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

REPLY BRIEF OF LEAD-PLAINTIFF/APPELLANT

Peter K. Stris
Dana Berkowitz
Victor O'Connell
STRIS & MAHER LLP
725 S. Figueroa St., Ste. 1830
Los Angeles, CA 90017
Telephone: (213) 995-6800
Facsimile: (213) 261-0299

Additional Counsel for Lead Plaintiff/Appellant

Laurence D. King
Mario M. Choi
KAPLAN FOX & KILSHEIMER LLP
350 Sansome Street, Suite 400
San Francisco, CA 94104
Telephone: (415) 772-4700
Facsimile: (415) 772-4707

Robert N. Kaplan
Jeffrey P. Campisi
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/Appellant

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INTRODUCTION

This case is about a public company that misrepresented and omitted material information to manipulate and artificially inflate the price of its stock. For almost two years, Arena Pharmaceuticals, Inc. ("Arena") and its executives (collectively, "Defendants") actively led the market to expect imminent approval of their new diet drug lorcaserin. They claimed to "have favorable results on everything that we've compiled so far" and implied that these results satisfied the safety concerns of the Food and Drug Administration ("FDA"). When FDA scientists disclosed that lorcaserin causes cancer in rats (the "Rat Study" results), which Defendants knew all along, Arena stock fell 40 percent in one day.

Arena and its executives now insist that they "reasonably believed" that the results of the Rat Study were "favorable," that their follow-up studies alleviated the FDA's concerns, and that the Rat Study's cancer findings did not alter the prospects for seamless approval of lorcaserin. Even if Defendants' self-serving litigation position were credible, however, it cannot possibly justify the district court's dismissal of this case *on the pleadings*.

Plaintiff has clearly alleged sufficient facts to proceed to discovery on his theory of securities fraud – i.e., that Arena and its executives misrepresented and concealed the Rat Study cancer findings because they correctly feared that disclosure would cause investors to sell Arena stock and that such fraud artificially inflated the

price of Arena stock long enough for Defendants to raise the funds necessary to keep the company afloat. Tellingly, Defendants do not attempt to argue they were unaware that the cancer findings of the Rat Study were material to investors. To the contrary, Defendants *admit* that they suppressed the results of the Rat Study precisely to prevent lay investors from overreacting. The district court erred in dismissing Plaintiff's complaint. Reversal is warranted.

I. Plaintiff's Detailed Factual Allegations Give Rise to a Strong Inference of Scienter.

The district court dismissed Plaintiff's Second Amended Complaint ("SAC") and denied leave to amend on the grounds that Plaintiff had not adequately pled scienter. ER-5; ER-8. In this appeal, Plaintiff explained that Defendants acted with scienter because they intentionally deprived the market of material information about whether and when the FDA would likely approve lorcaserin. *See* Brief of Lead-Plaintiff/Appellant, Dkt. No. 18-1 (Aug. 27, 2014) ("Br."), at 32-40. Defendants respond by reiterating the district court's holding: that their misstatements and omissions reflected a legitimate and unanticipated scientific disagreement with the FDA. *See* Answering Brief of Appellees, Dkt. No. 25-1 (Oct. 24, 2014) ("Appellees' Br."), at 38-42, 51-53.

Like the district court's opinion, Defendants' brief misses the point. Plaintiff has alleged in painstaking detail that Defendants intentionally suppressed the cancer findings of the Rat Study and the FDA's reaction because Defendants knew that such

information was material to investors. As explained next, Plaintiff's allegations are sufficient to satisfy the pleading standards of the Private Securities Litigation Reform Act ("PSLRA").

A. Plaintiff Alleges with Particularity that Defendants Intentionally Suppressed Information about the Rat Study's Cancer Findings and the FDA's Reaction.

The SAC and Proposed Third Amended Complaint ("TAC") allege that Arena and its executives intentionally suppressed the results of the Rat Study, a long-term nonclinical carcinogenicity study required for FDA approval. ER-120-22 (SAC ¶¶ 62, 63, 69).[1] The Rat Study found that lorcaserin causes mammary tumors, brain cancer, and other cancers in rats. ER-111 (SAC ¶ 12); ER-122 (SAC ¶ 72); ER-127 (SAC ¶ 100-01). When a drug causes cancer in rats, its