many of you know, we're already manufacturing lorcaserin in our own facility in Switzerland as – and we are completing the build out of our commercial supply chain. We will supply final drug product through this facility irrespective of whether we or another pharmaceutical company markets lorcaserin. With controlled product manufacturing, we'll be ready to ship quickly once lorcaserin is approved.

The second area involves understanding the underdeveloped and dissatisfied weight management market. It's important to build market awareness and educate physicians, patients and payers on the potential medical benefits of adding pharmacotherapy to a weight loss and weight management program. To this end, we're taking several steps. We've assembled a team of highly respected physician thought leaders. Our interaction with these physicians provides us with invaluable insight into the current and desired treatment of obesity and the issues physicians and their patients are facing. To support the use of lorcaserin, we're developing a formulary access plan for managed care and a lifestyle modification program designed to meet the needs of primary care physicians.

The third area is commercial readiness. We're developing marketing materials that we'll test with target audiences, including physicians and payers. At the appropriate time, we'll be prepared to submit launch marketing materials to the FDA for approval. The activities I've outlined call for milestone-driven investments that need to be incorporated in a timely manner by ourselves or by the company responsible for marketing and distributing lorcaserin.

We'll add internal infrastructure only as necessary and after evaluating the options available with external vendors and providers. For example, we plan to put in place an agreement with contract sales organizations to build a targeted sales force that, if needed, we can trigger at the time of approval. Importantly, no significant upfront payments are needed to put this type of sales force agreement in place.

This milestone-driven approach will allow for flexibility. We'll implement activities and deploy financial resources only as needed as we move towards approval. With the execution of our plan, we intend to be ready to launch lorcaserin either with another company or on our own within 12 weeks following approval.

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expenses including manufacturing cost to be approximately \$17 to \$21 million that total over 92% related to lorcaserin, including approximately \$10 million for launch supply materials and approximately four million to complete the BLOOM-DM clinical trial of lorcaserin.

This compares to actual 2009 external clinical and pre-clinical expenses including manufacturing costs of nearly \$46 million. General and administrative expenses of approximately \$31 to \$35 million, including non-cash expenses of approximately three million. We expect the cash, cash equivalents and short-term investments of approximately \$97 to \$107 million for our operating expenses and interest expense in 2010, and approximately seven million for our capital expenditures primarily for manufacturing facility in Switzerland.

This assumes that Arena and not another pharmaceutical company pays for lorcaserin pre-launch – pre-commercial launch activities and also assumes no new collaborations, milestone achievements or financings including selling real estate that we currently own.

I'll now turn the call back over to Jack.

Jack Lief, Co-Founder, Chairman, President and Chief Executive Officer

Thanks, Robert. To summarize, our goal is to optimize the value of lorcaserin in a commercial agreement by building the foundation for launch that I outlined. Our primary objective is getting lorcaserin approved and we are focused on pre-launch and launch activities based on a strategic timetable.

Lorcaserin holds significant potential to re-energize and expand the weight management category based on its unique combination of safety, efficacy and tolerability. We look forward to working with the FDA to complete its review of lorcaserin application and to delivering this novel treatment designed to help address the obesity epidemic. With a launch potentially insight, the already established global composition of matter patent coverage and our Swiss manufacturing facility ready to meet demand, we believe that lorcaserin represents a significant medical and commercial opportunity.

Before opening the call for your questions, I'd like to thank our Arena employees in San Diego and Switzerland. It required an incredible team effort to advance lorcaserin from discovery to the recent NDA filing. Our team rose to the challenge with dedication and a strong focus on excellence. We focus each day on innovative science for patient benefit and we look forward to improving the treatment of obesity.

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I'll now take your questions. Mary?

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<Q – Cory Kasimov>: Okay. And then my last question is I'm just wondering if you are at all worried that the SCOUT trial for sibutramine could adversely impact the FDA's general sentiment towards obesity drugs or obesity pharmacotherapy? Thanks.

<A – Jack Lief>: Well, no, of course, not. But it's really hard to tell what the final result will be from that SCOUT trial. We've known for a long time that sibutramine did have a blood pressure effect and it's good to know that lorcaserin did not have such an effect. So patients do not have a – an increase in blood pressure and actually there's a reduction in blood pressure as a result of weight loss on patients taking lorcaserin. And so we've reported that and so we think that we have a good opportunity to allow physicians to use lorcaserin as their first-line therapy for the majority of their patients that need to lose weight or control their weight.

<A – Dominic Behan>: Just to elaborate on that, just to make one point, I don't think we can specifically say that in SCOUT, blood pressure was the reason for those cardiovascular events. But we do believe of course that any increase in blood pressure is not desirable and we've clearly shown in our studies across the broad population that we don't have that. And as Jack mentioned, actually across the whole broad population, we have a decrease in blood pressure that we think is very desirable from a cardiovascular risk perspective.

<Q – Cory Kasimov>: Okay. Thanks for taking the questions.

Operator: Our next question comes from Jason Zhang from BMO Capital Markets.

<Q – Jason Zhang>: Hey, thanks for taking my question. Jack, I have question regarding BLOOM-DM result. I remember you mentioned that this will be kind of the supplementary data to the package, I'm just wondering what kind of mechanism do you have to guarantee that additional base data will not result in a six months delay of the PDUFA date?

<A – Jack Lief>: Yeah, so the FDA accepted our package as we submitted it. Obviously, we submitted our package, if we don't – we still don't have the BLOOM-DM data, the FDA has said that there is sufficient data to review and – lorcaserin on its merits. We've also had discussions and meetings around that. So while there can never be any guarantees on anything these days, we're reasonably confident, I am reasonably confident that the FDA will review our current package as submitted in a scientific fashion.

<Q – Jason Zhang>: So in other words, the focus will be just the two phase III you submitted and this will be really some data they will be looking at for, I guess, mostly for safety reasons, because if they indeed consider this meaningful clinical data and that typically result in Class II kind of complete response and that will result in a six months delay?

<A – Jack Lief>: Well, Jason keep in mind that we submitted our NDA with I believe something like 18 different human clinical studies included in that NDA and with about over 8,500 patients taking our lorcaserin for, some of them for up to two years. So we've shown that there is significant improvements in cardiovascular and other risk factors, the risk factors such as elevated CRP, elevated triglycerides and insulin resistance. So we've shown very significant improvements in those as we previously reported. So I think that the FDA will certainly review our package on its merits and do the right thing.

<Q – Jason Zhang>: Okay. And then the second question is, I guess, you mentioned that you have a contract research – a contract sales organization in place to launch this drug, if you don't have a pharma partner. I know you cannot disclose the term, but in general this type of arrangement, what kind of commission you think are reasonable to give to the contract sales organization in terms of revenue?

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<A – Jack Lief>: Yeah, so clearly, I can't elaborate on that right now. At this time, I can tell you that there are numerous contract sales organizations in – available that work in this area and whatever arrangement we decide to do, we'll be successful at launching lorcaserin. But having said that, my intention – our intention is to sign a commercial agreement with a pharmaceutical company. And so, I don't think we'll be using a contract sales organization. But it would be, it's just nice to know that such an opportunity is available.

<Q – Jason Zhang>: Okay. Thanks.

<A – Jack Lief>: Pleasure, Jason.

Operator: Our next question comes from Thomas Wei from Jefferies.

<Q – Thomas Wei>: Hi. Thanks. I had a question actually on the regulatory process so far for lorcaserin. Can you share with us any of the questions or issues that were raised in the 74-day letter from the FDA that you must have just gotten from them?

<A – Jack Lief>: Well, Thomas, we can't – we typically do not go into the details of FDA correspondence. Having said that, we're confident that we have the ability to work with the FDA in the future and for – during their review of the NDA. And I think we'll be able to satisfy their – any questions that they might have in the future. Dominic, do you have anything to add?

<A – Dominic Behan>: I don't think I have anything...

<Q – Thomas Wei>: And then maybe a question on the whole combination strategy with phentermine, when you do end up going down that road and starting those trials, how should we think about how you would get a combination on to the label? Does that require a whole new large two-year development program or is it some much shorter safety database that you would need to submit you think in order to get combination enabled on the label?

<A – Jack Lief>: Dominic?

<A – Dominic Behan>: Yeah, well, let me just take a step back for a second. As you know, Thomas, we are focused heavily now on building a foundation as a single agent for lorcaserin. And that's the plan, that's the focus, and complete focus on approval as a single agent. In terms of life cycle management with phentermine and what those studies may look like, we haven't settled completely on that, we're still in the planning process. I should point out though, to be successful we think as a single agent, lorcaserin has a tremendous potential. But we will be settling on those plans in the future, but those will be post approval activities, and we haven't really got a lot of specifics around that just yet.

<A – Jack Lief>: And of course we'll discuss that with the agency if we do go that way. Obviously, the FDA will be heavily involved in guiding us along those lines, but as Dominic said, we believe based on our market research that the vast majority of primary care physicians will use lorcaserin as a single agent for most of their patients, keep in mind, we did show that two-thirds of patients who actually take lorcaserin lose at least 5% of their body weight, the average weight loss in that group was 26 pounds. So I think that for the vast majority of patients, they will be well served just by taking the drug that's well tolerated, that's safe and that has the opportunity to lose an average of 26 pounds.

<Q – Thomas Wei>: Okay. Thank you.

<A – Jack Lief>: Pleasure.

Operator: Our next question comes from Jeff Elliott from UBS Securities.

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<Q – Jeff Elliott>: Thanks. Maybe just a follow-up on an entirely different line. Since in your report you guys did not include a REMS with your NDA for lorcaserin, so I was just curious if your plan is to add that to your submission at some point before panel and the potential PDUFA or you're going to wait to see if the FDA asks for it?

<A – Jack Lief>: You know we've discussed the need for such follow-up studies with the agency and obviously REMS or any sort of thing like that is a review issue, but we can't find anything, any signal that we would evaluate in such a program. Dominic?

<A – Dominic Behan>: Yeah, this will be a review issue, but which – what signal would we follow, that's something that's not clear to us now. And of course, we'll work with the FDA on that, it will be a review issue. If we do require a REMS study, we think we're well positioned to execute well and we just have – don't have any more specifics right now. And as I said, there is no obvious signal to us currently that we would need to monitor.

<Q – Jeff Elliott>: I guess the question I would have and everybody has asked about the combination therapy, but given that you said the bulk of the primary care physicians may not use it in combination, but certainly there will be some doctors using in combination. Do you not think that will potentially be an issue with the FDA that would justify a REMS? By our math, 50% of drugs last year more or less had REMS programs. So it seems surprising that you wouldn't sort of have a plan in place?

<A – Jack Lief>: Well, as we said, we're not sure of what to measure, what the FDA will want us to measure. Lorcaserin was so well tolerated and we don't see any safety signals that requires special attention right now. And when – if that should be combined with phentermine, again I am not sure what we would need to measure in that regard, keep in mind that most physicians will use lorcaserin as a single agent, the vast majority of patients will take lorcaserin as a single agent for weight management. And so we don't think that that's going to enter into the picture.

<Q – Jeff Elliott>: And so, you – obviously then you don't – your current sort of forecast cash guidance does not include anything for developing a REMS program right or anything like that?

<A – Jack Lief>: Well, again, we don't – this is a review issue.

<Q – Jeff Elliott>: Yeah.

<A – Jack Lief>: But we just don't have specifics on – and this is something that we'll just have to wait and see how the FDA view our data. All we're saying is that it's not obvious to us based on our Phase III program and our extended lorcaserin program at this time what exact signal or signals we would be required to monitor. And so, this is a review issue and we'll just have to have wait and see how that plays out with the FDA and we work closely with the FDA on it.

<Q – Jeff Elliott>: Okay. And then in terms of your financial position, you said that you didn't want it to be an issue in terms of potential partnership. but by my math, you've got a 115 million plus a 25 drawdown and you're guiding to about a – I think, a 104 to 114 million in expenditure this year. So it doesn't leave you a ton of cushion after 2010, are you considering something in the interim to bulk up your balance sheet further to give you a stronger negotiating position?

<A – Jack Lief>: Well, I think that we're flexible. I don't want to speculate on the future. Right now, I feel comfortable with our current position. And if our partnering discussions workout the way I think they will, I think we'll continue to be comfortable with our position. However, I don't want to speculate and we'll just have to be flexible and see how that turns out. So I'd like to limit future questions to one and a follow-up for – in the interest of time.

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<Q – Jeff Elliott>: All right. Well, I will jump back into the queue.

<A – Jack Lief>: Mary?

Operator: Our next question comes from Terence Flynn from Lazard Capital Markets.

<Q – Terence Flynn>: Thanks for taking the question. I was just wondering you mentioned the launch preparations you were undertaking in manufacturing and building market awareness and commercial readiness. I'm just wondering under building market awareness you talked specifically about the – your formulary access plan and the lifestyle management plan. I'm just wondering if you could expand on that a little bit in terms of your initial thoughts there and how that would work?

<A – Jack Lief>: Well, for competitive reasons, I can't really get much into that. Suffice it to say that these are quite common, commonly used today. And, obviously we will do what's appropriate at the right time.

<Q – Terence Flynn>: Okay. And then just a follow-up question, there has been a lot of focus obviously on a potential panel. I'm just wondering what you guys are doing to prepare for that and how you potentially plan to frame the discussion around the risk benefit of the drug at that potential panel if it does occur?

<A – Jack Lief>: Dominic?

<A – Dominic Behan>: Well, again, we haven't got any specific data or communication regarding if a panel will occur, we're assuming one will and we're preparing intensely for it. So this is quite a process, there are thousands of slides that will need to be prepared that will be needed to be appropriately brought up to address questions almost instantaneously.

So we have a team focused on that process. And in terms of framing the overall risk benefit profile of lorcasein, I think, the data will speak for itself, we'll obviously talk about the efficacy, we'll talk about the improvements and all the co-morbid factors that we saw across the board. Things like decreases in blood pressure will, I think, be important. So we will go through the whole data package of the phase say, pivotal program and be well prepared for questions. So this is an area of intense focus now, we're preparing and working very hard to be, in a good position for an advisory panel if it does occur.

Operator: Our next question comes from Ryan Martins from Barclays Capital.

<Q – Ryan Martins>: Hi thanks for taking the questions. In the past you've said that, if you didn't have a partnership by around mid-2010, that's when you would initiate some of your contingency plans. Is that something we should still think about as a time point at which you would initiate these, or today's guidance on pre-commercial launch activities contemplate that?

<A – Jack Lief>: Well, I can't elaborate at this time, but we provided you with a lot of information on our pre-commercial plans and activities right now. So, obviously, we expect to have a commercial agreement with a pharmaceutical company, but we're flexible and we'll see how that goes.

<Q – Ryan Martins>: Okay. And then maybe one final one. In terms of the FDA, have they already initiated any pre-approval inspection for your Swiss facility?

<A – Jack Lief>: We can't really go into specifics around what the FDA is doing. Suffice it to say that we are ready, we are currently ready, we were ready in the past, we will be ready in the future for pre-approval inspections. Our Swiss facility does manufacture GMP product that is used by

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MANAGEMENT DISCUSSION SECTION

Operator: Good day everyone, and welcome to Arena Pharmaceuticals second quarter 2010 conference call. This call is being recorded.

At this time, for opening remarks and introduction, I would like to turn the call over to Arena's Vice President, Finance and Chief Financial Officer, Mr. Robert Hoffman. Mr. Hoffman, please go ahead, sir.

Robert E. Hoffman, Vice President, Finance and Chief Financial Officer

Thank you. Good afternoon, and welcome to Arena Pharmaceuticals second quarter 2010 conference call. I'm Robert Hoffman, Arena's Vice President, Finance and Chief Financial Officer. Joining me on the call today are Jack Lief, our President and Chief Executive Officer; Dominic Behan, our Chief Scientific Officer; Bill Shanahan, our Chief Medical Officer, and Christy Anderson, our Vice President of Clinical Development.

Before I turn the call over to Jack, I'd like to point out that we'll be making forward-looking statements during this conference call. Such forward-looking statements include statements about our internal and collaborative programs, drug development, regulatory review and commercialization, financial guidance, strategy and plans, and other statements that are not historical facts. Such statements include the words plan, will, expect or similar words. You're cautioned to not place undue reliance on these forward-looking statements, which are only predictions and reflect the company's beliefs, expectations, and assumptions based on currently available information and speak only as of the time they are made.

Risks and uncertainties that could cause actual results to differ materially from those described in our forward-looking statements include the timing and outcome of the regulatory process, the commercialization of lorcaserin, the timing and outcome of our efforts to enter into agreements to develop or commercialize our compounds or programs, the timing and success in cost of clinical trials, preclinical studies and research activities, our ability to obtain adequate funding and other risks that are identified in our SEC reports. For a discussion of these and other factors, please refer to the risk factors described in our filings with the SEC. For forward-looking statements, we claim the protection of the Private Securities Litigation Reform Act of 1995.

Now, I'd like to turn the call over to our President and Chief Executive Officer, Jack Lief.

Jack Lief, Chairman, President and Chief Executive Officer

Thanks, Robert. Good afternoon everyone. We've recently announced a number of important milestones in lorcaserin program, and we're right on track with our plans.

On today's call, I will highlight these milestones, Christy Anderson will present the pooled data set for BLOOM and BLOSSOM, and Robert Hoffman will review our financials. Before concluding, I will provide you with a brief overview of our on-going drug development initiatives, and then take your questions.

First, let's take a quick look back at the key milestones that we've recently achieved. As previously discussed, our plans have been to conclude a commercial agreement for lorcaserin and publish the BLOOM data in a peer-review journal.

Last month, we entered into an agreement with Eisai for the marketing of lorcaserin in the U.S. following the FDA approval. In addition, data from the two-year BLOOM trial were published in the

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New England Journal of Medicine. We're very proud of these achievements that provides validation of lorcaserin's potential and clinical trial results. Furthermore, our agreement with Eisai brings us another step closer to providing lorcaserin to patients in a timely manner following approval.

Today, I'm pleased to announce the achievement of another significant milestone in the lorcaserin program.

The FDA has completed the pre-approval inspection, or PAI, of our drug product manufacturing facility in Switzerland and classified the inspection as no-action indicated, or NAI, with no Form 483 issued. Those of you who are familiar with the regulatory process know the importance of a successful PAI.

In addition, one of our contract manufacturing organizations, Siegfried, where lorcaserin active pharmaceutical ingredients, or API, is manufactured, was also inspected by the FDA. The Siegfried inspection was also classified as NAI with no Form 483 issued. These successful PAIs allow us to manufacture commercial product for marketing and distribution following approval.

For our commercialization plans outside the U.S., we will also utilize our Swiss manufacturing facility to produce final packaged drug product.

Returning to the agreement with Eisai, I want to reinforce what I stated on our July 1 conference call. The U.S. marketing and supply agreement reflects the type of deal we sought for lorcaserin. Arena Pharmaceuticals GmbH, our wholly-owned subsidiary, has granted Eisai exclusive U.S. rights to commercialize lorcaserin. We will manufacture lorcaserin at our facility in Switzerland and sell finished product to Eisai for marketing and distribution in the U.S.

Eisai is a fully-integrated pharmaceutical company with nearly \$4 billion in 2009 U.S. sales. Eisai's launch of Aciphex and Aricept are two of the most successful in U.S. history with each of the drugs becoming billion-dollar products. Lorcaserin has strong synergies with Eisai's existing U.S. primary care and specialty business, especially Aciphex, a product for the treatment of gastro esophageal reflux disease, commonly known as GERD.

As a person's BMI rises, so does the incidence of GERD symptoms. The risk of reflux symptoms doubles for patients who are overweight and triples for patients who are obese. 75% of GERD sufferers are either overweight or obese, and 60% of the physicians who prescribe Aciphex are also prescribers of current weight management products.

Eisai has a successful track record bringing important treatments to patients as evidenced by Aricept, the number one prescribed Alzheimer's medication worldwide. With lorcaserin, Eisai plans to become the patient-focused leader in obesity. Lorcaserin can be efficiently commercialized and integrated into Eisai's current commercial infrastructure and its extensive patent life will allow for thorough lifecycle management and development.

By incorporating our Swiss facility into this agreement, we can control supply chain, capacity and costs, while potentially realizing tax efficiencies in Switzerland. The structure of this agreement also provides us with flexibility for commercialization of lorcaserin outside the U.S. on a regional or country-by-country basis, enabling us to maintain control of lorcaserin while maximizing its commercial value. By executing our plans for lorcaserin with a robust U.S. commercial agreement, a prestigious, peer-reviewed publication of the BLOOM data and a successful inspection of our manufacturing facility, now more than ever we are well-positioned for success.

Our primary objective at this time is to obtain FDA approval for lorcaserin. We are preparing for our advisory committee meeting tentatively scheduled for September 16 and look forward to our October 22 PDUFA date. We've always stated that safety is of paramount importance to the FDA and that the right profile of efficacy, safety and tolerability is essential for a weight management

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QUESTION AND ANSWER SECTION

Operator: Thank you, sir. The first question comes from Phil Nadeau from Cowen & Company.

<Q – Phil Nadeau>: Good afternoon and thanks for taking my questions. My first is on the FDA panel because it's somewhat less than 45 days before the panel. I'm just curious whether the FDA has indicated to you what is likely to be discussed or given you any idea of what you should prepare for September 16?

<A – Jack Lief>: Bill, do you want to answer that question?

<A – William Shanahan, Jr.>: Yeah, they have not and typically don't. So.

<Q – Phil Nadeau>: Okay. Can you maybe give us some idea of what you think the issues could be or where you're focusing your preparation?

<A – Jack Lief Well, we're not expecting any surprises associated with the panel. Obviously, we will present our view of lorcaserin and the FDA will present their view. I think the views will overlap substantially, and I look forward to a very positive panel. Christy you want – have anything to add to that?

<A – Christen Anderson>: I agree with what Jack said. Obviously we've always said that the primary focus would be on safety and we are well prepared to thoroughly address the safety issues or the safety data as well as the efficacy data with the panel.

<Q – Phil Nadeau>: Okay. That's very helpful. And then one financial question. Could you give us some idea of what you expect will be your R&D run-rate going forward? So after lorcaserin's approval, as you enter next year, what should we look at as an approximate spend in R&D?

<A – Jack Lief>: Well, we have some new programs that are just starting up, but the total expense associated with these programs near-term is quite modest especially when you put that – those in front of the backdrop of lorcaserin, the extensive studies that we've just completed there. So I think you should expect R&D spend will be relatively modest. However, keep in mind that we are committed to, as an R&D company and we expect to develop new innovative, best-in-class compounds. And so we'll try and keep you updated and Robert will give you guidance along those lines.

<Q – Phil Nadeau>: Great. Thanks for taking my questions.

<A – Jack Lief>: Pleasure.

Operator: Our next question comes from Alan Carr from Needham & Company.

<Q – Alan Carr>: [audio gap] question. I wanted to follow on one of the things from Phil. So can you tell us what lessons you all learned from the Qnexa advisory meeting? And now how that might apply to lorcaserin?

<A – Jack Lief>: Well, remember Qnexa was a very, very different compound than lorcaserin. And so we will present much of the data, as we understand it, on lorcaserin. And I don't think we're going to have any surprises. Christy, do you want to further comment on that?

<A – Christen Anderson>: I think this is going to be [inaudible] same. As we anticipated, safety was the focus of that panel. And I think we can anticipate that safety will be a key focus of the lorcaserin panel. We're doing everything in our power to be well-prepared to discuss all the safety data with the advisory panel.

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<A – Jack Lief>: So Eisai is very much incentivized to provide a very high level of effort in the launch and follow-up to the launch of lorcaserin. They are in charge of the commercialization. And while we've had discussions in the past about a variety of different areas and issues, I can't really – it would be not appropriate for me to comment right now on exactly what they're going to be doing, given the near-term of an imminent approval and launch. So we'll just have to wait and see.

<Q – Steven Barlow>: And one cost question. If your Swiss plant were running near capacity levels, can you provide an estimate of what the full book costs would be per tablet of lorcaserin?

<A – Jack Lief>: It would be very small. I prefer not to get into the penny details right now, but it would be what you would expect a high-class pharmaceutical small molecule to cost.

<Q – Steven Barlow>: Okay. Thank you.

Operator: Our next question comes from Bill Tanner from Lazard Capital Markets.

<Q – Bill Tanner>: Thanks for taking the question. Jack or Christy maybe, it seems like it's going to come down to how much convergence or overlap there is of opinion, I guess, with what you guys have agreed with the FDA on how to conduct the trials and what the panel does. And it sounds like from a two years worth of data, that's going to be a reasonably adequate duration especially relative to Qnexa. I guess, I'm just wondering as you look at the phenotype, if you will, of the patients have been tested, how comfortable are you guys that nothing is going to get tripped up there?

<A – Jack Lief>: I mean we can only do what we've done. And Christy, do you have anything to add? I mean...

<A – Christen Anderson>: Again, we've always been very comfortable with the safety profile. The phenotype of the patients that we've studied, I think, is going to be fairly a representative of the target patient population post-approval. So again, I think we are pretty comfortable that we've shown good safety and tolerability profile, and we are prepared to support that at the advisory committee.

<A – Jack Lief>: Yeah, and it's not just in Phase 3. Also in Phase 2 studies, we've – those were very robust. Bill, you have anything to add?

<A – William Shanahan>: The only thing I would add is some of the data that Christy presented at the ADA, which I'm going to show that we have about 40% of the people having at least one comorbidity and about 30% have dyslipidemia, and about 20% have hypertension, and about 8% has a history of depression. So it's a wide spectrum of patients and I think it is, as Christy said, indicative of the kind of patients who will be using this drug.

<Q – Bill Tanner>: Fair enough. And Jack, maybe if I could just follow-on, on the BLOOM-DM data, I'm guessing this is a post-approval submission. Is that correct?

<A – Jack Lief>: Yes, it's a supplement. So once lorcaserin is approved, we will supplement that with additional data.

<Q – William Tanner>: Okay. Presumably at least from the perspective of not delaying the initial approval.

<A – Jack Lief>: We don't expect a delay but you never know. The FDA will be the final arbiter.

<Q – Bill Tanner>: Right. Okay. Thank you.

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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2008

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number: 000-31161

ARENA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or
organization)

23-2908305
(I.R.S. Employer Identification No.)

6166 Nancy Ridge Drive, San Diego, CA
(Address of principal executive offices)

92121
(Zip Code)

858.453.7200
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company.

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐ (Do not check if a smaller reporting company)

Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

☐ Yes ☒ No

The number of shares of common stock outstanding as of the close of business on May 7, 2008:

Class	Number of Shares Outstanding
Common Stock, \$0.0001 par value	73,844,005

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We model interest rate exposure by a sensitivity analysis that assumes a hypothetical parallel shift downward in the US Treasury yield curve of 100 basis points. Under these assumptions, if the yield curve were to shift lower by 100 basis points from the level existing at March 31, 2008, we would expect future interest income from our portfolio to decline by approximately \$3.3 million over the following 12 months. As of December 31, 2007, this same hypothetical reduction in interest rates would have resulted in a decline in interest income of approximately \$4.0 million over the 12 months following December 31, 2007. The difference in these two estimates is due to the difference in our cash and cash equivalents, short-term investments and securities available-for-sale between these two periods.

The model we use is not intended to forecast actual losses in interest income, but is used as a risk estimation and investment management tool. These hypothetical changes and assumptions are likely to be different from what actually occurs in the future. Furthermore, such computations do not incorporate any actions our management could take if the hypothetical interest rate changes actually occur. As a result, the impact on actual earnings will likely differ from those quantified herein.

We have a wholly owned subsidiary in Switzerland that exposes us to foreign exchange risk. The functional currency of our subsidiary in Switzerland is the Swiss franc. Accordingly, all assets and liabilities of our subsidiary are translated to US dollars based on the applicable exchange rate on the balance sheet date. Revenue and expense components are translated to US dollars at weighted-average exchange rates in effect during the period. Gains and losses resulting from foreign currency translation are reported as a separate component of accumulated other comprehensive gain or loss in our stockholders' equity. Other foreign currency transaction gains and losses are included in results of operations and, to date, have not been significant for us. We have not hedged exposures denominated in foreign currencies, but may do so in the future.

Item 4. Controls and Procedures.

Based on an evaluation carried out as of the end of the period covered by this quarterly report, under the supervision and with the participation of our management, including our Chief Executive Officer and Vice President, Finance and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures, our Chief Executive Officer and Vice President, Finance and Chief Financial Officer have concluded that, as of the end of such period, our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934) were effective.

In the quarter ended March 31, 2008, we acquired from Siegfried Ltd certain drug product manufacturing and packaging facility assets in Zofingen, Switzerland. In connection with the acquisition, we have implemented additional internal controls over financial reporting, including those surrounding cash disbursements for our Swiss location.

Other than as described above, there was no change in our internal control over financial reporting that occurred during the quarter covered by this quarterly report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1A. Risk Factors.

RISK FACTORS

Investment in our stock involves a high degree of risk. You should consider carefully the risks described below, together with other information in this quarterly report on Form 10-Q and our other public filings, before making investment decisions regarding our stock. If any of the following events actually occur, our business, operating results, prospects or financial condition could be materially and adversely affected. This could cause the trading price of our common stock to decline and you may lose all or part of your investment. Moreover, the risks described below are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business, operating results, prospects or financial condition.

The risk factors set forth below with an asterisk () before the title are risk factors containing changes, including any material changes, from the risk factors previously disclosed in Item 1A to Part I of our annual report on Form 10-K for the year ended December 31, 2007, as filed with the Securities and Exchange Commission.*

Risks Relating to Our Business

***We will need additional funds to conduct our planned research and development efforts, and we may not be able to obtain such funds.**

Our accumulated deficit since inception has resulted in large part from the significant research and development expenditures we have made in seeking to identify and validate new drug targets and develop compounds that could become marketed drugs.

We expect that our operating expenses over the next several years will be significant and that we will continue to have significant operating losses for at least the next several years, even if we or our collaborators are successful in advancing our compounds or partnered compounds.

We do not have any commercially available drugs. It takes many years and potentially hundreds of millions of dollars to successfully develop a preclinical or early clinical compound into a marketed drug, and our efforts may not result in a marketed drug. We have substantially less money than we need to develop our compounds into marketed drugs. Additional funding may not be available to us or may not be available on terms that you or we believe are favorable. If additional funding is not available, we may have to delay, reduce the scope of or eliminate one or more of our research or development programs.

In addition, provisions of our series B redeemable convertible preferred stock require us to obtain approval of the preferred stockholders, or otherwise trigger rights of first refusal or payment provisions, which may make it more difficult for us to take certain corporate actions and could delay, discourage or prevent future financings.

***Our stock price could decline significantly based on the results and timing of clinical trials and preclinical studies of, and decisions affecting, our lead drug candidates.**

Results of clinical trials and preclinical studies (including preclinical studies conducted after initiation of clinical trials) of our lead drug candidates may not be viewed favorably by us or third parties, including investors, analysts, potential collaborators, the academic and medical community, and regulators. The same may be true of how we design the development programs of our lead drug candidates and regulatory decisions (including by us or regulatory authorities) affecting those development programs. Biotechnology company stock prices have declined significantly when such results and decisions were unfavorable or perceived negatively or when a drug candidate did not otherwise meet expectations.

We have several drug programs that are currently in clinical trials. In addition to successfully completing clinical trials, in order to conduct long-term clinical trials and gain regulatory approval to commercialize drug candidates, regulatory authorities require that all drug candidates complete short- and long-term preclinical toxicity and carcinogenicity studies. These studies in animals are required to help determine the potential risk that drug candidates may be toxic or cause cancer in humans. The preclinical assessment of carcinogenic potential includes short-term in vitro and in vivo studies to look for chromosomal damage. Short-term carcinogenicity and toxicity studies have been completed for all of our clinical-stage programs. To date, we have only completed long-term preclinical toxicity studies for lorcaserin, and we have not completed carcinogenicity studies for lorcaserin or any of our other clinical-stage programs. The results of our clinical trials and preclinical studies are uncertain, and the design of these trials and studies (which may change significantly and be more expensive than currently anticipated depending on our results and regulatory decisions) may also be viewed negatively by third parties. We may not be successful in advancing our programs on our projected timetable, if at all. Failure to initiate or delays in the development programs for any of our drug candidates, or unfavorable results or decisions or negative perceptions regarding any of such programs, could cause our stock price to decline significantly. This is particularly the case with respect to our most advanced drug candidate, lorcaserin, for which we have three ongoing Phase 3 clinical trials.

Our development of lorcaserin may be adversely impacted by cardiovascular side effects previously associated with fenfluramine and dexfenfluramine.

We have developed lorcaserin to more selectively stimulate the 5-HT_{2C} serotonin receptor because we believe this may avoid the cardiovascular side effects associated with fenfluramine and dexfenfluramine (often used in combination with phentermine, the combination of which was commonly referred to as "fen-phen"), two serotonin-releasing agents and non-selective serotonin receptor agonists, both of which were withdrawn from the market in 1997 after reported incidences of

heart valve disease and pulmonary hypertension associated with their usage. We may not be correct in this belief, however, or lorcaserin's selectivity profile may not avoid these undesired side effects. Moreover, the potential relationship between the activity of lorcaserin and the activity of fenfluramine and dexfenfluramine may result in increased United States Food and Drug Administration, or FDA, regulatory scrutiny of the safety of lorcaserin and may raise potential adverse publicity in the marketplace, which could affect clinical enrollment or ultimately sales if lorcaserin is approved for sale.

The development programs for our drug candidates are expensive, time consuming, uncertain and susceptible to change, interruption, delay or termination.

Drug development programs are very expensive, time consuming and difficult to design and implement. Our drug candidates are in various stages of development and are prone to the risks of failure inherent in drug development. We will need to complete additional clinical trials and preclinical studies before we can demonstrate that our drug candidates are safe and effective to the satisfaction of the FDA and similar non-US regulatory authorities. These trials are expensive and uncertain processes that take years to complete. Failure can occur at any stage of the process, and successful early clinical or preclinical trials do not ensure that later trials or studies will be successful. In addition, the commencement of our planned clinical trials could be substantially delayed or prevented by several factors, including:

- limited number of, and competition for, suitable patients required for enrollment in our clinical trials;
- limited number of, and competition for, suitable sites to conduct our clinical trials;
- delay or failure to obtain FDA approval or agreement to commence a clinical trial;
- delay or failure to obtain sufficient supplies of our drug candidates for our clinical trials;
- delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or investigators; and
- delay or failure to obtain institutional review board, or IRB, approval to conduct a clinical trial at a prospective site.

Even if the results of our development programs are favorable, the development programs of our most advanced drug candidates, including those being developed by our collaborators, may take significantly longer than expected to complete. In addition, the FDA, other regulatory authorities, our collaborators, or we may suspend, delay or terminate our development programs at any time for various reasons, including:

- lack of effectiveness of any drug candidate during clinical trials;
- side effects experienced by study participants or other safety issues;
- slower than expected rates of patient recruitment and enrollment or lower than expected patient retention rates;
- delays or inability to manufacture or obtain sufficient quantities of materials for use in clinical trials;
- inadequacy of or changes in our manufacturing process or compound formulation;
- delays in obtaining regulatory approvals to commence a study, or "clinical holds," or delays requiring suspension or termination of a study by a regulatory authority, such as the FDA, after a study is commenced;
- changes in applicable regulatory policies and regulations;
- delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites;
- uncertainty regarding proper dosing;
- unfavorable results from ongoing clinical trials and preclinical studies;

- failure of our clinical research organizations to comply with all regulatory and contractual requirements or otherwise perform their services in a timely or acceptable manner;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to construct appropriate clinical trial protocols;
- insufficient data to support regulatory approval;
- termination of clinical trials by one or more clinical trial sites;
- inability or unwillingness of medical investigators to follow our clinical protocols;
- difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data; or
- lack of sufficient funding to continue clinical trials and preclinical studies.

There is typically a high rate of attrition from the failure of drug candidates proceeding through clinical trials, and many companies have experienced significant setbacks in advanced development programs even after promising results in earlier studies or trials. We may experience similar setbacks in our development programs. If we or our collaborators abandon or are delayed in our development efforts related to lorcaserin, APD125, APD791 or any other drug candidate, we may not be able to generate sufficient revenues to continue our operations at the current level or become profitable, our reputation in the industry and in the investment community would likely be significantly damaged, additional funding may not be available to us or may not be available on terms you or we believe are favorable, and our stock price would likely decrease significantly.

Our drug candidates are subject to extensive regulation, and we may not receive required regulatory approvals for any of our drug candidates.

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, marketing and distribution, and other possible activities relating to our drug candidates are, and any resulting drugs will be, subject to extensive regulation by the FDA and other regulatory agencies in the United States. Neither our collaborators nor we are permitted to market our drug candidates in the United States until we receive regulatory approval from the FDA. Neither our collaborators nor we have received marketing approval for any of our drug candidates. Specific preclinical data, chemistry, manufacturing and controls data, a proposed clinical study protocol and other information must be submitted to the FDA as part of an investigational new drug, or IND, application, and clinical trials may commence only after the IND application becomes effective. To market a new drug in the United States, we must submit to the FDA and obtain FDA approval of a New Drug Application, or NDA. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls to demonstrate the safety and effectiveness of the drug candidate.

Obtaining approval of an NDA can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable regulatory requirements may, either before or after product approval, if any, subject our company to administrative or judicially imposed sanctions, including:

- Warning Letters;
- civil and criminal penalties;
- injunctions;
- withdrawal of approved products;
- product seizure or detention;
- product recalls;

- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements; and
- refusal to approve pending NDAs or supplements to approved NDAs.

Regulatory approval of an NDA or NDA supplement is not guaranteed. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional preclinical studies and clinical trials. The number of preclinical studies and clinical trials that will be required for FDA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to target, and the regulations applicable to any particular drug candidate. The FDA can delay, limit or deny approval of a drug candidate for many reasons, including:

- a drug candidate may not be deemed adequately safe and effective;
- FDA officials may not find the data from preclinical studies and clinical trials sufficient;
- the FDA may not approve the manufacturing processes or facilities; or
- the FDA may change its approval policies or adopt new regulations.

We do not expect any drugs resulting from our research and development efforts to be commercially available until 2010 or later. Our most advanced drug candidates, including lorcaserin and APD125, have not completed all preclinical studies and the large, pivotal Phase 3 clinical trials for efficacy and safety that are required for FDA approval. Also, we have not previously filed NDAs with the FDA, nor have we previously conducted Phase 3 clinical trials, which are significantly larger and more complex than earlier-stage trials. This lack of corporate experience may impede our ability to successfully complete these trials and obtain FDA approval in a timely manner, if at all, for our drug candidates for which development and commercialization is our responsibility. Even if we believe that data collected from our preclinical studies and clinical trials of our drug candidates are promising and that our information and procedures regarding chemistry, manufacturing and controls are sufficient, our data may not be sufficient to support approval by the FDA or any other United States or foreign regulatory authority. As a result, we cannot predict when or whether regulatory approval will be obtained for any drug we develop. In addition, we believe that the regulatory review of NDAs for drug candidates intended for widespread use by a large proportion of the general population is becoming increasingly focused on safety. In this regard, it is possible that some of our drug candidates, including lorcaserin and APD125, will be subject to increased scrutiny to show adequate safety than would drug candidates for more acute and life-threatening diseases such as cancer. Even if approved, drug candidates may not be approved for all indications requested and such approval may be subject to limitations on the indicated uses for which the drug may be marketed. Our business and reputation may be harmed by any failure or significant delay in receiving regulatory approval for the sale of any drugs resulting from our drug candidates.

In order to market any drugs outside of the United States, we and our collaborators must comply with numerous and varying regulatory requirements of other countries. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks associated with FDA approval as well as additional, presently unanticipated, risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects associated with regulatory approval in the United States, including the risk that our drug candidates may not be approved for all indications requested and that such approval may be subject to limitations on the indicated uses for which the drug may be marketed.

The results of preclinical studies and completed clinical trials are not necessarily predictive of future results, and our current drug candidates may not have favorable results in later studies or trials.

Preclinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of a drug candidate, but rather to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the drug candidate's side effects at various doses and schedules. To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our drug candidates. Favorable results in our early studies or trials may not be repeated in later studies or trials,

including continuing preclinical studies and large-scale clinical trials, and our drug candidates in later-stage trials may fail to show desired safety and efficacy despite having progressed through earlier-stage trials. In particular, preclinical data and the limited clinical results that we have obtained for lorcaserin and APD125 may not predict results from studies in larger numbers of subjects drawn from more diverse populations treated for longer periods of time. They also may not predict the ability of lorcaserin or APD125 to achieve or sustain the desired effects in the intended population or to do so safely. Unfavorable results from ongoing preclinical studies or clinical trials could result in delays, modifications or abandonment of ongoing or future clinical trials, or abandonment of a clinical program. Preclinical and clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated or terminated, or a clinical program abandoned. In addition, we may report top-line data from time to time, which is based on a preliminary analysis of key efficacy and safety data, and is subject to change following a more comprehensive review of the data related to the applicable clinical trial.

Many of our research and development programs are in early stages of development, and may not result in the commencement of clinical trials.

Many of our research and development programs are in the discovery or preclinical stage of development. The process of discovering compounds with therapeutic potential is expensive, time consuming and unpredictable. Similarly, the process of conducting preclinical studies of compounds that we discover requires the commitment of a substantial amount of our technical and financial resources and personnel. We may not discover additional compounds with therapeutic potential, and any of the compounds for which we are conducting preclinical studies may not result in the commencement of clinical trials. We cannot be certain that results sufficiently favorable to justify commencement of Phase 1 clinical trials will be obtained in these preclinical investigations. If we are unable to identify and develop new drug candidates, we may not be able to maintain a clinical development pipeline or generate revenues.

Drug discovery and development is intensely competitive in the therapeutic areas on which we focus. If our competitors develop treatments that are approved faster, marketed better or demonstrated to be more effective or safer than our drug candidates, our commercial opportunities will be reduced or eliminated.

We focus our efforts on GPCRs. Because GPCRs are an important target class for drug discovery efforts, we believe that many pharmaceutical and biotechnology companies and other organizations have internal drug discovery programs focused on GPCRs. Many of the drugs that our collaborators or we are attempting to discover and develop would compete with existing therapies. In addition, many companies are pursuing the development of new drugs that target the same diseases and conditions that we target. Many of our competitors, particularly large pharmaceutical companies, have substantially greater research, development and marketing capabilities and greater financial, scientific and human resources than we do. Companies that complete clinical trials, obtain required regulatory agency approvals and commence commercial sale of their drugs before we do for the same indication may achieve a significant competitive advantage, including certain patent and FDA marketing exclusivity rights. In addition, our competitors may develop drugs with fewer side effects, more desirable characteristics (such as route of administration or frequency of dosing) or greater efficacy than our drug candidates or drugs, if any, for the same indication. Any results from our research and development efforts, or from our joint efforts with our existing or any future collaborators, may not compete successfully with existing or newly discovered products or therapies.

If we do not partner one or more unpartnered programs or raise additional funds, we may have to curtail some of our activities.

Without additional capital or funding from partners, we would need to re-evaluate our strategy of moving multiple drug discovery and development programs forward while at the same time maintaining our research and discovery capabilities. Based on such evaluation, we may need to significantly curtail some of our current and planned programs and expenditures. We do not know what programs, if any, we would need to curtail, but we believe narrowing our pipeline would reduce our opportunities for success.

***Our revenues depend upon the actions of our existing and potential collaborators.**

We expect that, for at least the next few years, our revenues will depend upon the success of our existing collaborations, our ability to enter into new collaborations and our ability to generate revenues under our subsidiary, Arena Pharmaceuticals GmbH's, or Arena GmbH, contract manufacturing agreement with Siegfried Ltd. Our revenues of \$19.3 million for the year ended December 31, 2007 were derived exclusively from our collaborations with Merck and

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
 EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2008

or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
 EXCHANGE ACT OF 1934

For the transition period from to

Commission File Number: 000-31161

ARENA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
 (State or other jurisdiction of incorporation or
 organization)

23-2908305
 (I.R.S. Employer Identification No.)

6166 Nancy Ridge Drive, San Diego, CA
 (Address of principal executive offices)

92121
 (Zip Code)

858.453.7200
 (Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company.

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐ (Do not check if a smaller reporting company) Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

☐ Yes ☒ No

The number of shares of common stock outstanding as of the close of business on July 31, 2008:

Class	Number of Shares Outstanding
Common Stock, \$0.0001 par value	73,954,283

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We have a wholly owned subsidiary in Switzerland that exposes us to foreign exchange risk. The functional currency of our subsidiary in Switzerland is the Swiss franc. Accordingly, all assets and liabilities of our subsidiary are translated to US dollars based on the applicable exchange rate on the balance sheet date. Revenue and expense components are translated to US dollars at weighted-average exchange rates in effect during the period. Gains and losses resulting from foreign currency translation are reported as a separate component of accumulated other comprehensive gain or loss in our stockholders' equity. Other foreign currency transaction gains and losses are included in results of operations and, to date, have not been significant for us. We have not hedged exposures denominated in foreign currencies, but may do so in the future.

Item 4. Controls and Procedures.

Based on an evaluation carried out as of the end of the period covered by this quarterly report, under the supervision and with the participation of our management, including our Chief Executive Officer and Vice President, Finance and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures, our Chief Executive Officer and Vice President, Finance and Chief Financial Officer have concluded that, as of the end of such period, our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934) were effective. There was no change in our internal control over financial reporting that occurred during the quarter covered by this quarterly report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION**Item 1A. Risk Factors.****RISK FACTORS**

Investment in our stock involves a high degree of risk. You should consider carefully the risks described below, together with other information in this quarterly report on Form 10-Q and our other public filings, before making investment decisions regarding our stock. If any of the following events actually occur, our business, operating results, prospects or financial condition could be materially and adversely affected. This could cause the trading price of our common stock to decline and you may lose all or part of your investment. Moreover, the risks described below are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business, operating results, prospects or financial condition.

The risk factors set forth below with an asterisk () before the title are new risk factors or risk factors containing substantive changes, including any material changes, from the risk factors previously disclosed in Item 1A to Part I of our annual report on Form 10-K for the year ended December 31, 2007, as filed with the Securities and Exchange Commission.*

Risks Relating to Our Business

***We will need additional funds to conduct our planned research and development efforts, and we may not be able to obtain such funds.**

Our accumulated deficit since inception has resulted in large part from the significant research and development expenditures we have made in seeking to identify and validate new drug targets and develop compounds that could become marketed drugs.

We expect that our operating expenses over the next several years will be significant and that we will continue to have significant operating losses for at least the next several years, even if we or our collaborators are successful in advancing our compounds or partnered compounds.

We do not have any commercially available drugs. It takes many years and potentially hundreds of millions of dollars to successfully develop a preclinical or early clinical compound into a marketed drug, and our efforts may not result in a marketed drug. We have substantially less money than we need to develop our compounds into marketed drugs. Additional funding may not be available to us or may not be available on terms that you or we believe are favorable. If additional funding is not available, we may have to delay, reduce the scope of or eliminate one or more of our research or development programs.

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In addition, provisions of our series B redeemable convertible preferred stock require us to obtain approval of the preferred stockholders, or otherwise trigger rights of first refusal or payment provisions, which may make it more difficult for us to take certain corporate actions and could delay, discourage or prevent future financings.

***Our stock price could decline significantly based on the results and timing of clinical trials and preclinical studies of, and decisions affecting, our lead drug candidates.**

Results of clinical trials and preclinical studies (including preclinical studies conducted after initiation of clinical trials) of our lead drug candidates may not be viewed favorably by us or third parties, including investors, analysts, potential collaborators, the academic and medical community, and regulators. The same may be true of how we design the development programs of our lead drug candidates and regulatory decisions (including by us or regulatory authorities) affecting those development programs. Biotechnology company stock prices have declined significantly when such results and decisions were unfavorable or perceived negatively or when a drug candidate did not otherwise meet expectations.

We have several drug programs that are currently in clinical trials. In addition to successfully completing clinical trials, in order to conduct long-term clinical trials and gain regulatory approval to commercialize drug candidates, regulatory authorities require that all drug candidates complete short- and long-term preclinical toxicity and carcinogenicity studies. These studies in animals are required to help determine the potential risk that drug candidates may be toxic or cause cancer in humans. The preclinical assessment of carcinogenic potential includes short-term in vitro and in vivo studies to look for chromosomal damage. Short-term carcinogenicity and toxicity studies have been completed for all of our clinical-stage programs. To date, we have only completed long-term preclinical toxicity studies for lorcaserin, and we have not completed carcinogenicity studies for lorcaserin or any of our other clinical-stage programs. The results of our clinical trials and preclinical studies are uncertain, and the design of these trials and studies (which may change significantly and be more expensive than currently anticipated depending on our results and regulatory decisions) may also be viewed negatively by third parties. We may not be successful in advancing our programs on our projected timetable, if at all. Failure to initiate or delays in the development programs for any of our drug candidates, or unfavorable results or decisions or negative perceptions regarding any of such programs, could cause our stock price to decline significantly. This is particularly the case with respect to our most advanced drug candidate, lorcaserin, for which we have three ongoing Phase 3 clinical trials.

Our development of lorcaserin may be adversely impacted by cardiovascular side effects previously associated with fenfluramine and dexfenfluramine.

We have developed lorcaserin to more selectively stimulate the 5-HT_{2C} serotonin receptor because we believe this may avoid the cardiovascular side effects associated with fenfluramine and dexfenfluramine (often used in combination with phentermine, the combination of which was commonly referred to as "fen-phen"), two serotonin-releasing agents and non-selective serotonin receptor agonists, both of which were withdrawn from the market in 1997 after reported incidences of heart valve disease and pulmonary hypertension associated with their usage. We may not be correct in this belief, however, or lorcaserin's selectivity profile may not avoid these undesired side effects. Moreover, the potential relationship between the activity of lorcaserin and the activity of fenfluramine and dexfenfluramine may result in increased United States Food and Drug Administration, or FDA, regulatory scrutiny of the safety of lorcaserin and may raise potential adverse publicity in the marketplace, which could affect clinical enrollment or ultimately sales if lorcaserin is approved for sale.

The development programs for our drug candidates are expensive, time consuming, uncertain and susceptible to change, interruption, delay or termination.

Drug development programs are very expensive, time consuming and difficult to design and implement. Our drug candidates are in various stages of development and are prone to the risks of failure inherent in drug development. We will need to complete additional clinical trials and preclinical studies before we can demonstrate that our drug candidates are safe and effective to the satisfaction of the FDA and similar non-US regulatory authorities. These trials are expensive and uncertain processes that take years to complete. Failure can occur at any stage of the process, and successful early clinical or preclinical trials do not ensure that later trials or studies will be successful. In addition, the commencement of our planned clinical trials could be substantially delayed or prevented by several factors, including:

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- limited number of, and competition for, suitable patients required for enrollment in our clinical trials;
- limited number of, and competition for, suitable sites to conduct our clinical trials;
- delay or failure to obtain FDA approval or agreement to commence a clinical trial;
- delay or failure to obtain sufficient supplies of our drug candidates for our clinical trials;
- delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or investigators; and
- delay or failure to obtain institutional review board, or IRB, approval to conduct a clinical trial at a prospective site.

Even if the results of our development programs are favorable, the development programs of our most advanced drug candidates, including those being developed by our collaborators, may take significantly longer than expected to complete. In addition, the FDA, other regulatory authorities, our collaborators, or we may suspend, delay or terminate our development programs at any time for various reasons, including:

- lack of effectiveness of any drug candidate during clinical trials;
- side effects experienced by study participants or other safety issues;
- slower than expected rates of patient recruitment and enrollment or lower than expected patient retention rates;
- delays or inability to manufacture or obtain sufficient quantities of materials for use in clinical trials;
- inadequacy of or changes in our manufacturing process or compound formulation;
- delays in obtaining regulatory approvals to commence a study, or "clinical holds," or delays requiring suspension or termination of a study by a regulatory authority, such as the FDA, after a study is commenced;
- changes in applicable regulatory policies and regulations;
- delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites;
- uncertainty regarding proper dosing;
- unfavorable results from ongoing clinical trials and preclinical studies;
- failure of our clinical research organizations to comply with all regulatory and contractual requirements or otherwise perform their services in a timely or acceptable manner;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to construct appropriate clinical trial protocols;
- insufficient data to support regulatory approval;
- termination of clinical trials by one or more clinical trial sites;
- inability or unwillingness of medical investigators to follow our clinical protocols;
- difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data; or
- lack of sufficient funding to continue clinical trials and preclinical studies.

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There is typically a high rate of attrition from the failure of drug candidates proceeding through clinical trials, and many companies have experienced significant setbacks in advanced development programs even after promising results in earlier studies or trials. We may experience similar setbacks in our development programs. If we or our collaborators abandon or are delayed in our development efforts related to lorcaserin, APD125, APD791 or any other drug candidate, we may not be able to generate sufficient revenues to continue our operations at the current level or become profitable, our reputation in the industry and in the investment community would likely be significantly damaged, additional funding may not be available to us or may not be available on terms you or we believe are favorable, and our stock price would likely decrease significantly.

Our drug candidates are subject to extensive regulation, and we may not receive required regulatory approvals for any of our drug candidates.

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, marketing and distribution, and other possible activities relating to our drug candidates are, and any resulting drugs will be, subject to extensive regulation by the FDA and other regulatory agencies in the United States. Neither our collaborators nor we are permitted to market our drug candidates in the United States until we receive regulatory approval from the FDA. Neither our collaborators nor we have received marketing approval for any of our drug candidates. Specific preclinical data, chemistry, manufacturing and controls data, a proposed clinical study protocol and other information must be submitted to the FDA as part of an investigational new drug, or IND, application, and clinical trials may commence only after the IND application becomes effective. To market a new drug in the United States, we must submit to the FDA and obtain FDA approval of a New Drug Application, or NDA. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls to demonstrate the safety and effectiveness of the drug candidate.

Obtaining approval of an NDA can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable regulatory requirements may, either before or after product approval, if any, subject our company to administrative or judicially imposed sanctions, including:

- Warning Letters;
- civil and criminal penalties;
- injunctions;
- withdrawal of approved products;
- product seizure or detention;
- product recalls;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements; and
- refusal to approve pending NDAs or supplements to approved NDAs.

Regulatory approval of an NDA or NDA supplement is not guaranteed. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional preclinical studies and clinical trials. The number of preclinical studies and clinical trials that will be required for FDA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to target, and the regulations applicable to any particular drug candidate. The FDA can delay, limit or deny approval of a drug candidate for many reasons, including:

- a drug candidate may not be deemed adequately safe and effective;
- FDA officials may not find the data from preclinical studies and clinical trials sufficient;

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- the FDA may not approve the manufacturing processes or facilities; or
- the FDA may change its approval policies or adopt new regulations.

We do not expect any drugs resulting from our research and development efforts to be commercially available until 2010 or later. Our most advanced drug candidates, including lorcaserin and APD125, have not completed all preclinical studies and the large, pivotal Phase 3 clinical trials for efficacy and safety that are required for FDA approval. Also, we have not previously filed NDAs with the FDA, nor have we previously conducted Phase 3 clinical trials, which are significantly larger and more complex than earlier-stage trials. This lack of corporate experience may impede our ability to successfully complete these trials and obtain FDA approval in a timely manner, if at all, for our drug candidates for which development and commercialization is our responsibility. Even if we believe that data collected from our preclinical studies and clinical trials of our drug candidates are promising and that our information and procedures regarding chemistry, manufacturing and controls are sufficient, our data may not be sufficient to support approval by the FDA or any other United States or foreign regulatory authority. As a result, we cannot predict when or whether regulatory approval will be obtained for any drug we develop. In addition, we believe that the regulatory review of NDAs for drug candidates intended for widespread use by a large proportion of the general population is becoming increasingly focused on safety. In this regard, it is possible that some of our drug candidates, including lorcaserin and APD125, will be subject to increased scrutiny to show adequate safety than would drug candidates for more acute and life-threatening diseases such as cancer. Even if approved, drug candidates may not be approved for all indications requested and such approval may be subject to limitations on the indicated uses for which the drug may be marketed. Our business and reputation may be harmed by any failure or significant delay in receiving regulatory approval for the sale of any drugs resulting from our drug candidates.

In order to market any drugs outside of the United States, we and our collaborators must comply with numerous and varying regulatory requirements of other countries. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks associated with FDA approval as well as additional, presently unanticipated, risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects associated with regulatory approval in the United States, including the risk that our drug candidates may not be approved for all indications requested and that such approval may be subject to limitations on the indicated uses for which the drug may be marketed.

The results of preclinical studies and completed clinical trials are not necessarily predictive of future results, and our current drug candidates may not have favorable results in later studies or trials.

Preclinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of a drug candidate, but rather to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the drug candidate's side effects at various doses and schedules. To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our drug candidates. Favorable results in our early studies or trials may not be repeated in later studies or trials, including continuing preclinical studies and large-scale clinical trials, and our drug candidates in later-stage trials may fail to show desired safety and efficacy despite having progressed through earlier-stage trials. In particular, preclinical data and the limited clinical results that we have obtained for lorcaserin and APD125 may not predict results from studies in larger numbers of subjects drawn from more diverse populations treated for longer periods of time. They also may not predict the ability of lorcaserin or APD125 to achieve or sustain the desired effects in the intended population or to do so safely. Unfavorable results from ongoing preclinical studies or clinical trials could result in delays, modifications or abandonment of ongoing or future clinical trials, or abandonment of a clinical program. Preclinical and clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated or terminated, or a clinical program abandoned. In addition, we may report top-line data from time to time, which is based on a preliminary analysis of key efficacy and safety data, and is subject to change following a more comprehensive review of the data related to the applicable clinical trial.

EXHIBIT AR

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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2008

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 000-31161

ARENA PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or
organization)

23-2908305
(I.R.S. Employer Identification No.)

6166 Nancy Ridge Drive, San Diego, CA
(Address of principal executive offices)

92121
(Zip Code)

858.453.7200
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company.

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐ (Do not check if a smaller reporting company) Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

☐ Yes ☒ No

The number of shares of common stock outstanding as of the close of business on October 31, 2008:

Class	Number of Shares Outstanding
Common Stock, \$0.0001 par value	74,044,088

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Table of Contents**Item 4. Controls and Procedures.**

Based on an evaluation carried out as of the end of the period covered by this quarterly report, under the supervision and with the participation of our management, including our Chief Executive Officer and Vice President, Finance and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures, our Chief Executive Officer and Vice President, Finance and Chief Financial Officer have concluded that, as of the end of such period, our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934) were effective. There was no change in our internal control over financial reporting that occurred during the quarter covered by this quarterly report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION**Item 1A. Risk Factors.****RISK FACTORS**

Investment in our stock involves a high degree of risk. You should consider carefully the risks described below, together with other information in this quarterly report on Form 10-Q and our other public filings, before making investment decisions regarding our stock. If any of the following events actually occur, our business, operating results, prospects or financial condition could be materially and adversely affected. This could cause the trading price of our common stock to decline and you may lose all or part of your investment. Moreover, the risks described below are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business, operating results, prospects or financial condition.

The risk factors set forth below with an asterisk () before the title are new risk factors or risk factors containing substantive changes, including any material changes, from the risk factors previously disclosed in Item 1A to Part I of our annual report on Form 10-K for the year ended December 31, 2007, as filed with the Securities and Exchange Commission. In addition, we deleted a risk factor entitled "Holders of the Series B Preferred can require us to redeem their Series B Preferred."*

Risks Relating to Our Business

***We will need additional funds to conduct our planned research and development efforts, and we may not be able to obtain such funds.**

We have accumulated a large deficit since inception that has primarily resulted from the significant research and development expenditures we have made in seeking to identify and validate new drug targets and develop compounds that could become marketed drugs.

We expect that our operating expenses over the next several years will be significant and that we will continue to have significant operating losses for at least the next several years, even if we or our collaborators are successful in advancing our compounds or partnered compounds.

We do not have any commercially available drugs. It takes many years and potentially hundreds of millions of dollars to successfully develop a preclinical or early clinical compound into a marketed drug, and our efforts may not result in a marketed drug. We have substantially less money than we need to develop our compounds into marketed drugs.

Additional funding may not be available to us or may not be available on terms that you or we believe are favorable. Even with positive results from our research and development or business development efforts, the current global economic difficulties, including reduced financial resources and changes in investment timelines, may further limit our access to additional funding. We also believe that, as our cash balances are depleted, it may become more difficult for us to obtain additional financing or enter into strategic relationships on terms acceptable to us, if at all. If additional funding is not available, we may have to delay, reduce the scope of or eliminate one or more of our research or development programs.

In addition, provisions of the Series B-1 Convertible Preferred Stock and Series B-2 Convertible Preferred Stock, which we refer to collectively as the Series B Preferred, require us to obtain approval of the holders of any outstanding shares of such stock, or otherwise trigger rights of first refusal or payment provisions, which may make it more difficult for us to take certain corporate actions and could delay, discourage or prevent future financings. We expect to redeem all outstanding shares of the Series B Preferred on November 13, 2008.

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***The current global economic environment poses severe challenges to our business strategy, which relies on access to capital from the markets and our collaborators, and creates other financial risks for us.**

In addition to the continuing deterioration in the global credit markets, the financial services industry and the global economy as a whole have been experiencing a period of substantial turmoil and uncertainty. The impact of these events on our business and the duration and severity of the current economic crisis is uncertain. It is possible that the current crisis in the global credit markets, the financial services industry and the global economy may adversely affect our business and the business of current and prospective collaborators and vendors, as well as our liquidity and financial condition.

We maintain a portfolio of investments in marketable debt securities which are recorded at fair value. Although we have established investment guidelines relative to diversification and maturity with the objective of maintaining safety of principal and liquidity, credit rating agencies may reduce the credit quality of our individual holdings which could adversely affect their value. Lower credit quality and other market events, such as increases in interest rates and further deterioration in the credit markets, may have an adverse effect on the fair value of our investment holdings and cash position.

***Our stock price could decline significantly based on the results and timing of clinical trials and preclinical studies of, and decisions affecting, our lead drug candidates.**

Results of clinical trials and preclinical studies (including preclinical studies conducted after initiation of clinical trials) of our lead drug candidates may not be viewed favorably by us or third parties, including investors, analysts, potential collaborators, the academic and medical community, and regulators. The same may be true of how we design the development programs of our lead drug candidates and regulatory decisions (including by us or regulatory authorities) affecting those development programs. Biotechnology company stock prices have declined significantly when such results and decisions were unfavorable or perceived negatively or when a drug candidate did not otherwise meet expectations.

We have several drug programs that are currently in clinical trials. In addition to successfully completing clinical trials, in order to conduct long-term clinical trials and gain regulatory approval to commercialize drug candidates, regulatory authorities require that all drug candidates complete short- and long-term preclinical toxicity and carcinogenicity studies. These studies in animals are required to help determine the potential risk that drug candidates may be toxic or cause cancer in humans. The preclinical assessment of carcinogenic potential includes short-term in vitro and in vivo studies to look for chromosomal damage. Short-term carcinogenicity and toxicity studies have been completed for all of our clinical-stage programs. To date, we have only completed long-term preclinical toxicity studies for lorcaserin, and we have not completed carcinogenicity studies for lorcaserin or any of our other clinical-stage programs. The results of our clinical trials and preclinical studies are uncertain, and the design of these trials and studies (which may change significantly and be more expensive than currently anticipated depending on our results and regulatory decisions) may also be viewed negatively by third parties. We may not be successful in advancing our programs on our projected timetable, if at all. Failure to initiate or delays in the development programs for any of our drug candidates, or unfavorable results or decisions or negative perceptions regarding any of such programs, could cause our stock price to decline significantly. This is particularly the case with respect to our most advanced drug candidate, lorcaserin, for which we have three ongoing Phase 3 clinical trials.

Our development of lorcaserin may be adversely impacted by cardiovascular side effects previously associated with fenfluramine and dexfenfluramine.

We have developed lorcaserin to more selectively stimulate the 5-HT_{2C} serotonin receptor because we believe this may avoid the cardiovascular side effects associated with fenfluramine and dexfenfluramine (often used in combination with phentermine, the combination of which was commonly referred to as "fen-phen"), two serotonin-releasing agents and non-selective serotonin receptor agonists, both of which were withdrawn from the market in 1997 after reported incidences of heart valve disease and pulmonary hypertension associated with their usage. We may not be correct in this belief, however, or lorcaserin's selectivity profile may not avoid these undesired side effects. Moreover, the potential relationship between the activity of lorcaserin and the activity of fenfluramine and dexfenfluramine may result in increased United States Food and Drug Administration, or FDA, regulatory scrutiny of the safety of lorcaserin and may raise potential adverse publicity in the marketplace, which could affect clinical enrollment or ultimately sales if lorcaserin is approved for sale.

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The development programs for our drug candidates are expensive, time consuming, uncertain and susceptible to change, interruption, delay or termination.

Drug development programs are very expensive, time consuming and difficult to design and implement. Our drug candidates are in various stages of development and are prone to the risks of failure inherent in drug development. We will need to complete additional clinical trials and preclinical studies before we can demonstrate that our drug candidates are safe and effective to the satisfaction of the FDA and similar non-US regulatory authorities. These trials are expensive and uncertain processes that take years to complete. Failure can occur at any stage of the process, and successful early clinical or preclinical trials do not ensure that later trials or studies will be successful. In addition, the commencement of our planned clinical trials could be substantially delayed or prevented by several factors, including:

- limited number of, and competition for, suitable patients required for enrollment in our clinical trials;
- limited number of, and competition for, suitable sites to conduct our clinical trials;
- delay or failure to obtain FDA approval or agreement to commence a clinical trial;
- delay or failure to obtain sufficient supplies of our drug candidates for our clinical trials;
- delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or investigators; and
- delay or failure to obtain institutional review board, or IRB, approval to conduct a clinical trial at a prospective site.

Even if the results of our development programs are favorable, the development programs of our most advanced drug candidates, including those being developed by our collaborators, may take significantly longer than expected to complete. In addition, the FDA, other regulatory authorities, our collaborators, or we may suspend, delay or terminate our development programs at any time for various reasons, including:

- lack of effectiveness of any drug candidate during clinical trials;
- side effects experienced by study participants or other safety issues;
- slower than expected rates of patient recruitment and enrollment or lower than expected patient retention rates;
- delays or inability to manufacture or obtain sufficient quantities of materials for use in clinical trials;
- inadequacy of or changes in our manufacturing process or compound formulation;
- delays in obtaining regulatory approvals to commence a study, or “clinical holds,” or delays requiring suspension or termination of a study by a regulatory authority, such as the FDA, after a study is commenced;
- changes in applicable regulatory policies and regulations;
- delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites;
- uncertainty regarding proper dosing;
- unfavorable results from ongoing clinical trials and preclinical studies;
- failure of our clinical research organizations to comply with all regulatory and contractual requirements or otherwise perform their services in a timely or acceptable manner;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to construct appropriate clinical trial protocols;

- insufficient data to support regulatory approval;

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- termination of clinical trials by one or more clinical trial sites;
- inability or unwillingness of medical investigators to follow our clinical protocols;
- difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data; or
- lack of sufficient funding to continue clinical trials and preclinical studies.

There is typically a high rate of attrition from the failure of drug candidates proceeding through clinical trials, and many companies have experienced significant setbacks in advanced development programs even after promising results in earlier studies or trials. We may experience similar setbacks in our development programs. If we or our collaborators abandon or are delayed in our development efforts related to lorcaserin, APD125, APD791 or any other drug candidate, we may not be able to generate sufficient revenues to continue our operations at the current level or become profitable, our reputation in the industry and in the investment community would likely be significantly damaged, additional funding may not be available to us or may not be available on terms you or we believe are favorable, and our stock price would likely decrease significantly.

***Our drug candidates are subject to extensive regulation, and we may not receive required regulatory approvals for any of our drug candidates.**

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, marketing and distribution, and other possible activities relating to our drug candidates are, and any resulting drugs will be, subject to extensive regulation by the FDA and other regulatory agencies in the United States. Neither our collaborators nor we are permitted to market our drug candidates in the United States until we receive regulatory approval from the FDA. Neither our collaborators nor we have received marketing approval for any of our drug candidates. Specific preclinical data, chemistry, manufacturing and controls data, a proposed clinical study protocol and other information must be submitted to the FDA as part of an investigational new drug, or IND, application, and clinical trials may commence only after the IND application becomes effective. To market a new drug in the United States, we must submit to the FDA and obtain FDA approval of a New Drug Application, or NDA. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls to demonstrate the safety and effectiveness of the drug candidate.

Obtaining approval of an NDA can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable regulatory requirements may, either before or after product approval, if any, subject our company to administrative or judicially imposed sanctions, including:

- Warning Letters;
- civil and criminal penalties;
- injunctions;
- withdrawal of approved products;
- product seizure or detention;
- product recalls;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements; and
- refusal to approve pending NDAs or supplements to approved NDAs.

Regulatory approval of an NDA or NDA supplement is not guaranteed. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional preclinical studies and clinical trials. The number of preclinical studies and clinical trials that will be required for FDA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to target, and

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the regulations applicable to any particular drug candidate. The FDA can delay, limit or deny approval of a drug candidate for many reasons, including:

- a drug candidate may not be deemed adequately safe and effective;
- FDA officials may not find the data from preclinical studies and clinical trials sufficient;
- the FDA may not approve the manufacturing processes or facilities; or
- the FDA may change its approval policies or adopt new regulations.

We do not expect any drugs resulting from our research and development efforts to be commercially available until at least late 2010. Our most advanced drug candidates, including lorcaserin and APD125, have not completed all preclinical studies and the large, pivotal Phase 3 clinical trials for efficacy and safety that are required for FDA approval. Also, we have not previously filed NDAs with the FDA, nor have we previously conducted Phase 3 clinical trials, which are significantly larger and more complex than earlier-stage trials. This lack of corporate experience may impede our ability to successfully complete these trials and obtain FDA approval in a timely manner, if at all, for our drug candidates for which development and commercialization is our responsibility. Even if we believe that data collected from our preclinical studies and clinical trials of our drug candidates are promising and that our information and procedures regarding chemistry, manufacturing and controls are sufficient, our data may not be sufficient to support approval by the FDA or any other United States or foreign regulatory authority. As a result, we cannot predict when or whether regulatory approval will be obtained for any drug we develop. In addition, we believe that the regulatory review of NDAs for drug candidates intended for widespread use by a large proportion of the general population is becoming increasingly focused on safety. In this regard, it is possible that some of our drug candidates, including lorcaserin and APD125, will be subject to increased scrutiny to show adequate safety than would drug candidates for more acute and life-threatening diseases such as cancer. Even if approved, drug candidates may not be approved for all indications requested and such approval may be subject to limitations on the indicated uses for which the drug may be marketed. Our business and reputation may be harmed by any failure or significant delay in receiving regulatory approval for the sale of any drugs resulting from our drug candidates.

In order to market any drugs outside of the United States, we and our collaborators must comply with numerous and varying regulatory requirements of other countries. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks associated with FDA approval as well as additional, presently unanticipated, risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects associated with regulatory approval in the United States, including the risk that our drug candidates may not be approved for all indications requested and that such approval may be subject to limitations on the indicated uses for which the drug may be marketed.

The results of preclinical studies and completed clinical trials are not necessarily predictive of future results, and our current drug candidates may not have favorable results in later studies or trials.

Preclinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of a drug candidate, but rather to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the drug candidate's side effects at various doses and schedules. To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our drug candidates. Favorable results in our early studies or trials may not be repeated in later studies or trials, including continuing preclinical studies and large-scale clinical trials, and our drug candidates in later-stage trials may fail to show desired safety and efficacy despite having progressed through earlier-stage trials. In particular, preclinical data and the limited clinical results that we have obtained for lorcaserin and APD125 may not predict results from studies in larger numbers of subjects drawn from more diverse populations treated for longer periods of time. They also may not predict the ability of lorcaserin or APD125 to achieve or sustain the desired effects in the intended population or to do so safely. Unfavorable results from ongoing preclinical studies or clinical trials could result in delays, modifications or abandonment of ongoing or future clinical trials, or abandonment of a clinical program. Preclinical and clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated or terminated, or a clinical program abandoned. In addition, we may report top-line data from time to time, which is based on a preliminary analysis of key efficacy and safety data, and is subject to change following a more comprehensive review of the data related to the applicable clinical trial.

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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2009

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 000-31161

ARENA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

23-2908305
(I.R.S. Employer Identification No.)

6166 Nancy Ridge Drive, San Diego, CA
(Address of principal executive offices)

92121
(Zip Code)

858.453.7200
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company.

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐

Smaller reporting company ☐

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

☐ Yes ☒ No

The number of shares of common stock outstanding as of the close of business on May 6, 2009:

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The above listing is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by GAAP. See our audited consolidated financial statements and notes thereto included in our 2008 Annual Report, which contain additional accounting policies and other disclosures required by GAAP.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

There have been no material changes from the information we included in this section of our annual report on Form 10-K for the year ended December 31, 2008.

Item 4. Controls and Procedures.

Based on an evaluation carried out as of the end of the period covered by this quarterly report, under the supervision and with the participation of our management, including our Chief Executive Officer and Vice President, Finance and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures, our Chief Executive Officer and Vice President, Finance and Chief Financial Officer have concluded that, as of the end of such period, our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934) were effective. There was no change in our internal control over financial reporting that occurred during the quarter covered by this quarterly report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION**Item 1A. Risk Factors.****RISK FACTORS**

Investment in our stock involves a high degree of risk. You should consider carefully the risks described below, together with other information in this quarterly report on Form 10-Q and our other public filings, before making investment decisions regarding our stock. If any of the following events actually occur, our business, operating results, prospects or financial condition could be materially and adversely affected. This could cause the trading price of our common stock to decline and you may lose all or part of your investment. Moreover, the risks described below are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business, operating results, prospects or financial condition.

The risk factors set forth below with an asterisk () before the title are risk factors containing substantive changes, including any material changes, from the risk factors previously disclosed in Item 1A to Part I of our annual report on Form 10-K for the year ended December 31, 2008, as filed with the Securities and Exchange Commission.*

Risks Relating to Our Business

***We will need additional funds to conduct our planned research and development efforts, we may not be able to obtain such funds and may never become profitable.**

We have accumulated a large deficit since inception that has primarily resulted from the significant research and development expenditures we have made in seeking to identify and validate new drug targets and develop compounds that could become marketed drugs. We expect that our losses will continue to be substantial for at least the next several years and that our operating expenses will also continue to be substantial, even if we or our collaborators are successful in advancing our compounds or partnered compounds.

We do not have any commercially available drugs, and we have substantially less money than we need to develop our compounds into marketed drugs. It takes many years and potentially hundreds of millions of dollars to successfully develop a preclinical or early clinical compound into a marketed drug, and our efforts may not result in any marketed drugs.

We will need additional funds or a partner to bring our most advanced drug candidate, lorcaserin, to market, if ever, and we may not be able to secure adequate funding or find an acceptable partner at all or on terms you or we believe are favorable. We also believe that due to global economic challenges, and as our cash balances are depleted, it may be difficult for us to obtain additional financing or enter into strategic relationships on terms acceptable to us, if at all. If additional funding is not available, we will have to eliminate or further postpone or scale back some or all of our research or development programs or delay the development of one or more of such programs, including our lorcaserin program.

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The current global economic environment poses severe challenges to our business strategy, which relies on access to capital from the markets and our collaborators, and creates other financial risks for us.

The global economy, including credit markets and the financial services industry, has been experiencing a period of substantial turmoil and uncertainty. These conditions have generally made equity and debt financing more difficult to obtain, and may negatively impact our ability to complete financing transactions. The duration and severity of these conditions is uncertain, as is the extent to which they may adversely affect our business and the business of current and prospective collaborators and vendors. If the global economy does not improve or worsens, we may be unable to secure additional funding to sustain our operations or to find suitable partners to advance our internal programs, even if we receive positive results from our research and development or business development efforts.

We maintain a portfolio of investments in marketable debt securities which are recorded at fair value. Although we have established investment guidelines relative to diversification and maturity with the objectives of maintaining safety of principal and liquidity, credit rating agencies may reduce the credit quality of our individual holdings which could adversely affect their value. Lower credit quality and other market events, such as changes in interest rates and further deterioration in the credit markets, may have an adverse effect on the fair value of our investment holdings and cash position.

We are focusing our activities and resources on the development of lorcaserin and depend on its success.

We are focusing our near-term research and development activities and resources on lorcaserin, and we believe a significant portion of the value of our company relates to our ability to develop this drug candidate. The development of lorcaserin is subject to many risks, including the risks discussed in other risk factors. If the results of clinical trials and preclinical studies of lorcaserin, the regulatory decisions affecting lorcaserin, the anticipated or actual timing and plan for commercializing lorcaserin, or, ultimately, the market acceptance of lorcaserin do not meet our, your, analysts' or others' expectations, the market price of our common stock could decline significantly.

***If we do not partner one or more unpartnered programs or raise additional funds, we may have to further curtail our activities.**

In light of our current financial resources, we decided to focus our near-term research and development efforts on our lorcaserin Phase 3 program and select earlier-stage preclinical and research programs. We also decreased the number of our US employees by approximately 31% in a workforce reduction expected to be substantially completed by June 22, 2009. While we believe this strategy will conserve resources, our ability to advance our drug candidate pipeline outside of lorcaserin will be limited. Without additional capital or funding from partners, we will need to significantly curtail some of our current and planned activities and expenditures. Any such further reductions may adversely impact our lorcaserin development and commercialization timeline or narrow or slow the development of our pipeline, which we believe would reduce our opportunities for success. Our decision to limit near-term development of drug candidates other than lorcaserin will likely extend the time it will take us to reach the market in these other therapeutic areas and may allow competing products to reach the market before our drug candidates.

***Our stock price could decline significantly based on the results and timing of clinical trials and preclinical studies of, and decisions affecting, our most advanced drug candidates.**

We announce results of clinical trials and preclinical studies from time to time. For example, we announced the results from our Phase 3 BLOOM pivotal trial for lorcaserin in March 2009 and expect to announce the results of our Phase 3 BLOSSOM pivotal trial for lorcaserin by the end of September 2009.

The results and timing of clinical trials and preclinical studies can affect our stock price. Preclinical studies include experiments performed in test tubes, in animals, or in cells or tissues from humans or animals. These studies include all drug studies except those conducted in human subjects, and may occur before or after initiation of clinical trials for a particular compound. Results of clinical trials and preclinical studies of lorcaserin or our other drug candidates may not be viewed favorably by us or third parties, including investors, analysts, potential collaborators, the academic and medical community, and regulators. The same may be true of how we design the development programs of our most advanced drug candidates and regulatory decisions (including by us or regulatory authorities) affecting those development programs. Biotechnology company stock prices have declined significantly when such results and decisions were unfavorable or perceived negatively or when a drug candidate did not otherwise meet expectations.

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We have drug programs that are currently in clinical trials. In addition to successfully completing clinical trials, to conduct long-term clinical trials and gain regulatory approval to commercialize drug candidates, regulatory authorities require that all drug candidates complete short- and long-term preclinical toxicity and carcinogenicity studies. These preclinical, animal studies are required to help us and regulatory authorities assess the potential risk that drug candidates may be toxic or cause cancer in humans. The results of clinical trials and preclinical studies are uncertain and subject to different interpretations, and the design of these trials and studies (which may change significantly and be more expensive than anticipated depending on results and regulatory decisions) may also be viewed negatively by us, regulatory authorities or other third parties and adversely impact the development and opportunities for regulatory approval and commercialization of our and our partnered drug candidates. We may not be successful in advancing our programs on our projected timetable, if at all. Failure to initiate or delays in the development programs for any of our drug candidates, or unfavorable results or decisions or negative perceptions regarding any of such programs, could cause our stock price to decline significantly. This is particularly the case with respect to lorcaserin.

Our development of lorcaserin may be adversely impacted by cardiovascular side effects previously associated with fenfluramine and dexfenfluramine.

We have developed lorcaserin to more selectively stimulate the serotonin 2C receptor because we believe this may avoid the cardiovascular side effects associated with fenfluramine and dexfenfluramine (often used in combination with phentermine, the combination of which was commonly referred to as "fen-phen"). These two drugs were serotonin-releasing agents and non-selective serotonin receptor agonists, and were withdrawn from the market in 1997 after reported incidences of heart valve disease and pulmonary hypertension associated with their usage. We may not be correct in our belief that selectively stimulating the serotonin 2C receptor will avoid these undesired side effects or lorcaserin's selectivity profile may not be adequate to avoid these side effects. Moreover, the potential relationship between the activity of lorcaserin and the activity of fenfluramine and dexfenfluramine may result in increased US Food and Drug Administration, or FDA, regulatory scrutiny of the safety of lorcaserin and may raise potential adverse publicity in the marketplace, which could affect clinical enrollment or sales if lorcaserin is approved for commercialization.

The development programs for our drug candidates are expensive, time consuming, uncertain and susceptible to change, interruption, delay or termination.

Drug development programs are very expensive, time consuming and difficult to design and implement. Our drug candidates are in various stages of research and development and are prone to the risks of failure inherent in drug development. We will need to complete additional clinical trials and preclinical studies before we can demonstrate that our drug candidates are safe and effective to the satisfaction of the FDA and similar non-US regulatory authorities. These trials are expensive and uncertain processes that take years to complete. Failure can occur at any stage of the process, and successful early clinical or preclinical trials do not ensure that later trials or studies will be successful. In addition, the commencement or completion of our planned clinical trials could be substantially delayed or prevented by several factors, including:

- limited number of, and competition for, suitable patients required for enrollment in our clinical trials;
- limited number of, and competition for, suitable sites to conduct our clinical trials;
- delay or failure to obtain FDA approval or agreement to commence a clinical trial;
- delay or failure to obtain sufficient supplies of our drug candidates for our clinical trials;
- delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or investigators; and
- delay or failure to obtain institutional review board, or IRB, approval to conduct a clinical trial at a prospective site.

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Even if the results of our development programs are favorable, the development programs of our most advanced drug candidates, including those being developed by our collaborators, may take significantly longer than expected to complete. In addition, the FDA, other regulatory authorities, our collaborators, or we may suspend, delay or terminate our development programs at any time for various reasons, including:

- lack of effectiveness of any drug candidate during clinical trials;
- side effects experienced by study participants or other safety issues;
- slower than expected rates of patient recruitment and enrollment or lower than expected patient retention rates;
- delays or inability to manufacture or obtain sufficient quantities of materials for use in clinical trials;
- inadequacy of or changes in our manufacturing process or compound formulation;
- delays in obtaining regulatory approvals to commence a study, or “clinical holds,” or delays requiring suspension or termination of a study by a regulatory authority, such as the FDA, after a study is commenced;
- changes in applicable regulatory policies and regulations;
- delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites;
- uncertainty regarding proper dosing;
- unfavorable results from ongoing clinical trials and preclinical studies;
- failure of our clinical research organizations to comply with all regulatory and contractual requirements or otherwise perform their services in a timely or acceptable manner;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to design appropriate clinical trial protocols;
- insufficient data to support regulatory approval;
- termination of clinical trials by one or more clinical trial sites;
- inability or unwillingness of medical investigators to follow our clinical protocols;
- difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data; or
- lack of sufficient funding to continue clinical trials and preclinical studies.

There is typically a high rate of attrition from the failure of drug candidates proceeding through clinical trials, and many companies have experienced significant setbacks in advanced development programs even after promising results in earlier studies or trials. For example, because our drug candidate for insomnia, APD125, did not meet the primary or secondary endpoints of a Phase 2b clinical trial, we are not planning any further clinical development of APD125. We have experienced setbacks in other development programs and may experience additional setbacks in the future. If we or our collaborators abandon or are delayed in our development efforts related to lorcaserin or any other drug candidate, we may not be able to generate sufficient revenues to continue our operations at the current level or become profitable, our reputation in the industry and in the investment community would likely be significantly damaged, additional funding may not be available to us or may not be available on terms you or we believe are favorable, and our stock price would likely decrease significantly.

***Our drug candidates are subject to extensive regulation, and we may not receive required regulatory approvals, or timely approvals, for any of our drug candidates.**

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, marketing and distribution, and other possible activities relating to our drug candidates are, and any resulting drugs will be, subject to extensive regulation by the FDA and other regulatory agencies in the United States. Neither our collaborators nor we are permitted to market our drug candidates in the United States until we receive regulatory approval from the FDA. Neither our collaborators nor we have

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received marketing approval for any of our drug candidates. Specific preclinical data, chemistry, manufacturing and controls data, a proposed clinical trial protocol and other information must be submitted to the FDA as part of an investigational new drug, or IND, application, and clinical trials may commence only after the IND application becomes effective. To market a new drug in the United States, we must submit to the FDA and obtain FDA approval of a New Drug Application, or NDA. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls to demonstrate the safety and effectiveness of the drug candidate.

Obtaining approval of an NDA can be a lengthy, expensive and uncertain process. As part of the Prescription Drug User Fee Act, or PDUFA, the FDA has a goal to review and act on a percentage of all submissions in a given time frame. The general review goal for a drug application is 10 months for a standard application and six months for priority review. The FDA has missed a portion of their PDUFA goals, and it is unknown whether the review of an NDA filing for lorcaserin, or for any of our other drug candidates, will be completed within the FDA review goals or will be delayed. Moreover, the duration of the FDA's review may depend on the number and type of other NDAs that are filed with the FDA around the same time period. For example, we believe that at least two companies are planning to file an NDA for a drug candidate for the treatment of obesity at around the time we expect the FDA will review our NDA for lorcaserin, which may impact the review of our NDA. Furthermore, any drug that acts on the central nervous system, or CNS, such as lorcaserin, has the potential to be scheduled as a controlled substance by the Drug Enforcement Administration of the United States Department of Justice, or DEA. DEA scheduling is an independent process that can delay drug launch beyond an NDA approval date.

In addition, failure to comply with FDA and other applicable regulatory requirements may, either before or after product approval, if any, subject our company to administrative or judicially imposed sanctions, including:

- Form 483 notices and Warning Letters;
- civil and criminal penalties;
- injunctions;
- withdrawal of approved products;
- product seizure or detention;
- product recalls;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements; and
- refusal to approve pending NDAs or supplements to approved NDAs.

Regulatory approval of an NDA or NDA supplement is not guaranteed. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional preclinical studies and clinical trials. The number of preclinical studies and clinical trials that will be required for FDA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to target and the regulations applicable to any particular drug candidate. The FDA can delay, limit or deny approval of a drug candidate for many reasons, including:

- a drug candidate may not be deemed adequately safe and effective;
- FDA officials may not find the data from preclinical studies and clinical trials sufficient;
- the FDA may not approve the manufacturing processes or facilities;
- the FDA may change its approval policies or adopt new regulations; or
- the FDA may not accept our NDA submission (which is expected to be electronic) due to, among other reasons, the formatting of the submission.

We do not expect any drugs resulting from our research and development efforts to be commercially available until at least late 2010. Our most advanced drug candidates, including lorcaserin, have not completed all preclinical studies and the large, pivotal Phase 3 clinical trials for efficacy and safety that are required for FDA approval. Also, we have not previously filed NDAs with the FDA, either by paper or electronically. This lack of corporate experience may impede our ability to successfully complete these trials and obtain FDA approval in a timely manner, if at all, for our drug candidates for which development and commercialization is our responsibility. Even if we believe that data collected from our preclinical studies and clinical trials of our drug candidates are

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promising and that our information and procedures regarding chemistry, manufacturing and controls are sufficient, our data may not be sufficient to support approval by the FDA or any other United States or foreign regulatory authority. In addition, we believe that the regulatory review of NDAs for drug candidates intended for widespread use by a large proportion of the general population is becoming increasingly focused on safety. In this regard, it is possible that some of our drug candidates, including lorcaserin, will be subject to increased scrutiny to show adequate safety than would drug candidates for more acute or life-threatening diseases such as cancer. Even if approved, drug candidates may not be approved for all indications requested and such approval may be subject to limitations on the indicated uses for which the drug may be marketed. Our business and reputation may be harmed by any failure or significant delay in receiving regulatory approval for the sale of any drugs resulting from our drug candidates. As a result, we cannot predict when or whether regulatory approval will be obtained for any drug we develop.

To market any drugs outside of the United States, we and our collaborators must comply with numerous and varying regulatory requirements of other countries. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks associated with FDA approval as well as additional, presently unanticipated, risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects associated with regulatory approval in the United States, including the risk that our drug candidates may not be approved for all indications requested and that such approval may be subject to limitations on the indicated uses for which the drug may be marketed.

***The results of preclinical studies and completed clinical trials are not necessarily predictive of future results, and our current drug candidates may not have favorable results in later studies or trials.**

Preclinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of a drug candidate, but rather to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the drug candidate's side effects at various doses and schedules. To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our drug candidates, except lorcaserin. Favorable results in our early studies or trials may not be repeated in later studies or trials, including continuing preclinical studies and large-scale clinical trials, and our drug candidates in later-stage trials may fail to show desired safety and efficacy despite having progressed through earlier-stage trials. In the case of lorcaserin, results in one pivotal trial (BLOOM) may not be confirmed in another pivotal trial (BLOSSOM). Unfavorable results from ongoing preclinical studies or clinical trials could result in delays, modifications or abandonment of ongoing or future clinical trials, or abandonment of a clinical program. Preclinical and clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated or terminated, or a clinical program to be abandoned. In addition, we may report top-line data from time to time, which is based on a preliminary analysis of key efficacy and safety data, and is subject to change following a more comprehensive review of the data related to the applicable clinical trial.

Many of our research and development programs are in early stages of development, and may not result in the commencement of clinical trials.

Many of our research and development programs are in the discovery or preclinical stage of development. The process of discovering compounds with therapeutic potential is expensive, time consuming and unpredictable. Similarly, the process of conducting preclinical studies of compounds that we discover requires the commitment of a substantial amount of our technical and financial resources and personnel. We may not discover additional compounds with therapeutic potential, and any of the compounds for which we are conducting preclinical studies may not result in the commencement of clinical trials. We cannot be certain that results sufficiently favorable to justify commencement of Phase 1 clinical trials will be obtained in these preclinical investigations. Even if such favorable preclinical results are obtained, our financial resources may not allow us to commence Phase 1 clinical trials. If we are unable to identify and develop new drug candidates, we may not be able to maintain a clinical development pipeline or generate revenues.

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
 Washington, D.C. 20549

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2010

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 000-31161

ARENA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
 (State or other jurisdiction of
 incorporation or organization)

23-2908305
 (I.R.S. Employer
 Identification No.)

6166 Nancy Ridge Drive, San Diego, CA
 (Address of principal executive offices)

92121
 (Zip Code)

858.453.7200
 (Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company.

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐ (Do not check if a smaller reporting company)

Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

The number of shares of common stock outstanding as of the close of business on May 5, 2010:

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As compensation expense recognized is based on awards ultimately expected to vest, we reduce the expense recognized based on an estimated forfeiture rate at the time of grant. If actual forfeitures vary from estimates, we will recognize the difference in compensation expense in the period the actual forfeitures occur or when options vest.

Accounting for lease financing obligations. We account for our sale and leaseback transactions using the financing method because our options to repurchase these properties in the future are considered continued involvement requiring such method. Under the financing method, the book value of the properties and related accumulated depreciation remain on our balance sheet and no sale is recognized. Instead, the sales price of the properties is recorded as a financing obligation, and a portion of each lease payment is recorded as interest expense. We estimated the borrowing rate that we use to impute interest expense on our lease payments.

The above listing is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by GAAP. See our audited consolidated financial statements and notes thereto included in our 2009 Annual Report, which contain additional accounting policies and other disclosures required by GAAP.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

There have been no material changes from the information we included in this section of our annual report on Form 10-K for the year ended December 31, 2009.

Item 4. Controls and Procedures.

Based on an evaluation carried out as of the end of the period covered by this quarterly report, under the supervision and with the participation of our management, including our President and Chief Executive Officer and Vice President, Finance and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures, our President and Chief Executive Officer and Vice President, Finance and Chief Financial Officer have concluded that, as of the end of such period, our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934) were effective. There was no change in our internal control over financial reporting that occurred during the quarter covered by this quarterly report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION**Item 1A. Risk Factors.****RISK FACTORS**

Investment in our stock involves a high degree of risk. You should consider carefully the risks described below, together with other information in this quarterly report on Form 10-Q and our other public filings, before making investment decisions regarding our stock. If any of the following events actually occur, our business, operating results, prospects or financial condition could be materially and adversely affected. This could cause the trading price of our common stock to decline and you may lose all or part of your investment. Moreover, the risks described below are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business, operating results, prospects or financial condition.

The risk factors set forth below with an asterisk () before the title are risk factors containing substantive changes, including any material changes, from the risk factors previously disclosed in Item 1A to Part I of our annual report on Form 10-K for the year ended December 31, 2009, as filed with the Securities and Exchange Commission.*

Risks Relating to Our Business

***We will need additional funds to conduct our planned research, development and commercialization efforts, we may not be able to obtain such funds and we may never become profitable.**

We have accumulated a large deficit since inception that has primarily resulted from the significant research and development expenditures we have made in seeking to identify and validate new drug targets and develop compounds that could become marketed drugs. We expect that our losses will continue to be substantial for at least the short term and that our operating expenses will also continue to be substantial, even if we or our current or future collaborators are successful in advancing our compounds.

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We do not have any commercially available drugs, and we have substantially less money than we need to develop our compounds into marketed drugs. It takes many years and potentially hundreds of millions of dollars to successfully develop a preclinical or early clinical compound into a marketed drug, and our efforts may not result in any marketed drugs.

We will need additional funds or a collaborative or other agreement with a pharmaceutical company or companies to bring our most advanced drug candidate, lorcaserin, to market, if ever, and we may not be able to secure adequate funding or find a pharmaceutical company to commercialize lorcaserin at all or on terms you or we believe are favorable. We also believe that it may be difficult for us

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to obtain additional financing or enter into strategic relationships on terms that we or third parties, including investors, analysts, or potential collaborators, view as acceptable, if at all. We may need additional funding even if we enter into such a relationship. If adequate funding is not available, we will have to eliminate or further postpone or scale back some or all of our research or development programs or delay the advancement of one or more of such programs, including our plans to commercialize lorcaserin.

***The current global economic environment poses severe challenges to our business strategy, which relies on access to capital from the markets or collaborators, and creates other financial risks for us.**

The global economy, including credit markets and the financial services industry, has been experiencing a period of substantial turmoil and uncertainty. These conditions have generally made equity and debt financing more difficult to obtain, and may negatively impact our ability to complete financing transactions. The duration and severity of these conditions is uncertain, as is the extent to which they may adversely affect our business and the business of current and prospective collaborators and vendors. If the global economy does not improve or worsens, we may be unable to secure additional funding to sustain our operations or to find suitable collaborators to advance our internal programs, even if we achieve positive results from our research and development or business development efforts.

From time to time, we may maintain a portfolio of investments in marketable debt securities, which are recorded at fair value. Although we have established investment guidelines relative to diversification and maturity with the objectives of maintaining safety of principal and liquidity, we rely on credit rating agencies to help evaluate the riskiness of investments, and such agencies may not accurately predict such risk. In addition, such agencies may reduce the credit quality of our individual holdings, which could adversely affect their value. Lower credit quality and other market events, such as changes in interest rates and further deterioration in the credit markets, may have an adverse effect on the fair value of our investment holdings and cash position.

***We are focusing a significant portion of our activities and resources on lorcaserin and depend on its marketing approval and commercial success.**

We are focusing a significant portion of our near-term activities and resources on lorcaserin, and we believe a significant portion of the value of our company relates to our ability to obtain marketing approval for and commercialize this drug candidate. The marketing approval and successful commercialization of lorcaserin is subject to many risks, including the risks discussed in other risk factors. If the results of clinical trials and preclinical studies of lorcaserin, the regulatory decisions affecting lorcaserin, the anticipated or actual timing and plan for commercializing lorcaserin, or, ultimately, the market acceptance of lorcaserin do not meet our, your, analysts' or others' expectations, the market price of our common stock could decline significantly. In 2010, for example, we could learn whether the US Food and Drug Administration, or FDA, refers our New Drug Application, or NDA, for lorcaserin to an advisory committee and, if so, whether that committee's recommendation is positive or negative, and whether the FDA will approve lorcaserin or issue a Complete Response Letter and, if approved, whether the DEA will schedule lorcaserin as a controlled substance and, if so, the level of scheduling.

Our stock price could decline significantly based on the results and timing of clinical trials and preclinical studies of, and decisions affecting, our most advanced drug candidates.

The results and timing of clinical trials and preclinical studies can affect our stock price. Preclinical studies include experiments performed in test tubes, in animals, or in cells or tissues from humans or animals. These studies include all drug studies except those conducted in human subjects, and may occur before or after initiation of clinical trials for a particular compound. Results of clinical trials and preclinical studies of lorcaserin or our other drug candidates may not be viewed favorably by us or third parties, including investors, analysts, potential collaborators, the academic and medical communities, and regulators. The same may be true of how we design the development programs of our most advanced drug candidates and regulatory decisions (including by us or regulatory authorities) affecting those development programs. Stock prices of companies in our industry have declined significantly when such results and decisions were unfavorable or perceived negatively or when a drug candidate did not otherwise meet expectations.

We have drug programs that are currently in clinical trials. In addition to successfully completing clinical trials, to conduct long-term clinical trials and gain regulatory approval to commercialize drug candidates, regulatory authorities require that all drug candidates complete short- and long-term preclinical toxicity and carcinogenicity studies. These preclinical, animal studies are required to help us and regulatory authorities assess the potential risk that drug candidates may be toxic or cause cancer in humans. The results of clinical trials and preclinical studies are uncertain and subject to different interpretations, and the design of these trials and studies (which may change significantly and be more expensive than anticipated depending on results and regulatory decisions) may also be viewed negatively by us, regulatory authorities or other third parties and

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adversely impact the development and opportunities for regulatory approval and commercialization of our drug candidates and those under collaborative agreements. We may not be successful in advancing our programs on our projected timetable, if at all. Failure to initiate or delays in the development programs for any of our drug candidates, or unfavorable results or decisions or negative perceptions regarding any of such programs, could cause our stock price to decline significantly. This is particularly the case with respect to lorcaserin.

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***Our drug candidates are subject to extensive regulation, and we may not receive required regulatory approvals, or timely approvals, for any of our drug candidates.**

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, marketing and distribution, and other possible activities relating to our drug candidates are, and any resulting drugs will be, subject to extensive regulation by the FDA and other regulatory agencies in the United States. Failure to comply with FDA and other applicable regulatory requirements may, either before or after product approval, if any, subject our company to administrative or judicially imposed sanctions.

Neither collaborators nor we are permitted to market our drug candidates in the United States until we receive regulatory approval from the FDA. Specific preclinical data, chemistry, manufacturing and controls data, a proposed clinical trial protocol and other information must be submitted to the FDA as part of an investigational new drug, or IND, application, and clinical trials may commence only after the IND application becomes effective. None of our drug candidates have received marketing approval. To market a new drug in the United States, we must submit to the FDA and obtain FDA approval of an NDA. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls to demonstrate the safety and effectiveness of the drug candidate.

Obtaining approval of an NDA can be a lengthy, expensive and uncertain process. As part of the Prescription Drug User Fee Act, or PDUFA, the FDA has a goal to review and act on a percentage of all submissions in a given time frame. The general review goal for a drug application is 10 months for a standard application and 6 months for priority review. The FDA's review goals are subject to change, and it is unknown whether the review of our NDA filing for lorcaserin, or an NDA filing for any of our other drug candidates, will be completed within the FDA's review goals or will be delayed. Moreover, the duration of the FDA's review may depend on the number and types of other NDAs that are submitted with the FDA around the same time period. We submitted our NDA for lorcaserin in December 2009. VIVUS, Inc., and Orexigen Therapeutics, Inc., submitted NDAs with the FDA for drug candidates for the treatment of obesity in December 2009 and March 2010, respectively. The review of such NDAs may impact the review of our lorcaserin NDA. Furthermore, any drug that acts on the central nervous system, or CNS, such as lorcaserin, has the potential to be scheduled as a controlled substance by the Drug Enforcement Administration of the US Department of Justice, or DEA. DEA scheduling is an independent process that can delay drug launch beyond an NDA approval date.

Regulatory approval of an NDA or NDA supplement is not guaranteed. The number and types of preclinical studies and clinical trials that will be required for FDA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to target and the regulations applicable to any particular drug candidate. Despite the time and expense exerted in preclinical and clinical studies, failure can occur at any stage, and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional preclinical studies and clinical trials. The FDA can delay, limit or deny approval of a drug candidate for many reasons, including:

- a drug candidate may not be deemed adequately safe and effective;
- FDA officials may not find the data from preclinical studies and clinical trials sufficient;
- the FDA's interpretation and our interpretation of data from preclinical studies and clinical trials may differ significantly;
- the FDA may not approve the manufacturing processes or facilities;
- the FDA may change its approval policies or adopt new regulations; or
- the FDA may not accept an NDA submission due to, among other reasons, the content or formatting of the submission.

With respect to lorcaserin, the FDA draft guidance document "Developing Products for Weight Management" dated February 2007 provides two alternate benchmarks for the development of drugs for the indication of weight management. The guidance provides that, in general, a product can be considered effective for weight management if after one year of treatment either of the following occurs: (1) the difference in mean weight loss between the active-product and placebo-treated groups is at least 5% and the difference is statistically significant, or (2) the proportion of patients who lose at least 5% of baseline body weight in the active-product group is at least 35%, is approximately double the proportion in the placebo-treated group, and the difference between groups is statistically significant. While we believe the results of our pivotal Phase 3 clinical trials of lorcaserin satisfy the latter of the two alternate efficacy benchmarks, the FDA may disagree with our view, not follow its draft guidance or impose other approval conditions that could delay or preclude approval of our lorcaserin NDA.

With the exception of our recently submitted lorcaserin NDA, we have not previously submitted NDAs to the FDA. This lack

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of corporate experience may impede our ability to obtain FDA approval in a timely manner, if at all, for lorcaserin or our other drug candidates for which development and commercialization is our responsibility. Even if we believe that data collected from our preclinical studies and clinical trials of our drug candidates are promising and that our information and procedures regarding

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chemistry, manufacturing and controls are sufficient, our data may not be sufficient to support approval by the FDA or any other US or foreign regulatory authority, or regulatory interpretation of these data and procedures may be unfavorable. In addition, we believe that the regulatory review of NDAs for drug candidates intended for widespread use by a large proportion of the general population is becoming increasingly focused on safety. In this regard, it is possible that some of our drug candidates, including lorcasearin, will be subject to increased scrutiny to show adequate safety than would drug candidates for more acute or life-threatening diseases such as cancer. Even if approved, drug candidates may not be approved for all indications requested and such approval may be subject to limitations on the indicated uses for which the drug may be marketed, restricted distribution methods or other limitations required by a Risk Evaluation and Mitigation Strategies, or REMS. Our business and reputation may be harmed by any failure or significant delay in receiving regulatory approval for the sale of any drugs resulting from our drug candidates. As a result, we cannot predict when or whether regulatory approval will be obtained for any drug we develop.

To market any drugs outside of the United States, we and current or future collaborators must comply with numerous and varying regulatory requirements of other countries. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks associated with FDA approval as well as additional, presently unanticipated, risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects associated with regulatory approval in the United States, including the risk that our drug candidates may not be approved for all indications requested and that such approval may be subject to limitations on the indicated uses for which the drug may be marketed.

Even if any of our drug candidates receives regulatory approval, our drug candidates will still be subject to extensive post-marketing regulation.

If we or collaborators receive regulatory approval for our drug candidates in the United States or other jurisdictions, we will also be subject to ongoing obligations and continued regulatory review from the FDA and other applicable regulatory agencies, such as continued adverse event reporting requirements. We may also be subject to additional FDA post-marketing obligations, all of which may result in significant expense and limit our ability to commercialize such drugs in the United States or other jurisdictions.

If any of our drug candidates receive US regulatory approval or approval in other jurisdictions, the FDA or other regulatory agencies may also require that the sponsor of the NDA conduct additional clinical trials to further assess the drug after NDA approval under a post-approval commitment. Such additional studies may be costly and may impact the commercialization of the drug. The FDA or other regulatory agencies may also impose significant restrictions on the indicated uses for which such drug may be marketed.

If the FDA or other regulatory agencies approve any of our drug candidates, the labeling, packaging, adverse event reporting, storage, advertising and promotion for the drug will be subject to extensive regulatory requirements. We and the manufacturers of our products are also required to comply with Good Manufacturing Practices, or cGMPs, regulations, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory agencies must approve these manufacturing facilities before they can be used to manufacture our products, and these facilities are subject to ongoing regulatory inspections. In addition, regulatory agencies subject a drug, its manufacturer and the manufacturer's facilities to continual review and inspections. The subsequent discovery of previously unknown problems with a drug, including adverse events of unanticipated severity or frequency, or problems with the facility where the drug is manufactured, may result in restrictions on the marketing of that drug, up to and including withdrawal of the drug from the market. In the United States, the DEA and comparable state-level agencies also heavily regulate the manufacturing, holding, processing, security, recordkeeping and distribution of drugs that are considered controlled substances. If any of our drug candidates are scheduled by the DEA as controlled substances (due to abuse potential), we will become subject to the DEA's regulations. The DEA periodically inspects facilities for compliance with its rules and regulations. If our manufacturing facilities or those of our suppliers fail to comply with applicable regulatory requirements, it could result in regulatory action and additional costs to us. Failure to comply with applicable FDA and other regulatory requirements may, either before or after product approval, if any, subject our company to administrative or judicially imposed sanctions, including:

- issuance of Form 483 notices or Warning Letters by the FDA or other regulatory agencies;
- imposition of fines and other civil penalties;

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- criminal prosecutions;
- injunctions, suspensions or revocations of regulatory approvals;
- suspension of any ongoing clinical trials;
- total or partial suspension of manufacturing;
- delays in commercialization;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or collaborators;

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- refusals to permit drugs to be imported into or exported from the United States;
- restrictions on operations, including costly new manufacturing requirements; and
- product recalls or seizures.

The FDA's and other regulatory agencies' policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our drug candidates or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we might not be permitted to market our drugs and our business could suffer.

Even if we receive regulatory approval to commercialize our drug candidates, our ability to generate revenues from any resulting products will be subject to a variety of risks, many of which are out of our control.

Even if our drug candidates obtain regulatory approval, resulting products may not gain market acceptance among physicians, patients, healthcare payers or the medical community. We believe that the degree of market acceptance and our ability to generate revenues from such products will depend on a number of factors, including:

- timing of market introduction of our drugs and competitive drugs;
- efficacy and safety of our drug candidates;
- prevalence and severity of any side effects;
- potential or perceived advantages or disadvantages over alternative treatments;
- strength of sales, marketing and distribution support;
- price of our future products, both in absolute terms and relative to alternative treatments;
- the effect of current and future healthcare laws on our drug candidates;
- availability of coverage and reimbursement from government and other third-party payers; and
- product labeling or product insert requirements of the FDA or other regulatory authorities.

If our approved drugs, if any, fail to achieve market acceptance, we may not be able to generate significant revenue to achieve or sustain profitability.

In addition, if lorcaserin is approved for marketing, regulatory authorities may determine that lorcaserin will be a scheduled drug if it is found to have abuse potential or for other reasons. Based on our interpretation of a formal abuse potential clinical trial we conducted, lorcaserin's clinical safety profile and certain other factors, we believe that lorcaserin has a limited abuse potential. If regulatory agencies disagree and lorcaserin were to be scheduled as a controlled substance by the DEA, we would expect it would be a schedule IV or V drug, which we believe would have little or no impact on our ability to commercialize lorcaserin. However, if lorcaserin were scheduled in a more tightly controlled category, such scheduling could negatively impact the ability to prescribe lorcaserin, a patient's willingness to use it and other aspects of our ability to commercialize it.

Our development and commercialization of lorcaserin may be adversely impacted by cardiovascular side effects previously associated with fenfluramine and dexfenfluramine.

We developed lorcaserin to more selectively stimulate the serotonin 2C receptor because we believe this may avoid the cardiovascular side effects associated with fenfluramine and dexfenfluramine (often used in combination with phentermine, the combination of which was commonly referred to as "fen-phen"). These two drugs were serotonin-releasing agents and non-selective serotonin receptor agonists, and were withdrawn from the market in 1997 after reported incidences of heart valve disease and pulmonary hypertension associated with their usage. We may not be correct in our belief that more selectively stimulating the serotonin 2C receptor will avoid these undesired side effects or lorcaserin's selectivity profile may not be adequate to avoid these side effects. Moreover, the potential relationship between the activity of lorcaserin and the activity of fenfluramine and dexfenfluramine may result in increased FDA regulatory scrutiny of the safety of lorcaserin and may raise potential adverse publicity in the marketplace, which could affect clinical enrollment or sales if lorcaserin is approved for commercialization. We have completed two large pivotal Phase 3 lorcaserin trials of one and two years' duration, both of which showed no apparent effects on heart valves or pulmonary artery pressures, but these results will need to be reviewed by the FDA.

The development programs for our drug candidates are expensive, time consuming, uncertain and susceptible to change, interruption, delay or termination.

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Drug development programs are very expensive, time consuming and difficult to design and implement. Our drug candidates are in various stages of research and development and are prone to the risks of failure inherent in drug development. Clinical trials and

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preclinical studies are needed to demonstrate that drug candidates are safe and effective to the satisfaction of the FDA and similar non-US regulatory authorities. These trials are expensive and uncertain processes that take years to complete. Failure can occur at any stage of the process, and successful early clinical or preclinical trials do not ensure that later trials or studies will be successful. In addition, the commencement or completion of our planned clinical trials could be substantially delayed or prevented by several factors, including:

- limited number of, and competition for, suitable patients required for enrollment in our clinical trials;
- limited number of, and competition for, suitable sites to conduct our clinical trials;
- delay or failure to obtain FDA approval or agreement to commence a clinical trial;
- delay or failure to obtain sufficient supplies of our drug candidates for our clinical trials;
- delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or investigators; and
- delay or failure to obtain institutional review board, or IRB, approval to conduct a clinical trial at a prospective site.

Even if the results of our development programs are favorable, the development programs of our most advanced drug candidates, including those being developed by current or future collaborators, may take significantly longer than expected to complete. In addition, the FDA, other regulatory authorities, collaborators, or we may suspend, delay or terminate our development programs at any time for various reasons, including:

- lack of effectiveness of any drug candidate during clinical trials;
- side effects experienced by study participants or other safety issues;
- slower than expected rates of patient recruitment and enrollment or lower than expected patient retention rates;
- delays or inability to manufacture or obtain sufficient quantities of materials for use in clinical trials;
- inadequacy of or changes in our manufacturing process or compound formulation;
- delays in obtaining regulatory approvals to commence a study, or “clinical holds,” or delays requiring suspension or termination of a study by a regulatory authority, such as the FDA, after a study is commenced;
- changes in applicable regulatory policies and regulations;
- delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites;
- uncertainty regarding proper dosing;
- unfavorable results from ongoing clinical trials and preclinical studies;
- failure of our clinical research organizations to comply with all regulatory and contractual requirements or otherwise perform their services in a timely or acceptable manner;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to design appropriate clinical trial protocols;
- insufficient data to support regulatory approval;
- termination of clinical trials by one or more clinical trial sites;
- inability or unwillingness of medical investigators to follow our clinical protocols;
- difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data; or
- lack of sufficient funding to continue clinical trials and preclinical studies.

There is typically a high rate of attrition from the failure of drug candidates proceeding through clinical trials, and many companies have experienced significant setbacks in advanced development programs even after promising results in earlier studies or trials. We have experienced setbacks in our internal and partnered development programs and may experience additional setbacks in the future. If we or our collaborators abandon or are delayed in our development efforts related to lorcaserin or any other drug candidate, we may not be able to generate sufficient revenues to continue our operations at the current level or become profitable, our reputation in the industry and in the investment community would likely be significantly damaged, additional funding may not be available to us or may not be available on terms you or we believe are favorable, and our stock price would likely decrease significantly.

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The results of preclinical studies and completed clinical trials are not necessarily predictive of future results, and our current drug candidates may not have favorable results in later studies or trials.

Preclinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of a drug candidate, but rather to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the drug candidate's side effects at various doses.

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and schedules. To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our drug candidates, except lorcaserin. Favorable results in our early studies or trials may not be repeated in later studies or trials, including continuing preclinical studies and large-scale clinical trials, and our drug candidates in later-stage trials may fail to show desired safety and efficacy despite having progressed through earlier-stage trials. Unfavorable results from ongoing preclinical studies or clinical trials could result in delays, modifications or abandonment of ongoing or future clinical trials, or abandonment of a clinical program. Preclinical and clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated or terminated, or a clinical program to be abandoned.

Many of our research and development programs are in early stages of development, and may not result in the commencement of clinical trials.

Many of our research and development programs are in the discovery or preclinical stage of development. The process of discovering compounds with therapeutic potential is expensive, time consuming and unpredictable. Similarly, the process of conducting preclinical studies of compounds that we discover requires the commitment of a substantial amount of our technical and financial resources and personnel. We may not discover additional compounds with therapeutic potential, and any of our preclinical compounds may not result in the commencement of clinical trials. We cannot be certain that results sufficiently favorable to justify commencement of Phase 1 clinical trials will be obtained in these preclinical investigations. Even if such favorable preclinical results are obtained, our financial resources may not allow us to commence Phase 1 clinical trials. If we are unable to identify and develop new drug candidates, we may not be able to maintain a clinical development pipeline or generate revenues.

Our ability to generate significant revenues, for at least the short term, depends upon the actions of our current and future collaborators.

We expect that, for at least the short term, our ability to generate significant revenues will depend upon the success of our existing collaboration with Ortho-McNeil-Janssen Pharmaceuticals, Inc., or Ortho-McNeil-Janssen, and our ability to enter into new collaborations. Future revenues from our collaboration with Ortho-McNeil-Janssen will depend on, in addition to patent reimbursements, milestone and royalty payments, if any. Thus, we will receive little additional revenues from Ortho-McNeil-Janssen if our own or Ortho-McNeil-Janssen's research, development or, ultimately, marketing efforts are unsuccessful. In addition, we intend to commercialize lorcaserin with a pharmaceutical company or companies, and any such company may not be successful in such efforts.

Typically, collaborators (and not us) control the development of compounds subject to the collaboration after we have met early preclinical scientific milestones. In addition, we may not have complete access to information about the results and status of such collaborators' clinical trials and regulatory programs and strategies. We are not entitled to the more significant milestone payments under our agreement with Ortho-McNeil-Janssen until it has advanced compounds in clinical testing.

Our collaborators may not devote adequate resources to the research, development or commercialization of our compounds and may not develop or implement a successful clinical, regulatory or commercialization strategy. We cannot guarantee that any development, approval or sales milestones in our existing or future collaborations will be achieved in the future, or that we will receive any payments for the achievement of any milestones. In addition, our collaboration with Ortho-McNeil-Janssen may be terminated early in certain circumstances, in which case we may not receive future milestone or royalty payments or patent reimbursements.

Moreover, our ability to enter into new collaborations depends on the outcomes of our preclinical and clinical testing. We do not control these outcomes. In addition, even if our testing is successful, pharmaceutical companies may not enter into agreements with us on terms that we believe are acceptable until we have advanced our drug candidates into the clinic and, possibly, through later-stage clinical trials, approval or successful commercialization, if at all.

We may participate in new strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time we consider strategic transactions, such as out-licensing or in-licensing of compounds or technologies, acquisitions of companies and asset purchases. Additional potential transactions we may consider include a variety of different business arrangements, including strategic collaborations, joint ventures, spin-offs, restructurings, divestitures, business combinations and investments. In addition, another entity may pursue us as an acquisition target. Any such transactions may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges, require additional expertise or disrupt our management or business, which could

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
 Washington, D.C. 20549

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☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2010

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 000-31161

ARENA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
 (State or other jurisdiction of
 incorporation or organization)

23-2908305
 (I.R.S. Employer Identification No.)

6166 Nancy Ridge Drive, San Diego, CA
 (Address of principal executive offices)

92121
 (Zip Code)

858.453.7200
 (Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company.

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐ (Do not check if a smaller reporting company)

Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

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As compensation expense recognized is based on awards ultimately expected to vest, we reduce the expense recognized based on an estimated forfeiture rate at the time of grant. If actual forfeitures vary from estimates, we will recognize the difference in compensation expense in the period the actual forfeitures occur or when options vest.

Accounting for lease financing obligations. We account for our sale and leaseback transactions using the financing method because our options to repurchase these properties in the future are considered continued involvement requiring such method. Under the financing method, the book value of the properties and related accumulated depreciation remain on our balance sheet and no sale is recognized. Instead, the sales price of the properties is recorded as a financing obligation, and a portion of each lease payment is recorded as interest expense. We estimated the borrowing rate that we use to impute interest expense on our lease payments.

The above listing is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by GAAP. See our audited consolidated financial statements and notes thereto included in our 2009 Annual Report, which contain additional accounting policies and other disclosures required by GAAP.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

There have been no material changes from the information we included in this section of our annual report on Form 10-K for the year ended December 31, 2009.

Item 4. Controls and Procedures.

Based on an evaluation carried out as of the end of the period covered by this quarterly report, under the supervision and with the participation of our management, including our President and Chief Executive Officer and Vice President, Finance and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures, our President and Chief Executive Officer and Vice President, Finance and Chief Financial Officer have concluded that, as of the end of such period, our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934) were effective. There was no change in our internal control over financial reporting that occurred during the quarter covered by this quarterly report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION**Item 1A. Risk Factors.****RISK FACTORS**

Investment in our stock involves a high degree of risk. You should consider carefully the risks described below, together with other information in this quarterly report on Form 10-Q and our other public filings, before making investment decisions regarding our stock. If any of the following events actually occur, our business, operating results, prospects or financial condition could be materially and adversely affected. This could cause the trading price of our common stock to decline and you may lose all or part of your investment. Moreover, the risks described below are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business, operating results, prospects or financial condition.

The risk factors set forth below with an asterisk () before the title are new risk factors or risk factors containing substantive changes, including any material changes, from the risk factors previously disclosed in Item 1A to Part I of our annual report on Form 10-K for the year ended December 31, 2009, as filed with the Securities and Exchange Commission.*

Risks Relating to Our Business

***We will need additional funds to conduct our planned research, development and commercialization efforts, we may not be able to obtain such funds and we may never become profitable.**

We have accumulated a large deficit since inception that has primarily resulted from the significant research and development expenditures we have made in seeking to identify and validate new drug targets and develop compounds that could become marketed drugs. We expect that our losses will continue to be substantial for at least the short term and that our operating expenses will also continue to be substantial, even if we are successful in advancing lorcaserin, including under our

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marketing and supply agreement with Eisai Inc., or Eisai, or our other compounds and drug candidates, independently or with another company.

We do not have any commercially available drugs, and may not have adequate funds to develop our compounds into marketed drugs. It takes many years and potentially hundreds of millions of dollars to successfully develop a preclinical or early clinical compound into a marketed drug, and our efforts may not result in any marketed drugs.

Our wholly owned subsidiary, Arena Pharmaceuticals GmbH, or Arena GmbH, has entered into a marketing and supply agreement with Eisai for the commercialization of our most advanced drug candidate, lorcaserin, in the United States and its territories and

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possessions following approval by the US Food and Drug Administration, or FDA, of our lorcaserin New Drug Application, or NDA. We will need additional funds or a collaborative or other agreement with a pharmaceutical company or companies to commercialize lorcaserin outside of the United States, and we may not be able to secure adequate funding or find a pharmaceutical company to commercialize lorcaserin outside the United States at all or on terms you or we believe are favorable. Even if we receive approval of our lorcaserin NDA and commence commercialization of lorcaserin under our marketing and supply agreement with Eisai, we cannot assure you that payments, if any, we receive under such agreement will be sufficient to conduct our planned research and development and other activities or to result in profitability. We also believe that it may be difficult for us to obtain additional financing or enter into strategic relationships on terms that we or third parties, including investors, analysts, or potential collaborators, view as acceptable, if at all. We may need additional funding even if we enter into such a relationship. If adequate funding is not available, we may eliminate or postpone or scale back some or all of our research or development programs or delay the advancement of one or more of such programs. Any such reductions may adversely impact our lorcaserin development and commercialization timeline or narrow or slow the development of our pipeline, which we believe would reduce our opportunities for success and result in a decline in the market price of our common stock.

***The current global economic environment poses severe challenges to our business strategy, which relies on access to capital from the markets or collaborators, and creates other financial risks for us.**

The global economy, including credit markets and the financial services industry, has been experiencing a period of substantial turmoil and uncertainty. These conditions have generally made equity and debt financing more difficult to obtain, and may negatively impact our ability to complete financing transactions. The duration and severity of these conditions is uncertain, as is the extent to which they may adversely affect our business and the business of current and prospective vendors or our distributors, licensees and collaborators, which we sometimes refer to generally as our collaborators. If the global economy does not improve or worsens, we may be unable to secure additional funding to sustain our operations or to find suitable collaborators to advance our internal programs, even if we achieve positive results from our research and development or business development efforts.

From time to time, we may maintain a portfolio of investments in marketable debt securities, which are recorded at fair value. Although we have established investment guidelines relative to diversification and maturity with the objectives of maintaining safety of principal and liquidity, we rely on credit rating agencies to help evaluate the riskiness of investments, and such agencies may not accurately predict such risk. In addition, such agencies may reduce the credit quality of our individual holdings, which could adversely affect their value. Lower credit quality and other market events, such as changes in interest rates and further deterioration in the credit markets, may have an adverse effect on the fair value of our investment holdings and cash position.

***We are focusing a significant portion of our activities and resources on lorcaserin and depend on its marketing approval and commercial success.**

We are focusing a significant portion of our near-term activities and resources on lorcaserin, and we believe a significant portion of the value of our company relates to our ability to obtain marketing approval for and commercialize this drug candidate. The marketing approval and successful commercialization of lorcaserin is subject to many risks, including the risks discussed in other risk factors. If the results of clinical trials and preclinical studies of lorcaserin, the regulatory decisions affecting lorcaserin, the anticipated or actual timing and plan for commercializing lorcaserin, or, ultimately, the market acceptance of lorcaserin do not meet our, your, analysts' or others' expectations, the market price of our common stock could decline significantly. In 2010, for example, we may learn the results of the September 16, 2010 FDA advisory committee meeting for the review of the NDA for lorcaserin, whether the FDA will approve lorcaserin or issue a Complete Response Letter and, if approved, whether the Drug Enforcement Administration of the US Department of Justice, or DEA, will schedule lorcaserin as a controlled substance and, if so, the level of scheduling.

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***Our ability to generate significant revenues, for at least the short term, depends upon the regulatory approval of lorcaserin, the commercialization of lorcaserin and the actions of collaborators.**

We expect that, for at least the short term, our ability to generate significant revenues will depend on the regulatory approval of lorcaserin, the success of Eisai in commercializing lorcaserin, if approved, in the United States, the success of our existing collaboration with Ortho-McNeil-Janssen Pharmaceuticals, Inc., or Ortho-McNeil-Janssen, and our ability to enter into new collaborations. Future revenues under the marketing and supply agreement with Eisai will depend on the achievement of milestones under the agreement and Eisai's commercialization of lorcaserin, and we may receive no additional revenues from Eisai if lorcaserin is not approved by the FDA or further development of lorcaserin is unfavorable. Future revenues from our collaboration with Ortho-McNeil-Janssen will depend on patent reimbursements and milestone and royalty payments, if any, and we are not entitled to the more significant milestone payments under the collaboration until compounds are further advanced in clinical testing. In addition, we intend to commercialize lorcaserin outside of the United States with one or more pharmaceutical companies or independently, and we or our collaborators may not be successful in such efforts.

With the exception of the marketing and supply agreement with Eisai, collaborators (and not us) typically control the development of compounds subject to the collaboration after we have met early preclinical scientific milestones. In addition, we may not have complete access to information about the results and status of such collaborators' clinical trials and regulatory programs and strategies.

In addition to the specific risks identified above with respect to Eisai, our collaborators may not devote adequate resources to the research, development or commercialization of our compounds and may not develop or implement a successful clinical, regulatory or commercialization strategy. We cannot guarantee that any development, approval or sales milestones in our existing or future collaborations will be achieved in the future, or that we will receive any payments for the achievement of any milestones. In addition, our agreements with Eisai and Ortho-McNeil-Janssen may be terminated early in certain circumstances, in which case we may not receive future milestone or other payments under the applicable agreement.

Moreover, our ability to enter into new collaborations may depend on the outcomes of our preclinical and clinical testing. We do not control these outcomes. In addition, even if our testing is successful, pharmaceutical companies may not enter into agreements with us on terms that we believe are acceptable until we have advanced our drug candidates into the clinic and, possibly, through later-stage clinical trials, approval or successful commercialization, if at all.

***We are dependent on the marketing and supply agreement with Eisai to commercialize lorcaserin in the United States and, if applicable, to further develop lorcaserin, and the failure to maintain such agreement, or poor performance under such agreement, could negatively impact our business.**

Pursuant to the terms of Arena GmbH's marketing and supply agreement with Eisai, Arena GmbH granted Eisai exclusive rights to commercialize lorcaserin in the United States and its territories and possessions following approval by the FDA of our lorcaserin NDA.

Our ability to generate payments from Eisai substantially depends on the regulatory approval and market acceptance of lorcaserin in the United States. Eisai has primary responsibility for the marketing and sale of lorcaserin in the United States and responsibility for compliance with certain US regulatory requirements, and we have limited control over the amount and timing of resources that Eisai will dedicate to the commercialization of lorcaserin in the United States.

We are subject to a number of other risks associated with our dependence on the marketing and supply agreement with Eisai, including:

- Eisai may not comply with applicable regulatory guidelines with respect to commercializing lorcaserin, which could adversely impact sales or any development of lorcaserin;
- there could be disagreements regarding the marketing and supply agreement that delay or terminate the commercialization or development of lorcaserin, delay or eliminate potential payments under the agreement or increase our costs under the agreement; or
- Eisai may not perform as expected, and the marketing and supply agreement may not provide adequate protection or may not be effectively enforced.

Either party has the right to terminate the agreement in certain circumstances. If the agreement is terminated early, we may not be able to find another company for the commercialization of lorcaserin in the United States and further development of

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lorcaserin on acceptable terms, if at all, and even if we elected to pursue continued commercialization or further development of lorcaserin on our own, we might not have the funds, or otherwise be able, to do so successfully.

We may enter into additional agreements for the commercialization of lorcaserin or other of our drug candidates, and may be similarly dependent on the performance of third parties with similar risk.

Our stock price could decline significantly based on the results and timing of clinical trials and preclinical studies of, and decisions affecting, our most advanced drug candidates.

The results and timing of clinical trials and preclinical studies can affect our stock price. Preclinical studies include experiments performed in test tubes, in animals, or in cells or tissues from humans or animals. These studies include all drug studies except those conducted in human subjects, and may occur before or after initiation of clinical trials for a particular compound. Results of clinical trials and preclinical studies of lorcaserin or our other drug candidates may not be viewed favorably by us or third parties, including investors, analysts, current or potential collaborators, the academic and medical communities, and regulators. The same may be true of how we design the development programs of our most advanced drug candidates and regulatory decisions (including by us or regulatory authorities) affecting those development programs. Stock prices of companies in our industry have declined significantly when such results and decisions were unfavorable or perceived negatively or when a drug candidate did not otherwise meet expectations.

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We have drug programs that are currently in clinical trials. In addition to successfully completing clinical trials, to conduct long-term clinical trials and gain regulatory approval to commercialize drug candidates, regulatory authorities require that all drug candidates complete short- and long-term preclinical toxicity and carcinogenicity studies. These preclinical, animal studies are required to help us and regulatory authorities assess the potential risk that drug candidates may be toxic or cause cancer in humans. The results of clinical trials and preclinical studies are uncertain and subject to different interpretations, and the design of these trials and studies (which may change significantly and be more expensive than anticipated depending on results and regulatory decisions) may also be viewed negatively by us, regulatory authorities or other third parties and adversely impact the development and opportunities for regulatory approval and commercialization of our drug candidates and those under collaborative agreements. We may not be successful in advancing our programs on our projected timetable, if at all. Failure to initiate or delays in the development programs for any of our drug candidates, or unfavorable results or decisions or negative perceptions regarding any of such programs, could cause our stock price to decline significantly. This is particularly the case with respect to lorcaserin.

We may report top-line data from time to time, which is based on a preliminary analysis of key efficacy and safety data, and is subject to change following a more comprehensive review of the data related to the applicable clinical trial.

***We have significant indebtedness and debt service obligations as a result of our Deerfield secured loan, which may adversely affect our cash flow, cash position and stock price.**

In July 2009, we received a \$100.0 million loan from Deerfield Private Design Fund, L.P., Deerfield Private Design International, L.P., Deerfield Partners, L.P., Deerfield International Limited, Deerfield Special Situations Fund, L.P., and Deerfield Special Situations Fund International Limited, or collectively Deerfield, which substantially increased our total debt and debt service obligations. This loan matures on June 17, 2013, and the outstanding principal accrues interest at a rate of 7.75% per annum on the stated principal balance, payable quarterly in arrears. Our agreement, or Facility Agreement, with Deerfield sets forth the following schedule of our remaining required principal repayments: \$20.0 million in July 2011, \$30.0 million in July 2012, and \$40 million at maturity. We may be required to make the scheduled repayments earlier in connection with certain equity issuances. For example, we were required to repay \$10.0 million, which was initially required to be repaid in July 2010, in connection with the closing of our July 2009 public offering. In addition, we are required to make mandatory prepayments of the loan upon certain changes of control and in the event we issue equity securities (other than certain exempted issuances) at a price of less than \$2.00 per share. The Facility Agreement also places certain restrictions on our business, including our ability to incur additional indebtedness and to undertake certain business transactions.

As part of our August 5, 2010 offering of common stock to Deerfield, we amended the Facility Agreement, pursuant to which (i) \$30.0 million of the proceeds from the stock issuance will be used to prepay the portion of the principal amount that we otherwise would have been required to repay in July 2012, and (ii) the \$20.0 million principal repayment currently required to be made in July 2011 will be deferred until June 17, 2013, provided that we receive FDA approval for lorcaserin by such July 2011 repayment date. The closing of the offering is expected to take place on or before August 10, 2010.

On or before June 17, 2011, Deerfield may elect to provide us with an additional loan in a principal amount of up to \$20.0 million under similar terms as the \$100.0 million loan, with the additional loan also maturing on June 17, 2013.

In the future, if we are unable to generate cash from operations sufficient to meet these debt obligations, we will need to obtain additional funds from other sources, which may include one or more financings. However, we may be unable to obtain sufficient additional funds when we need them on favorable terms or at all. The sale of equity or convertible debt securities in the future may be dilutive to our stockholders, and debt-financing arrangements may require us to enter into covenants that would further restrict certain business activities or our ability to incur additional indebtedness, and may contain other terms that are not favorable to our stockholders or us.

Also, if we are unable to generate cash from operations or obtain additional funds from other sources sufficient to meet these debt obligations, or we need to use existing cash to fund these debt obligations, we may have to delay or curtail some or all of our research, development and commercialization programs or sell or license some or all of our assets. Our indebtedness could have significant additional negative consequences, including, without limitation:

- increasing our vulnerability to general adverse economic conditions;
- limiting our ability to obtain additional funds; and

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- placing us at a possible competitive disadvantage to less leveraged competitors and competitors that have better access to capital resources.

If an event of default occurs under our loan documents, including in certain circumstances under the warrants issued in connection with the loan transaction, the lenders may declare the outstanding principal balance and accrued but unpaid interest owed to them immediately due and payable, which would have a material adverse affect on our financial position. We may not have sufficient cash to satisfy this obligation. Also, if a default occurs under our secured loan, and we are unable to repay the lenders, the lenders could

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seek to enforce their rights under their security interests in our assets. If this were to happen, we may lose or be forced to sell some or all of our assets to satisfy our debt, which could cause our business to fail.

***If we do not commercialize lorcaserin outside of the United States with one or more pharmaceutical companies or raise additional funds, we may have to commercialize lorcaserin outside of the United States on our own and curtail certain of our activities.**

We expect to commercialize lorcaserin outside of the United States, following regulatory approval, with one or more pharmaceutical companies or independently. We may not be able to enter into agreements to commercialize lorcaserin outside of the United States on acceptable terms, if at all. If we are unable to enter into such agreements, and we develop our own capabilities to commercialize lorcaserin outside of the United States, we may require additional capital to develop such capabilities and the marketing and sale of lorcaserin outside of the United States may be delayed or limited. Even if we were able to develop our own commercialization capabilities, we have not previously commercialized a drug, and our limited experience may make us less effective at marketing and selling lorcaserin than a pharmaceutical company. Our lack of corporate experience and adequate resources may impede our effort to successfully commercialize lorcaserin.

We face competition in our search for pharmaceutical companies to commercialize lorcaserin outside of the United States. In addition, if our competitors are able to establish commercialization arrangements with companies who have substantially greater resources than we have (or, with respect to commercializing lorcaserin in the United States, Eisai, has), our competitors may be more successful in marketing and selling their drugs, and our ability to successfully commercialize our drug candidates will be limited.

***Our drug candidates are subject to extensive regulation, and we may not receive required regulatory approvals, or timely approvals, for any of our drug candidates.**

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, marketing and distribution, and other possible activities relating to our drug candidates are, and any resulting drugs will be, subject to extensive regulation by the FDA and other regulatory agencies in the United States. Failure to comply with FDA and other applicable regulatory requirements may, either before or after product approval, if any, subject our company to administrative or judicially imposed sanctions.

Neither collaborators nor we are permitted to market our drug candidates in the United States until we receive regulatory approval from the FDA. Specific preclinical data, chemistry, manufacturing and controls data, a proposed clinical trial protocol and other information must be submitted to the FDA as part of an investigational new drug, or IND, application, and clinical trials may commence only after the IND application becomes effective. None of our drug candidates has received marketing approval. To market a new drug in the United States, we must submit to the FDA and obtain FDA approval of an NDA. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls to demonstrate the safety and effectiveness of the drug candidate.

Obtaining approval of an NDA can be a lengthy, expensive and uncertain process. As part of the Prescription Drug User Fee Act, or PDUFA, the FDA has a goal to review and act on a percentage of all submissions in a given time frame. The general review goal for a drug application is 10 months for a standard application and 6 months for priority review. The FDA's review goals are subject to change, and it is unknown whether the review of our NDA filing for lorcaserin, or an NDA filing for any of our other drug candidates, will be completed within the FDA's review goals or will be delayed. Moreover, the duration of the FDA's review may depend on the number and types of other NDAs that are submitted with the FDA around the same time period. We submitted our NDA for lorcaserin in December 2009, and the FDA has assigned an October 22, 2010 PDUFA date for their review of our NDA. VIVUS, Inc., and Orexigen Therapeutics, Inc., submitted NDAs with the FDA for drug candidates for the treatment of obesity in December 2009 and March 2010, respectively. The review of such NDAs may impact the review of our lorcaserin NDA. For example, on July 15, 2010, the FDA's Endocrinologic and Metabolic Drugs Advisory Committee recommended that the drug candidate sponsored by VIVUS, Inc. should not be approved by the FDA because of safety concerns. It is uncertain how this development will impact the FDA's review of our lorcaserin NDA. Furthermore, any drug that acts on the central nervous system, or CNS, such as lorcaserin, has the potential to be scheduled as a controlled substance by the DEA. DEA scheduling is an independent process that can delay drug launch beyond an NDA approval date.

Regulatory approval of an NDA or NDA supplement is not guaranteed. The number and types of preclinical studies and clinical trials that will be required for FDA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to target and the regulations applicable to any particular drug candidate. Despite the time and

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expense exerted in preclinical and clinical studies, failure can occur at any stage, and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional preclinical studies and clinical trials. The FDA can delay, limit or deny approval of a drug candidate for many reasons, including:

- a drug candidate may not be deemed adequately safe and effective;
- FDA officials may not find the data from preclinical studies and clinical trials sufficient;

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- the FDA's interpretation and our interpretation of data from preclinical studies and clinical trials may differ significantly;
- the FDA may not approve the manufacturing processes or facilities;
- the FDA may change its approval policies or adopt new regulations; or
- the FDA may not accept an NDA submission due to, among other reasons, the content or formatting of the submission.

With respect to lorcaserin, the FDA draft guidance document "Developing Products for Weight Management" dated February 2007 provides two alternate benchmarks for the development of drugs for the indication of weight management. The guidance provides that, in general, a product can be considered effective for weight management if after one year of treatment either of the following occurs: (1) the difference in mean weight loss between the active-product and placebo-treated groups is at least 5% and the difference is statistically significant, or (2) the proportion of patients who lose at least 5% of baseline body weight in the active-product group is at least 35%, is approximately double the proportion in the placebo-treated group, and the difference between groups is statistically significant. While we believe the results of our pivotal Phase 3 clinical trials of lorcaserin satisfy the latter of the two alternate efficacy benchmarks, the FDA may disagree with our view, not follow its draft guidance or impose other approval conditions that could delay or preclude approval of our lorcaserin NDA.

With the exception of our recently submitted lorcaserin NDA, we have not previously submitted NDAs to the FDA. This lack of corporate experience may impede our ability to obtain FDA approval in a timely manner, if at all, for lorcaserin or our other drug candidates for which development and commercialization is our responsibility. Even if we believe that data collected from our preclinical studies and clinical trials of our drug candidates are promising and that our information and procedures regarding chemistry, manufacturing and controls are sufficient, our data may not be sufficient to support approval by the FDA or any other US or foreign regulatory authority, or regulatory interpretation of these data and procedures may be unfavorable. In addition, we believe that the regulatory review of NDAs for drug candidates intended for widespread use by a large proportion of the general population is becoming increasingly focused on safety. In this regard, it is possible that some of our drug candidates, including lorcaserin, will be subject to increased scrutiny to show adequate safety than would drug candidates for more acute or life-threatening diseases such as cancer. Even if approved, drug candidates may not be approved for all indications requested and such approval may be subject to limitations on the indicated uses for which the drug may be marketed, restricted distribution methods or other limitations required by a Risk Evaluation and Mitigation Strategies, or REMS. Our business and reputation may be harmed by any failure or significant delay in receiving regulatory approval for the sale of any drugs resulting from our drug candidates. As a result, we cannot predict when or whether regulatory approval will be obtained for any drug we develop.

To market any drugs outside of the United States, we and current or future collaborators must comply with numerous and varying regulatory requirements of other countries. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks associated with FDA approval as well as additional risks, some of which may be unanticipated. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects associated with regulatory approval in the United States, including the risk that our drug candidates may not be approved for all indications requested and that such approval may be subject to limitations on the indicated uses for which the drug may be marketed.

***Even if any of our drug candidates receives regulatory approval, our drug candidates will still be subject to extensive post-marketing regulation.**

If we or collaborators receive regulatory approval for our drug candidates in the United States or other jurisdictions, we and our collaborators will also be subject to ongoing obligations and continued regulatory review from the FDA and other applicable regulatory agencies, such as continued adverse event reporting requirements. There may also be additional FDA post-marketing obligations, all of which may result in significant expense and limit the ability to commercialize such drugs in the United States or other jurisdictions.

If any of our drug candidates receive US regulatory approval or approval in other jurisdictions, the FDA or other regulatory agencies may also require that the sponsor of the NDA conduct additional clinical trials to further assess the drug after NDA

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approval under a post-approval commitment. Such additional studies may be costly and may impact the commercialization of the drug. The FDA or other regulatory agencies may also impose significant restrictions on the indicated uses for which such drug may be marketed.

If the FDA or other regulatory agencies approve any of our drug candidates, the labeling, packaging, adverse event reporting, storage, advertising and promotion for the drug will be subject to extensive regulatory requirements. We and the manufacturers of our products are also required to comply with current Good Manufacturing Practices, or cGMPs, regulations, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory agencies must approve these manufacturing facilities before they can be used to manufacture our products, and these facilities are

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subject to ongoing regulatory inspections. In addition, regulatory agencies subject a drug, its manufacturer and the manufacturer's facilities to continual review and inspections. The subsequent discovery of previously unknown problems with a drug, including adverse events of unanticipated severity or frequency, or problems with the facility where the drug is manufactured, may result in restrictions on the marketing of that drug, up to and including withdrawal of the drug from the market. In the United States, the DEA and comparable state-level agencies also heavily regulate the manufacturing, holding, processing, security, recordkeeping and distribution of drugs that are considered controlled substances. If any of our drug candidates are scheduled by the DEA as controlled substances (due to abuse potential), we will become subject to the DEA's regulations. The DEA periodically inspects facilities for compliance with its rules and regulations. If our manufacturing facilities or those of our suppliers fail to comply with applicable regulatory requirements, it could result in regulatory action and additional costs to us. Failure to comply with applicable FDA and other regulatory requirements may, either before or after product approval, if any, subject our company to administrative or judicially imposed sanctions, including:

- issuance of Form 483 notices or Warning Letters by the FDA or other regulatory agencies;
- imposition of fines and other civil penalties;
- criminal prosecutions;
- injunctions, suspensions or revocations of regulatory approvals;
- suspension of any ongoing clinical trials;
- total or partial suspension of manufacturing;
- delays in commercialization;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or collaborators;
- refusals to permit drugs to be imported into or exported from the United States;
- restrictions on operations, including costly new manufacturing requirements; and
- product recalls or seizures.

The FDA's and other regulatory agencies' policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our drug candidates or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we or our collaborators might not be permitted to market our drugs and our business could suffer.

***Even if we receive regulatory approval to commercialize our drug candidates, our ability to generate revenues from any resulting products will be subject to a variety of risks, many of which are out of our control.**

Even if our drug candidates obtain regulatory approval, resulting products may not gain market acceptance among physicians, patients, healthcare payers or the medical community. We believe that the degree of market acceptance and our ability to generate revenues from such products will depend on a number of factors, including:

- timing of market introduction of our drugs and competitive drugs;
- actual and perceived efficacy and safety of our drug candidates;
- prevalence and severity of any side effects;
- potential or perceived advantages or disadvantages over alternative treatments;
- strength of sales, marketing and distribution support;
- price of our future products, both in absolute terms and relative to alternative treatments;

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- the effect of current and future healthcare laws on our drug candidates;
- availability of coverage and reimbursement from government and other third-party payers; and
- product labeling or product insert requirements of the FDA or other regulatory authorities.

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If our approved drugs, if any, fail to achieve market acceptance, we may not be able to generate significant revenue to achieve or sustain profitability.

In addition, if lorcaserin is approved for marketing, regulatory authorities may determine that lorcaserin will be a scheduled drug if it is found to have abuse potential or for other reasons. Based on our interpretation of a formal abuse potential clinical trial we conducted, lorcaserin's clinical safety profile and certain other factors, we believe that lorcaserin has a limited abuse potential. If regulatory agencies disagree and lorcaserin were to be scheduled as a controlled substance by the DEA, we would expect it would be a schedule IV or V drug, which we believe would have little or no impact on our ability to commercialize lorcaserin. However, if lorcaserin were scheduled in a more tightly controlled category, such scheduling could negatively impact the ability to prescribe lorcaserin, a patient's willingness to use it and other aspects of our ability to commercialize it.

Our development and commercialization of lorcaserin may be adversely impacted by cardiovascular side effects previously associated with fenfluramine and dexfenfluramine.

We developed lorcaserin to more selectively stimulate the serotonin 2C receptor because we believe this may avoid the cardiovascular side effects associated with fenfluramine and dexfenfluramine (often used in combination with phentermine, the combination of which was commonly referred to as "fen-phen"). These two drugs were serotonin-releasing agents and non-selective serotonin receptor agonists, and were withdrawn from the market in 1997 after reported incidences of heart valve disease and pulmonary hypertension associated with their usage. We may not be correct in our belief that more selectively stimulating the serotonin 2C receptor will avoid these undesired side effects or lorcaserin's selectivity profile may not be adequate to avoid these side effects. Moreover, the potential relationship between the activity of lorcaserin and the activity of fenfluramine and dexfenfluramine may result in increased FDA regulatory scrutiny of the safety of lorcaserin and may raise potential adverse publicity in the marketplace, which could affect clinical enrollment or sales if lorcaserin is approved for commercialization. We have completed two large pivotal Phase 3 lorcaserin trials of one and two years' duration, both of which showed no apparent effects on heart valves or pulmonary artery pressures, but these results will need to be reviewed by the FDA.

The development programs for our drug candidates are expensive, time consuming, uncertain and susceptible to change, interruption, delay or termination.

Drug development programs are very expensive, time consuming and difficult to design and implement. Our drug candidates are in various stages of research and development and are prone to the risks of failure inherent in drug development. Clinical trials and preclinical studies are needed to demonstrate that drug candidates are safe and effective to the satisfaction of the FDA and similar non-US regulatory authorities. These trials are expensive and uncertain processes that take years to complete. Failure can occur at any stage of the process, and successful early clinical or preclinical trials do not ensure that later trials or studies will be successful. In addition, the commencement or completion of our planned clinical trials could be substantially delayed or prevented by several factors, including:

- limited number of, and competition for, suitable patients required for enrollment in our clinical trials;
- limited number of, and competition for, suitable sites to conduct our clinical trials;
- delay or failure to obtain FDA approval or agreement to commence a clinical trial;
- delay or failure to obtain sufficient supplies of our drug candidates for our clinical trials;
- delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or investigators; and
- delay or failure to obtain institutional review board, or IRB, approval to conduct a clinical trial at a prospective site.

Even if the results of our development programs are favorable, the development programs of our most advanced drug candidates, including those being developed by current or future collaborators, may take significantly longer than expected to complete. In addition, the FDA, other regulatory authorities, collaborators, or we may suspend, delay or terminate our development programs at any time for various reasons, including:

- lack of effectiveness of any drug candidate during clinical trials;

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- side effects experienced by study participants or other safety issues;
- slower than expected rates of patient recruitment and enrollment or lower than expected patient retention rates;
- delays or inability to manufacture or obtain sufficient quantities of materials for use in clinical trials;
- inadequacy of or changes in our manufacturing process or compound formulation;

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- delays in obtaining regulatory approvals to commence a study, or “clinical holds,” or delays requiring suspension or termination of a study by a regulatory authority, such as the FDA, after a study is commenced;
- changes in applicable regulatory policies and regulations;
- delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites;
- uncertainty regarding proper dosing;
- unfavorable results from ongoing clinical trials and preclinical studies;
- failure of our clinical research organizations to comply with all regulatory and contractual requirements or otherwise perform their services in a timely or acceptable manner;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to design appropriate clinical trial protocols;
- insufficient data to support regulatory approval;
- termination of clinical trials by one or more clinical trial sites;
- inability or unwillingness of medical investigators to follow our clinical protocols;
- difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data; or
- lack of sufficient funding to continue clinical trials and preclinical studies.

There is typically a high rate of attrition from the failure of drug candidates proceeding through clinical trials, and many companies have experienced significant setbacks in advanced development programs even after promising results in earlier studies or trials. We have experienced setbacks in our internal and partnered development programs and may experience additional setbacks in the future. If we or our collaborators abandon or are delayed in our development efforts related to lorcaserin or any other drug candidate, we may not be able to generate sufficient revenues to continue our operations at the current level or become profitable, our reputation in the industry and in the investment community would likely be significantly damaged, additional funding may not be available to us or may not be available on terms you or we believe are favorable, and our stock price would likely decrease significantly.

The results of preclinical studies and completed clinical trials are not necessarily predictive of future results, and our current drug candidates may not have favorable results in later studies or trials.

Preclinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of a drug candidate, but rather to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the drug candidate's side effects at various doses and schedules. To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our drug candidates, except lorcaserin. Favorable results in our early studies or trials may not be repeated in later studies or trials, including continuing preclinical studies and large-scale clinical trials, and our drug candidates in later-stage trials may fail to show desired safety and efficacy despite having progressed through earlier-stage trials. Unfavorable results from ongoing preclinical studies or clinical trials could result in delays, modifications or abandonment of ongoing or future clinical trials, or abandonment of a clinical program. Preclinical and clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated or terminated, or a clinical program to be abandoned.

Many of our research and development programs are in early stages of development, and may not result in the commencement of clinical trials.

Many of our research and development programs are in the discovery or preclinical stage of development. The process of discovering compounds with therapeutic potential is expensive, time consuming and unpredictable. Similarly, the process of conducting preclinical studies of compounds that we discover requires the commitment of a substantial amount of our technical and financial resources and personnel. We may not discover additional compounds with therapeutic potential, and

EXHIBIT AV

June 2, 2010

Arena Pharmaceuticals Announces Notification of Tentative September 16th FDA Advisory Committee Meeting to Review Lorcaserin for Weight Management

SAN DIEGO, June 2, 2010 /PRNewswire via COMTEX News Network/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) announced today that the US Food and Drug Administration (FDA) has notified the company of the tentative scheduling of an Endocrinologic and Metabolic Drugs Advisory Committee meeting on September 16, 2010, for the review of the lorcaserin New Drug Application (NDA). Lorcaserin is Arena's internally discovered and developed drug candidate for weight management, including weight loss and maintenance of weight loss, and it is intended for overweight patients with at least one weight-related co-morbid condition and obese patients.

"We are focused on obtaining the FDA's approval of lorcaserin, and have been preparing for this anticipated advisory committee meeting," said Jack Lief, Arena's President and Chief Executive Officer. "With its unique combination of safety, tolerability and efficacy, we believe that lorcaserin, if approved, has the potential to serve as first-line therapy to help patients achieve sustainable weight loss in a well-tolerated manner."

Arena submitted the lorcaserin NDA on December 22, 2009, and the FDA assigned a PDUFA date, the target date for the agency to complete its review of the application, of October 22, 2010. Confirmation and details of the meeting will be published in the Federal Register about six to eight weeks prior to the scheduled meeting date. The Federal Register notice will be available at the following website: <http://www.accessdata.fda.gov/scripts/oc/ohrms/index.cfm>.

Lorcaserin New Drug Application

The lorcaserin New Drug Application is based on a data package from lorcaserin's development program that includes 18 clinical trials totaling 8,576 patients. The pivotal Phase 3 clinical trial program, BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management) and BLOSSOM (Behavioral modification and Lorcaserin Second Study for Obesity Management), evaluated nearly 7,200 patients treated for up to two years. In both trials, lorcaserin produced statistically significant weight loss with excellent safety and tolerability.

About Lorcaserin

Lorcaserin is a novel single agent that represents the first in a new class of selective serotonin 2C receptor agonists. The serotonin 2C receptor is expressed in the brain, including the hypothalamus, an area involved in the control of appetite and metabolism. Stimulation of this receptor is strongly associated with feeding behavior and satiety. Arena has patents that cover lorcaserin in the US and other jurisdictions, which in most cases are capable of continuing into 2023 without taking into account any patent term extensions or other exclusivity Arena might obtain.

About Arena Pharmaceuticals

Arena is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing oral drugs that target G protein-coupled receptors, an important class of validated drug targets, in four major therapeutic areas: cardiovascular, central nervous system, inflammatory and metabolic diseases. Arena's most advanced drug candidate, lorcaserin, is intended for weight management, including weight loss and maintenance of weight loss, and has completed a pivotal Phase 3 clinical trial program. Arena has filed an NDA for lorcaserin, and the FDA has assigned a PDUFA date of October 22, 2010, for review of the application.

Arena Pharmaceuticals(R) and Arena(R) are registered service marks of the company. "APD" is an abbreviation for Arena Pharmaceuticals Development.

Forward-Looking Statements

Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include statements about the advancement, therapeutic indication and use, safety, efficacy, tolerability and regulatory review and approval of lorcaserin; the advisory committee for the review of the lorcaserin NDA; lorcaserin's commercial and other potential, including to serve as first-line therapy to help patients achieve sustainable weight loss in a well-tolerated manner; the timing for the FDA to complete its review of the lorcaserin NDA; availability of information in the Federal Register; lorcaserin's patent coverage; and Arena's focus, goals, strategy, research and development programs, and ability to develop compounds and commercialize drugs. For such statements, Arena claims the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from Arena's expectations. Factors that could cause actual results to differ materially from the forward-looking statements include, but are not limited to, regulatory authorities or advisors may not find data from Arena's clinical trials and other studies sufficient for regulatory approval; the timing and ability of Arena to receive regulatory approval for its drug candidates; the timing, success and cost of Arena's lorcaserin program and other of its research and development programs; results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results; clinical trials and other studies may not proceed at the time or in the manner Arena or others expect or at all; Arena's ability to enter into agreements to develop or commercialize its compounds or programs; Arena's ability to commercialize lorcaserin with a pharmaceutical company or independently; Arena's ability to obtain adequate funds; Arena's ability to obtain and defend its patents; and the timing and receipt of payments and fees, if any, from Arena's collaborators. Additional factors that could cause actual results to differ materially from those stated or implied by Arena's forward-looking statements are disclosed in Arena's filings with the Securities and Exchange Commission. These forward-looking statements represent Arena's judgment as of the time of this release. Arena disclaims any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

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Arena Pharmaceuticals Announces Notification of Tentative September 16th FDA Adviso... Page 2 of 2

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December 22, 2010

Arena and Eisai Complete End-of-Review Meeting with FDA for Lorcaserin New Drug Application

-- Meeting Provides Additional Clarity on Next Steps Toward Approval --

-- Arena to Host Conference Call and Webcast at 8:30 a.m. Eastern Time Today --

SAN DIEGO and WOODCLIFF LAKE, N.J., Dec. 22, 2010 /PRNewswire/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) and Eisai Inc. announced today the completion of an end-of-review meeting with the US Food and Drug Administration (FDA) for the lorcaserin New Drug Application (NDA).

"The meeting discussions reinforce our position that we have a path forward to seek FDA approval of lorcaserin," said Jack Lief, Arena's President and Chief Executive Officer. "Based on guidance we have received from the agency, we are executing several activities and expect to resubmit the lorcaserin NDA by the end of 2011. As we continue discussions with the FDA to refine elements of our plan, we may identify ways to shorten this timeline. We will provide more details about our plan on the conference call and webcast this morning."

Arena submitted an NDA for lorcaserin to the FDA in December 2009, and the FDA issued a Complete Response Letter (CRL) in October 2010. In the CRL, the FDA outlined non-clinical and clinical reasons for its decision and provided recommendations relating to addressing such issues. The end-of-review meeting with the FDA included a discussion of the FDA's position on issues identified in the CRL and Arena's plan to respond.

Conference Call & Webcast

Arena will host a conference call and webcast today, December 22, 2010, at 8:30 a.m. Eastern Time (5:30 a.m. Pacific Time) to discuss its plan to address the CRL and resubmit the lorcaserin NDA. The conference call may be accessed by dialing 877.643.7155 for domestic callers and 914.495.8552 for international callers. Please specify to the operator that you would like to join the "Lorcaserin" conference call. The conference call will be webcast live under the investor relations section of Arena's website at www.arenapharm.com, and will be archived there for 30 days following the call. Please connect to Arena's website several minutes prior to the start of the broadcast to ensure adequate time for any software download that may be necessary.

About Lorcaserin

Lorcaserin is intended for weight management, including weight loss and maintenance of weight loss, in patients who are obese (BMI ≥ 30) or patients who are overweight (BMI ≥ 27) and have at least one weight-related co-morbid condition. Lorcaserin is a new chemical entity that is believed to act as a selective serotonin 2C receptor agonist. The serotonin 2C receptor is expressed in the brain, including the hypothalamus, an area believed to be involved in the control of appetite and metabolism. Arena has patents that cover lorcaserin in the United States and other jurisdictions that in most cases are capable of continuing into 2023 without taking into account any patent term extensions or other exclusivity Arena might obtain.

About Arena Pharmaceuticals

Arena is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing oral drugs that target G protein-coupled receptors, an important class of validated drug targets, in four major therapeutic areas: cardiovascular, central nervous system, inflammatory and metabolic diseases. Arena's most advanced drug candidate, lorcaserin, is intended for weight management. Arena's wholly owned subsidiary, Arena Pharmaceuticals GmbH, has granted Eisai Inc. exclusive rights to market and distribute lorcaserin in the United States following FDA approval of the New Drug Application for lorcaserin.

Arena Pharmaceuticals(R) and Arena(R) are registered service marks of the company.

About Eisai Inc.

Eisai Inc. was established in 1995 and is ranked among the top-20 US pharmaceutical companies (based on retail sales). The company began marketing its first product in the United States in 1997 and has rapidly grown to become a fully integrated pharmaceutical business with fiscal year 2009 (year ended March 31, 2010) sales of approximately \$3.9 billion. Eisai's areas of commercial focus include neurology, gastrointestinal disorders and oncology/critical care. The company serves as the US pharmaceutical operation of Eisai Co., Ltd.

Eisai has a global product creation organization that includes US-based R&D facilities in Maryland, Massachusetts, New Jersey, North Carolina and Pennsylvania as well as manufacturing facilities in Maryland and North Carolina. The company's areas of R&D focus include neuroscience; oncology; vascular, inflammatory and immunological reaction; and antibody-based programs. For more information about Eisai, please visit www.eisai.com.

Forward-Looking Statements

Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include statements about discussions with the FDA and the results of such discussions; next steps and the path forward to seek FDA approval of lorcaserin; the potential resubmission of the lorcaserin NDA and the related timing; the potential FDA approval and commercialization of lorcaserin; the advancement, therapeutic indication and use, safety, efficacy, tolerability, and mechanism of action of lorcaserin; the Eisai collaboration and potential activities thereunder; lorcaserin's patent coverage; and Arena's focus, goals, strategy, research and development programs, and ability to develop compounds and commercialize drugs. For such statements, Arena claims the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from Arena's expectations. Factors that could cause actual results to differ materially from the forward-looking statements include, but are not limited to, the following: the risk that regulatory authorities may not find data and other information related to Arena's clinical trials and other studies meet safety or efficacy requirements or are otherwise sufficient for regulatory approval; the timing of regulatory review and approval is uncertain; Arena's response to the complete response letter for the lorcaserin NDA may not be submitted in a timely manner or the information provided in such response may not satisfy the FDA; the FDA may request other information prior to or after Arena resubmits the lorcaserin NDA or approval of the lorcaserin NDA; unexpected or unfavorable new data; risks related to commercializing new products; Arena's ability to obtain and defend its patents; the timing, success and cost of Arena's research and development programs; results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results; clinical trials and other studies may not proceed at the time or in the manner Arena or others expect or at all; Arena's ability to obtain adequate funds; risks related to relying on collaborative agreements; the timing and receipt of payments and fees, if any, from collaborators; and satisfactory resolution of pending and any future litigation or other disagreements with others. Additional factors that could cause actual results to differ materially from those stated or implied by Arena's forward-looking statements are disclosed in Arena's filings with the Securities and Exchange Commission. These forward-looking statements represent Arena's judgment as of the time of this release. Arena disclaims any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

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**U.S. District Court
Southern District of California (San Diego)
CIVIL DOCKET FOR CASE #: 3:10-cv-01959-CAB-BLM**

Schueneman v. Arena Pharmaceuticals, Inc. et al
Assigned to: Judge Cathy Ann Bencivengo
Referred to: Magistrate Judge Barbara Lynn Major
Case in other court: USCA, 14-55633
Cause: 15:77 Securities Fraud

Date Filed: 09/20/2010
Date Terminated: 03/21/2014
Jury Demand: Plaintiff
Nature of Suit: 850
Securities/Commodities
Jurisdiction: Federal Question

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*on behalf of himself and all others
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Date Filed	#	Docket Text
09/20/2010	1	COMPLAINT with Jury Demand against All Defendants (Filing fee \$ 350 receipt number 18187.), filed by Todd Schueneman.(cge) (cap). (Entered: 09/21/2010)
09/20/2010	2	Summons Issued as to All Defendants. (jer) (Entered: 09/21/2010)
09/20/2010	3	NOTICE of Party With Financial Interest by Todd Schueneman. (jer) (Entered: 09/21/2010)
09/22/2010	4	Joint MOTION Regarding Response to Class Action Complaint by Christy Anderson, Arena Pharmaceuticals, Inc., Dominic P. Behan, Robert E. Hoffman, Jack Lief, William R. Shanahan. (Attachments: # 1 Proof of Service)(Blair, Ryan) Modified on 9/23/2010 to correct event and clarify text (mjj) (Entered: 09/22/2010)
09/23/2010	5	ORDER Granting 4 Joint Motion Re: Response to Class Action Complaint. Signed by Judge M. James Lorenz on 9/23/2010. (mjj) (jrl). (Entered: 09/23/2010)
10/07/2010	6	NOTICE of Appearance by Mary Kathryn Kelley on behalf of Christy Anderson, Arena Pharmaceuticals, Inc., Dominic P. Behan, Robert E. Hoffman, Jack Lief, William R. Shanahan (Attachments: # 1 Proof of Service)(Kelley, Mary) (mjj) (Entered: 10/07/2010)
10/07/2010	7	NOTICE of Appearance by Peter M Adams on behalf of Christy Anderson, Arena Pharmaceuticals, Inc., Dominic P. Behan, Robert E. Hoffman, Jack Lief, William R. Shanahan (Attachments: # 1 Proof of Service)(Adams, Peter) (mjj) (Entered: 10/07/2010)
10/07/2010	8	NOTICE of Appearance by William E Grauer on behalf of Christy Anderson, Arena Pharmaceuticals, Inc., Dominic P. Behan, Robert E. Hoffman, Jack Lief, William R. Shanahan (Attachments: # 1 Proof of Service)(Grauer, William) (mjj) (Entered: 10/07/2010)
10/15/2010	9	Minute Order. Judge Judge M. James Lorenz recuses from this case and requests another district judge be assigned. Judge Barry Ted Moskowitz randomly assigned. The new case number is 10CV1959-BTM(BLM).(mtb) (Entered: 10/15/2010)
10/27/2010	10	ORDER Granting 4 Joint MOTION Regarding Response to Class Action Complaint filed. Signed by Judge Barry Ted Moskowitz on 10/21/2010.(jer) (jrl). (Entered: 10/27/2010)
11/15/2010	11	WAIVER OF SERVICE Returned Executed by Todd Schueneman. All Defendants. (King, Laurence) (jer). (Entered: 11/15/2010)
11/19/2010	12	MOTION to Appoint Counsel, MOTION to Consolidate Cases, MOTION for Lead Plaintiff by Chris Georgakopoulos, Larry Sprowl. (Attachments: # 1 Memo of Points and Authorities, # 2 Declaration of Blake Muir Harper, # 3 Proof of Service)(Harper, Blake)(jer). (Entered: 11/19/2010)
11/19/2010	13	NOTICE of Appearance by Sarah Weber on behalf of Chris Georgakopoulos, Larry Sprowl (Weber, Sarah)(jer). (Entered: 11/19/2010)
11/19/2010	14	DOCUMENT WITHDRAWN, per 27 - MOTION to Appoint Counsel <i>Notice of Motion and Motion to Appoint Lead Plaintiffs and Lead and Liaison Counsel</i> by William Sutliff, Jean Sutliff, Maxat Amankossov, David Prince. (Attachments: # 1

		Memo of Points and Authorities, # 2 Declaration, # 3 Proof of Service)(Mogin, Daniel)(jer). Modified on 1/4/2011 to note document was withdrawn; termed motion (jer). (Entered: 11/19/2010)
11/19/2010	15	MOTION to Consolidate Cases <i>Arena Investors Groups Notice Of Motion And Motion For Consolidation, Appointment As Lead Plaintiff, And Approval Of Its Selection Of Lead Counsel</i> by Arena Investors Group. (Attachments: # 1 Memo of Points and Authorities Memorandum Of Points And Authorities In Support Of The Arena Investors Groups Notice Of Motion And Motion For Consolidation, Appointment As Lead Plaintiff, And Approval Of Its Selection Of Lead Counsel, # 2 Declaration Declaration Of Richard M. Heimann In Support Of The Arena Investors Groups Motion For Consolidation, Appointment As Lead Plaintiff, And Approval Of Selection Of Lead Counsel, and Exhibits, # 3 Proof of Service)(Heimann, Richard) (jer). (Entered: 11/19/2010)
11/19/2010	16	MOTION to Appoint Counsel, MOTION to Consolidate Cases <i>and Appointment as Lead Plaintiff</i> by Anthony Caravella. (Attachments: # 1 Memo of Points and Authorities in Support of the Motion of Antony Caravella, # 2 Declaration of Aaron M. Sheanin)(Sheanin, Aaron) (jer). (Entered: 11/19/2010)
11/19/2010	17	MOTION to Consolidate Cases <i>and Appoint Lead Plaintiff and Lead Counsel</i> by Ford L. Williams. (Attachments: # 1 Memo of Points and Authorities, # 2 Declaration, # 3 Exhibit A, # 4 Exhibit B, # 5 Exhibit C, # 6 Exhibit D, # 7 Exhibit E)(Peterson, Erik) (jer). (Entered: 11/19/2010)
11/19/2010	18	MOTION to Appoint Counsel <i>Kaplan Fox & Kilsheimer LLP</i> , MOTION to Consolidate Cases, MOTION to Appoint <i>Carl Schwartz as Lead Plaintiff</i> by Carl Schwartz. (Attachments: # 1 Memo of Points and Authorities, # 2 Declaration Part 1 of 3, # 3 Declaration Part 2 of 3, # 4 Declaration Part 3 of 3, # 5 Proof of Service) (King, Laurence) (jer). (Entered: 11/19/2010)
11/19/2010	19	MOTION to Appoint Counsel <i>and Lead Plaintiff</i> , MOTION to Consolidate Cases by John Lee. (Attachments: # 1 Memo of Points and Authorities, # 2 Declaration) (Rosen, Laurence) (jer). (Entered: 11/19/2010)
11/19/2010	20	MOTION to Consolidate Cases , <i>for Appointment as Lead Plaintiff</i> , MOTION to Appoint Counsel by Babak Ghayour. (Attachments: # 1 Memo of Points and Authorities, # 2 Declaration of Brian O. O'Mara, # 3 Exhibit A to the O'Mara Decl., # 4 Exhibit B to the O'Mara Decl., # 5 Exhibit C to the O'Mara Decl., # 6 Exhibit D to the O'Mara Decl., # 7 Exhibit E to the O'Mara Decl., # 8 Exhibit F to the O'Mara Decl., # 9 Exhibit G to the O'Mara Decl., # 10 Exhibit H to the O'Mara Decl.) (O'Mara, Brian)(jer). (Entered: 11/19/2010)
12/30/2010	21	RESPONSE in Support re 17 MOTION to Consolidate Cases <i>and Appoint Lead Plaintiff and Lead Counsel</i> filed by Ford L. Williams. (Abadou, Ramzi) (jer). (Entered: 12/30/2010)
12/30/2010	22	RESPONSE to Motion re 17 MOTION to Consolidate Cases <i>and Appoint Lead Plaintiff and Lead Counsel</i> , 19 MOTION to Appoint Counsel <i>and Lead Plaintiff</i> MOTION to Consolidate Cases, 15 MOTION to Consolidate Cases <i>Arena Investors Groups Notice Of Motion And Motion For Consolidation, Appointment As Lead Plaintiff, And Approval Of Its Selection Of Lead Counsel</i> , 12 MOTION to Appoint Counsel MOTION to Consolidate Cases MOTION for Lead Plaintiff, 18 MOTION to Appoint Counsel <i>Kaplan Fox & Kilsheimer LLP</i> MOTION to Consolidate Cases

		MOTION to Appoint Carl Schwartz as Lead Plaintiff, 20 MOTION to Consolidate Cases ,for Appointment as Lead Plaintiff MOTION to Appoint Counsel, 14 MOTION to Appoint Counsel Notice of Motion and Motion to Appoint Lead Plaintiffs and Lead and Liaison Counsel, 16 MOTION to Appoint Counsel MOTION to Consolidate Cases and Appointment as Lead Plaintiff filed by John Lee. (Rosen, Laurence) (jer). (Entered: 12/30/2010)
12/30/2010	23	NON Opposition re 17 MOTION to Consolidate Cases and Appoint Lead Plaintiff and Lead Counsel, 19 MOTION to Appoint Counsel and Lead Plaintiff MOTION to Consolidate Cases, 18 MOTION to Appoint Counsel Kaplan Fox & Kilsheimer LLP MOTION to Consolidate Cases MOTION to Appoint Carl Schwartz as Lead Plaintiff, 20 MOTION to Consolidate Cases ,for Appointment as Lead Plaintiff MOTION to Appoint Counsel, 14 MOTION to Appoint Counsel Notice of Motion and Motion to Appoint Lead Plaintiffs and Lead and Liaison Counsel filed by Arena Investors Group. (Attachments: # 1 Proof of Service)(Heimann, Richard) (jer). (Entered: 12/30/2010)
12/30/2010	24	RESPONSE to Motion re 17 MOTION to Consolidate Cases and Appoint Lead Plaintiff and Lead Counsel, 19 MOTION to Appoint Counsel and Lead Plaintiff MOTION to Consolidate Cases, 15 MOTION to Consolidate Cases Arena Investors Groups Notice Of Motion And Motion For Consolidation, Appointment As Lead Plaintiff, And Approval Of Its Selection Of Lead Counsel, 12 MOTION to Appoint Counsel MOTION to Consolidate Cases MOTION for Lead Plaintiff, 18 MOTION to Appoint Counsel Kaplan Fox & Kilsheimer LLP MOTION to Consolidate Cases MOTION to Appoint Carl Schwartz as Lead Plaintiff, 20 MOTION to Consolidate Cases ,for Appointment as Lead Plaintiff MOTION to Appoint Counsel, 14 MOTION to Appoint Counsel Notice of Motion and Motion to Appoint Lead Plaintiffs and Lead and Liaison Counsel, 16 MOTION to Appoint Counsel MOTION to Consolidate Cases and Appointment as Lead Plaintiff Defendants' Statement in Response to Movants' Motions to Consolidate Related Cases, To Appoint Lead Plaintiff and Counsel for Lead Plaintiff filed by Christy Anderson, Arena Pharmaceuticals, Inc., Dominic P. Behan, Robert E. Hoffman, Jack Lief, William R. Shanahan. (Attachments: # 1 Proof of Service)(Grauer, William) (jer). (Entered: 12/30/2010)
12/30/2010	25	RESPONSE in Opposition re 17 MOTION to Consolidate Cases and Appoint Lead Plaintiff and Lead Counsel, 15 MOTION to Consolidate Cases Arena Investors Groups Notice Of Motion And Motion For Consolidation, Appointment As Lead Plaintiff, And Approval Of Its Selection Of Lead Counsel, 12 MOTION to Appoint Counsel MOTION to Consolidate Cases MOTION for Lead Plaintiff, 18 MOTION to Appoint Counsel Kaplan Fox & Kilsheimer LLP MOTION to Consolidate Cases MOTION to Appoint Carl Schwartz as Lead Plaintiff, 16 MOTION to Appoint Counsel MOTION to Consolidate Cases and Appointment as Lead Plaintiff, 19 MOTION to Appoint Counsel and Lead Plaintiff MOTION to Consolidate Cases, 14 MOTION to Appoint Counsel Notice of Motion and Motion to Appoint Lead Plaintiffs and Lead and Liaison Counsel filed by Babak Ghayour. (Attachments: # 1 Declaration of Brian O. O'Mara in Opposition to Competing Motions, # 2 Exhibit 1 to O'Mara Opp. Decl., # 3 Exhibit 2 to O'Mara Opp. Decl., # 4 Exhibit 3 to O'Mara Opp. Decl., # 5 Exhibit 4 to O'Mara Opp Decl., # 6 Exhibit 5 to O'Mara Opp. Decl., # 7 Exhibit 6 to O'Mara Opp. Decl., # 8 Exhibit 7 to O'Mara Opp. Decl.)(O'Mara, Brian) (jer). (Entered: 12/30/2010)

12/30/2010	<u>26</u>	RESPONSE in Opposition re <u>17</u> MOTION to Consolidate Cases <i>and Appoint Lead Plaintiff and Lead Counsel</i> , <u>19</u> MOTION to Appoint Counsel <i>and Lead Plaintiff</i> MOTION to Consolidate Cases, <u>15</u> MOTION to Consolidate Cases <i>Arena Investors Groups Notice Of Motion And Motion For Consolidation, Appointment As Lead Plaintiff, And Approval Of Its Selection Of Lead Counsel</i> , <u>12</u> MOTION to Appoint Counsel MOTION to Consolidate Cases MOTION for Lead Plaintiff, <u>20</u> MOTION to Consolidate Cases , <i>for Appointment as Lead Plaintiff</i> MOTION to Appoint Counsel, <u>14</u> MOTION to Appoint Counsel <i>Notice of Motion and Motion to Appoint Lead Plaintiffs and Lead and Liaison Counsel</i> , <u>16</u> MOTION to Appoint Counsel MOTION to Consolidate Cases <i>and Appointment as Lead Plaintiff</i> filed by Carl Schwartz. (King, Laurence) (jer). (Entered: 12/30/2010)
01/04/2011	<u>27</u>	NOTICE of Withdrawal of <u>14</u> Motion for Lead Counsel by Maxat Amankossov, David Prince, Jean Sutliff, William Sutliff (Mogin, Daniel) edited text; wrong case number in caption(jer). (Entered: 01/04/2011)
01/07/2011	<u>28</u>	REPLY to Response to Motion re <u>20</u> MOTION to Consolidate Cases , <i>for Appointment as Lead Plaintiff</i> MOTION to Appoint Counsel filed by Babak Ghayour. (Attachments: # <u>1</u> Exhibit A)(O'Mara, Brian) (jer). (Entered: 01/07/2011)
01/07/2011	<u>29</u>	REPLY to Response to Motion re <u>17</u> MOTION to Consolidate Cases <i>and Appoint Lead Plaintiff and Lead Counsel</i> , <u>19</u> MOTION to Appoint Counsel <i>and Lead Plaintiff</i> MOTION to Consolidate Cases, <u>15</u> MOTION to Consolidate Cases <i>Arena Investors Groups Notice Of Motion And Motion For Consolidation, Appointment As Lead Plaintiff, And Approval Of Its Selection Of Lead Counsel</i> , <u>18</u> MOTION to Appoint Counsel <i>Kaplan Fox & Kilsheimer LLP</i> MOTION to Consolidate Cases MOTION to Appoint Carl Schwartz as Lead Plaintiff, <u>20</u> MOTION to Consolidate Cases , <i>for Appointment as Lead Plaintiff</i> MOTION to Appoint Counsel, <u>16</u> MOTION to Appoint Counsel MOTION to Consolidate Cases <i>and Appointment as Lead Plaintiff</i> filed by Carl Schwartz. (Attachments: # <u>1</u> Declaration of Laurence D. King)(King, Laurence) (jer). (Entered: 01/07/2011)
01/18/2011	<u>30</u>	NOTICE by Babak Ghayour re <u>20</u> MOTION to Consolidate Cases , <i>for Appointment as Lead Plaintiff</i> MOTION to Appoint Counsel <i>Notice of Recent Supplemental Authority</i> (Attachments: # <u>1</u> Exhibit A)(O'Mara, Brian) (jer). (Entered: 01/18/2011)
01/19/2011	<u>31</u>	RESPONSE re <u>30</u> <i>Notice of Recent Supplemental Authority</i> filed by Babak Ghayour filed by Carl Schwartz. (King, Laurence) (jer). (Entered: 01/19/2011)
08/03/2011	<u>32</u>	NOTICE of Change of Address by Laurence M. Rosen (Rosen, Laurence) (ecs). (Entered: 08/03/2011)
08/08/2011	<u>33</u>	ORDER GRANTING <u>12</u> , <u>15</u> , <u>16</u> , <u>17</u> , <u>18</u> , <u>19</u> , <u>20</u> motions to consolidate the Class Actions and DENIES Defendants(10cv2111 - doc #23) motion to consolidate the Sharp action. The Court GRANTS Schwartzs <u>18</u> motion for appointment as lead plaintiff and approval of lead counsel and DENIES the competing motions. Signed by Judge Barry Ted Moskowitz on 8/8/2011. (mtb)(jrd) (Entered: 08/08/2011)
08/12/2011	<u>34</u>	ORDER Setting Telephonic Case Management Conference. The Court will conduct a telephonic, attorneys-only Case Management Conference on August 31, 2011 at 9:30 a.m. to discuss the status of the consolidated cases. The Court will initiate the conference call. Signed by Magistrate Judge Barbara Lynn Major on 8/12/11. (ecs) (jrd) (Entered: 08/12/2011)

08/12/2011	<u>35</u>	NOTICE of Voluntary Dismissal by Jean Sutliff, William Sutliff (Mogin, Daniel) (knh). (Entered: 08/12/2011)
08/17/2011	<u>36</u>	NOTICE by Jean Sutliff, William Sutliff re <u>35</u> Notice of Voluntary Dismissal <i>Notice of Withdrawal of Document</i> (Mogin, Daniel) (ecs). (Entered: 08/17/2011)
08/18/2011	<u>37</u>	Joint MOTION for Extension of Time to File <i>Setting Schedule for Filing of and Responding to Consolidated Complaint</i> by Christy Anderson, Arena Pharmaceuticals, Inc., Dominic P. Behan, Robert E. Hoffman, Jack Lief, William R. Shanahan. (Attachments: # <u>1</u> Proof of Service)(Blair, Ryan) (ecs). (Entered: 08/18/2011)
08/22/2011	<u>38</u>	ORDER Granting <u>37</u> Joint Motion Setting Schedule for Filing of and Responding to Consolidated Complaint. Signed by Judge Barry Ted Moskowitz on 8/22/11. (ecs) (jrd) (Entered: 08/22/2011)
08/23/2011	<u>39</u>	PRO HAC VICE APPLICATION AND ORDER: Attorney Jeffrey P. Campisi appearing for Movant Carl Schwartz. Signed by Judge Barry Ted Moskowitz on 8/22/2011. (aef)(jrd) (Entered: 08/24/2011)
08/23/2011	<u>40</u>	PRO HAC VICE APPLICATION AND ORDER: Attorney Robert N. Kaplan appearing for Movant Carl Schwartz. Signed by Judge Barry Ted Moskowitz on 8/22/2011. (All non-registered users served via U.S. Mail Service)(aef)(jrd) (Entered: 08/24/2011)
08/23/2011	<u>41</u>	ORDER vacating Telephonic Case Management Conference scheduled for 8/31/2011. Signed by Magistrate Judge Barbara Lynn Major on 8/23/2011. (All non-registered users served via U.S. Mail Service)(aef)(jrd) (Entered: 08/24/2011)
08/29/2011	<u>42</u>	NOTICE of Appearance by Robert N Kaplan on behalf of Carl Schwartz (Kaplan, Robert) (ecs). (Entered: 08/29/2011)
11/01/2011	<u>43</u>	AMENDED COMPLAINT with Jury Demand against Christy Anderson, Arena Pharmaceuticals, Inc., Dominic P. Behan, Robert E. Hoffman, Jack Lief, William R. Shanahan, filed by Carl Schwartz. (King, Laurence) (ecs). (Entered: 11/01/2011)
12/30/2011	<u>44</u>	MOTION to Dismiss <i>Consolidated Amended Class Action Complaint</i> by Christy Anderson, Arena Pharmaceuticals, Inc., Dominic P. Behan, Robert E. Hoffman, Jack Lief, William R. Shanahan. (Attachments: # <u>1</u> Memo of Points and Authorities, # <u>2</u> Request for Judicial Notice, # <u>3</u> Declaration of Ryan E. Blair, # <u>4</u> Exhibit A-G, # <u>5</u> Exhibit H-P, # <u>6</u> Exhibit Q-U, # <u>7</u> Exhibit V-W, # <u>8</u> Exhibit X-AC, # <u>9</u> Exhibit AD-AL, # <u>10</u> Exhibit AM-AS, # <u>11</u> Exhibit AT-AW, # <u>12</u> Proof of Service)(Blair, Ryan) (ecs). (Entered: 12/30/2011)
12/30/2011	<u>45</u>	NOTICE by Christy Anderson, Arena Pharmaceuticals, Inc., Dominic P. Behan, Robert E. Hoffman, Jack Lief, William R. Shanahan re <u>44</u> MOTION to Dismiss <i>Consolidated Amended Class Action Complaint Amended Notice of Motion and Motion to Dismiss Consolidated Amended Class Action Complaint</i> (Attachments: # <u>1</u> Proof of Service)(Grauer, William) (ecs). Modified on 9/5/2012 to term document (Notice) (nsp). (Entered: 12/30/2011)
01/11/2012	<u>46</u>	NOTICE by Christy Anderson, Arena Pharmaceuticals, Inc., Dominic P. Behan, Robert E. Hoffman, Jack Lief, William R. Shanahan re <u>44</u> MOTION to Dismiss <i>Consolidated Amended Class Action Complaint Supplemental Notice of Regulatory Action by U.S. Food and Drug Administration in Support of Motion to Dismiss</i>

		<i>Consolidated Amended Class Action Complaint</i> (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Proof of Service)(Grauer, William) (ecs). (Entered: 01/11/2012)
02/14/2012	47	MOTION to Strike <i>Documents Extraneous to the Consolidated Amended Class Action Complaint</i> by Carl Schwartz. (Attachments: # 1 Memo of Points and Authorities)(King, Laurence) (ecs). (Entered: 02/14/2012)
02/14/2012	48	RESPONSE in Opposition re 44 MOTION to Dismiss <i>Consolidated Amended Class Action Complaint</i> filed by Carl Schwartz. (King, Laurence) (ecs). (Entered: 02/14/2012)
02/15/2012	49	NOTICE of Appearance by Mario Man-Lung Choi on behalf of Carl Schwartz (Choi, Mario) (ecs). (Entered: 02/15/2012)
02/22/2012	50	TRANSFER ORDER: This consolidated case is transferred from the calendar of the Hon. Barry Ted Moskowitz to the calendar of the Hon. Cathy Ann Bencivengo. All motion hearing dates and other hearing dates on Judge Moskowitz's calendar are hereby Vacated to be reset by Judge Bencivengo. The new case numbers are 10-cv-1959-CAB-BLM, 10-cv-01977-CAB-BLM, 10-cv-01984-CAB-BLM, 10-cv-02026-CAB-BLM, 10-cv-02086-CAB-BLM and 10-cv-02335-CAB-BLM. Signed by Judge Barry Ted Moskowitz on 2/22/12.(All non-registered users served via U.S. Mail Service)(ecs)(jrd) Modified on 7/11/2012 to add consolidated case numbers (tel). (Entered: 02/22/2012)
02/27/2012		Minute Entry for proceedings held before Judge Cathy Ann Bencivengo: Set/Reset Deadlines as to 47 MOTION to Strike <i>Documents Extraneous to the Consolidated Amended Class Action Complaint</i> , 45 MOTION to Dismiss. Motion Hearing set for 4/13/2012 01:30 PM before Judge Cathy Ann Bencivengo. No oral argument unless requested by the Court. (ma) (Entered: 02/27/2012)
03/15/2012	51	RESPONSE in Support re 44 MOTION to Dismiss <i>Consolidated Amended Class Action Complaint</i> filed by Christy Anderson, Arena Pharmaceuticals, Inc., Dominic P. Behan, Robert E. Hoffman, Jack Lief, William R. Shanahan. (Attachments: # 1 Request for Judicial Notice (Supplemental), # 2 Declaration of Ryan E. Blair ISO Motion, # 3 Exhibit AX/AY to Declaration, # 4 Proof of Service)(Grauer, William) (yeb). (Entered: 03/15/2012)
03/15/2012	52	RESPONSE in Opposition re 47 MOTION to Strike <i>Documents Extraneous to the Consolidated Amended Class Action Complaint</i> filed by Christy Anderson, Arena Pharmaceuticals, Inc., Dominic P. Behan, Robert E. Hoffman, Jack Lief, William R. Shanahan. (Attachments: # 1 Proof of Service)(Grauer, William)(yeb). (Entered: 03/15/2012)
04/06/2012	53	REPLY to Response to Motion re 47 MOTION to Strike <i>Documents Extraneous to the Consolidated Amended Class Action Complaint</i> filed by Carl Schwartz. (King, Laurence)(yeb). (Entered: 04/06/2012)
10/09/2012	54	NOTICE by Christy Anderson, Arena Pharmaceuticals, Inc., Dominic P. Behan, Robert E. Hoffman, Jack Lief, William R. Shanahan re 44 MOTION to Dismiss <i>Consolidated Amended Class Action Complaint Supplemental Notice of Regulatory Action by U.S. Food and Drug Administration and Notice of Supplemental Authority in Support of Motion to Dismiss Consolidated Amended Class Action Complaint</i> (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Proof of Service)

		(Grauer, William)(yeb). (Entered: 10/09/2012)
10/11/2012	55	RESPONSE re 54 Notice (Other) <i>Lead Plaintiff's Response to Defendants' Supplemental Notice of Regulatory Action by the U.S. Food and Drug Administration and Notice of Supplemental Authority</i> filed by Carl Schwartz. (King, Laurence)(yeb). (Entered: 10/11/2012)
03/28/2013	56	ORDER granting 44 and 45 Motion to Dismiss without prejudice to Plaintiff filing an amended complaint on or before April 25, 2013 and denying 47 Motion to Strike as moot. Signed by Judge Cathy Ann Bencivengo on 03/28/2013. (All non-registered users served via U.S. Mail Service)(yeb) (Entered: 03/29/2013)
04/04/2013	57	Joint MOTION for Briefing Schedule <i>for Filing of a Second Consolidated Amended Complaint and Response Thereto</i> by Christy Anderson, Arena Pharmaceuticals, Inc., Dominic P. Behan, Robert E. Hoffman, Jack Lief, William R. Shanahan. (Attachments: # 1 Proof of Service)(Blair, Ryan) (knb). (Entered: 04/04/2013)
04/08/2013	58	ORDER Granting In Part 57 Joint Motion For Briefing Schedule For Filing an Amended Complaint and Response Thereto. Lead Plaintiff shall file an amended complaint on or before May 13, 2013. Signed by Judge Cathy Ann Bencivengo on 04/08/2013. (All non-registered users served via U.S. Mail Service)(yeb)(jrd) (Entered: 04/08/2013)
05/13/2013	59	SECOND AMENDED COMPLAINT with Jury Demand [<i>Second Amended</i>] against Christy Anderson, Arena Pharmaceuticals, Inc., Dominic P. Behan, Robert E. Hoffman, Jack Lief, William R. Shanahan, filed by Carl Schwartz. (King, Laurence) (yeb). (Entered: 05/13/2013)
06/14/2013	60	MOTION to Dismiss <i>Second Consolidated Amended Class Action Complaint</i> by Christy Anderson, Arena Pharmaceuticals, Inc., Dominic P. Behan, Robert E. Hoffman, Jack Lief, William R. Shanahan. (Attachments: # 1 Memo of Points and Authorities, # 2 Second Supplemental RJN, # 3 Second Supplemental Blair Decl, # 4 Exhibits AZ-BE, # 5 Proof of Service)(Grauer, William)(yeb). (Entered: 06/14/2013)
07/15/2013	61	RESPONSE in Opposition re 60 MOTION to Dismiss <i>Second Consolidated Amended Class Action Complaint</i> filed by Carl Schwartz. (Attachments: # 1 Declaration of Laurence D. King in Opposition to Motion to Dismiss, # 2 Exhibit A, # 3 Exhibit B, # 4 Exhibit C, # 5 Exhibit D, # 6 Exhibit E, # 7 Exhibit F, # 8 Exhibit G, # 9 Exhibit H, # 10 Exhibit I, # 11 Exhibit J, # 12 Exhibit K, # 13 Exhibit L) (King, Laurence) (yeb). (Entered: 07/15/2013)
07/15/2013	62	MOTION to Strike 60 MOTION to Dismiss <i>Second Consolidated Amended Class Action Complaint Motion to Strike Documents Extraneous to the Second Consolidated Amended Class Action Complaint</i> by Carl Schwartz. (Attachments: # 1 Memo of Points and Authorities, # 2 Proof of Service)(King, Laurence) (yeb). (Entered: 07/15/2013)
07/29/2013	63	RESPONSE in Opposition re 62 MOTION to Strike 60 MOTION to Dismiss <i>Second Consolidated Amended Class Action Complaint Motion to Strike Documents Extraneous to the Second Consolidated Amended Class Action Complaint</i> filed by Christy Anderson, Arena Pharmaceuticals, Inc., Dominic P. Behan, Robert E. Hoffman, Jack Lief, William R. Shanahan. (Attachments: # 1 Proof of Service) (Grauer, William) (yeb). (Entered: 07/29/2013)

07/29/2013	64	REPLY to Response to Motion re 60 MOTION to Dismiss <i>Second Consolidated Amended Class Action Complaint</i> filed by Christy Anderson, Arena Pharmaceuticals, Inc., Dominic P. Behan, Robert E. Hoffman, Jack Lief, William R. Shanahan. (Attachments: # 1 Proof of Service)(Grauer, William) (yeb). (Entered: 07/29/2013)
07/30/2013	65	MINUTE ORDER: The August 2, 2013 hearing on Defendant's Motion to Dismiss the Second Consolidated Amended Class Action Complaint [Doc. No. 60] and Plaintiff's Motion to Strike Documents Extraneous to the Second Consolidated Amended Class Action Complaint [Doc. No. 62] is hereby continued. No appearances are required in these matters on August 2, 2013. The Court will reset the hearing date in these matters by the end of the week.(All non-registered users served via U.S. Mail Service)(yeb)(jrd) (Entered: 07/30/2013)
07/30/2013	66	MINUTE ORDER: The hearing on Defendants Motion to Dismiss the Second Consolidated Amended Class Action Complaint [Doc. No. 60] and Plaintiffs Motion to Strike Documents Extraneous to the Second Consolidated Amended Class Action Complaint [Doc. No. 62] is hereby reset for October 25, 2013 at 2:30 p.m. in Courtroom 4C.(All non-registered users served via U.S. Mail Service)(yeb) (Entered: 07/30/2013)
10/18/2013	67	REPLY to Response to Motion re 62 MOTION to Strike 60 MOTION to Dismiss <i>Second Consolidated Amended Class Action Complaint Motion to Strike Documents Extraneous to the Second Consolidated Amended Class Action Complaint</i> filed by Todd Schueneman. (Attachments: # 1 Declaration)(King, Laurence) (yeb). (Entered: 10/18/2013)
10/22/2013	68	MINUTE ORDER: The Court hereby confirms that the October 25, 2013 hearing in this matter shall go forward as scheduled, [see Doc. No. 66]. The Court does not have a tentative decision for the parties. However, the Court directs the parties to focus their arguments on the sufficiency of the second amended complaint, [Doc. No. 59], with respect to the time period of March 12, 2009 through January 27, 2011.(All non-registered users served via U.S. Mail Service)(yeb) (Entered: 10/22/2013)
10/25/2013	69	Minute Order for proceedings held before Judge Cathy Ann Bencivengo: Motion Hearing held on 10/25/2013. Submitting 62 MOTION to Strike 60 MOTION to Dismiss <i>Second Consolidated Amended Class Action Complaint Motion to Strike Documents Extraneous to the Second Consolidated Amended Class Action Complaint</i> filed by Carl Schwartz, 60 MOTION to Dismiss <i>Second Consolidated Amended Class Action Complaint</i> . Court to issue written Order. (Court Reporter Mauralee Ramirez). (Plaintiff Attorney Laurence D. King, Jeffrey P. Campisi, Mario Choi).(Defendant Attorney Ryan E. Blair, William E. Grauer). (no document attached) (gxr) (Entered: 10/25/2013)
11/01/2013	70	MOTION for Leave to File <i>Sur-Reply Memorandum in Opposition to Defendants' Motion to Dismiss Second Consolidated Amended Class Action Complaint</i> by Carl Schwartz. (Attachments: # 1 Declaration of Jeffrey P. Campisi in Support of Motion for Leave to File Sur-Reply Memorandum in Opposition to Defendants' Motion to Dismiss Second Consolidated Amended Class Action Complaint)(King, Laurence) (yeb). (Entered: 11/01/2013)
11/04/2013	71	ORDER granting 60 Motion to Dismiss and denying as moot 62 Motion to Strike. It is so ordered Defendants Motion to Dismiss [Doc. No. 60] is granted without prejudice to Plaintiff filing a motion to amend the complaint for a putative class period

		not to exceed May 11, 2009 through January 27, 2011. Any motion to amend shall be filed on or before November 27, 2013. Defendant Hoffman is dismissed from this action with prejudice. No extensions of the motion to amend deadline will be granted. Plaintiffs Motion to Strike, the Motion [Doc. No. 62] is denied. Signed by Judge Cathy Ann Bencivengo on 11/4/2013. (All non-registered users served via U.S. Mail Service)(yeb) (Entered: 11/04/2013)
11/04/2013	72	ORDER denying as moot 70 Motion for Leave to File a Sur Reply. Signed by Judge Cathy Ann Bencivengo on 11/4/2013. (All non-registered users served via U.S. Mail Service)(yeb) (Entered: 11/04/2013)
11/27/2013	73	MOTION to Amend/Correct <i>Second Consolidated Amended Class Action Complaint</i> by Carl Schwartz. (Attachments: # 1 Memo of Points and Authorities in Support of Lead Plaintiff's Motion to Amend Second Consolidated Amended Class Action Complaint, # 2 Declaration of Laurence D. King in Support of Lead Plaintiff's Motion to Amend Second Consolidated Amended Class Action Complaint, # 3 Proof of Service)(King, Laurence) (sjt). (Entered: 11/27/2013)
12/20/2013	74	RESPONSE in Opposition re 73 MOTION to Amend/Correct <i>Second Consolidated Amended Class Action Complaint</i> filed by Christy Anderson, Arena Pharmaceuticals, Inc., Dominic P. Behan, Robert E. Hoffman, Jack Lief, William R. Shanahan. (Attachments: # 1 Declaration of Ryan E. Blair, # 2 Exhibit BF-BG, # 3 Proof of Service)(Grauer, William) (yeb). (Entered: 12/20/2013)
12/27/2013	75	REPLY to Response to Motion re 73 MOTION to Amend/Correct <i>Second Consolidated Amended Class Action Complaint</i> filed by Carl Schwartz. (King, Laurence)(yeb). (Entered: 12/27/2013)
12/30/2013	76	MINUTE ORDER: Currently on calendar for Friday, January 3, 2014 at 2:00 p.m. is a hearing on Plaintiffs motion to amend second consolidated amended class action complaint, [Doc. No. 73]. Pursuant to Civil Local Rule 7.1(d)(1), the Court finds this motion suitable for decision without oral argument. Accordingly, the hearing on this motion is taken off calendar and these matters are taken under submission. No appearances will be required in these matters on Friday, January 3, 2014.(All non-registered users served via U.S. Mail Service)(yeb)(jrd) (Entered: 12/30/2013)
03/20/2014	77	ORDER denying 73 Lead Plaintiff's Motion to Amend Second Consolidated Amended Class Action Complaint. The Court concludes that amendment of the complaint in this action would be futile as the allegations of the proposed third amended complaint fail to give rise to a strong inference of scienter. The motion to amend [Doc. No. 73] is therefore denied. The case is dismissed with prejudice. Signed by Judge Cathy Ann Bencivengo on 03/20/2014. (All non-registered users served via U.S. Mail Service)(yeb) (av1). (Entered: 03/21/2014)
03/21/2014	78	CLERK'S JUDGMENT. IT IS SO ORDERED AND ADJUDGED that judgment is in favor of Arena Pharmaceuticals, Inc., Christy Anderson, Dominic P. Behan, Jack Lief, Robert E. Hoffman, William R. Shanahan against Arena Investors Group, Anthony Caravella, Carl Schwartz, Jean Sutliff, Todd Schueneman, William Sutliff. The Court concludes that amendment of the complaint in this action would be futile as the allegations of the proposed third amended complaint fail to give rise to a strong inference of scienter. The motion to amend [Doc. No. 73] is therefore denied. The case is dismissed with prejudice.(All non-registered users served via U.S. Mail Service)(yeb) (Entered: 03/21/2014)

04/18/2014	79	NOTICE OF APPEAL to the 9th Circuit as to 78 Clerk's Judgment, 77 Order denying Lead Plaintiff's Motion to Amend Second Consolidated Amended Class Action Complaint, 71 Order granting Motion to Dismiss and denying as moot Motion to Strike, by Carl Schwartz. (Filing fee \$ 505 receipt number 0974-6954920.) (Notice of Appeal electronically transmitted to US Court of Appeals.) (Attachments: # 1 Representation Statement of Lead Plaintiff)(King, Laurence). Modified on 4/18/2014 to edit docket text re Judgment and Orders being appealed. (akr). (Entered: 04/18/2014)
04/18/2014	80	USCA Case Number 14-55633 for 79 Notice of Appeal to 9th Circuit, filed by Carl Schwartz. (akr) (Entered: 04/18/2014)
04/18/2014	81	USCA Time Schedule Order as to 79 Notice of Appeal to 9th Circuit, filed by Carl Schwartz. (NOTICE TO PARTIES of deadlines regarding appellate transcripts: Appellant shall file transcript designation and ordering form with the US District Court (see attached), provide a copy of the form to the court reporter, and make payment arrangements with the court reporter on or by 5/19/2014 (see Ninth Circuit Rule 10-3.1); Due date for filing of transcripts in US District Court is 6/17/2014.) (cc: Court Reporter). (Attachments: # 1 Transcript Designation and Ordering Form). (akr) (Entered: 04/18/2014)
04/22/2014	82	NOTICE OF FILING OF OFFICIAL TRANSCRIPT of Proceedings (Motion to Dismiss Hearing) held on 10/25/2013, before Judge Cathy Ann Bencivengo. Court Reporter/Transcriber: Mauralee A. Ramirez. Transcript may be viewed at the court public terminal or purchased through the Court Reporter/Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER or the Court Reporter/Transcriber. If redaction is necessary, parties have seven calendar days from the file date of the Transcript to E-File the Notice of Intent to Request Redaction. The following deadlines would also apply if requesting redaction: Redaction Request Statement due to Court Reporter/Transcriber 5/13/2014. Redacted Transcript Deadline set for 5/23/2014. Release of Transcript Restriction set for 7/21/2014. (All non-registered users served via U.S. Mail Service. Notice of electronic filing only.) (akr) (Entered: 04/22/2014)
04/22/2014	83	TRANSCRIPT DESIGNATION AND ORDERING FORM by Carl Schwartz for proceedings held on 10/25/13 re 79 Notice of Appeal to 9th Circuit. (Choi, Mario). (akr). (Entered: 04/22/2014)

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CERTIFICATE OF SERVICE

I hereby certify that, on August 27, 2014, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system. Participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system.

I further certify that some of the participants in the case are not registered CM/ECF users. Upon acceptance by the Clerk of the Court of the electronically filed document, one copy of the foregoing will be served, via U.S. Mail, postage prepaid on:

Erik D. Peterson
Kessler Topaz Meltzer & Check, LLP
One Sansome Street
Suite 1850
San Francisco, CA 94104

Dated: August 27, 2014

/s/ Peter K. Stris
Peter K. Stris
Counsel for Appellant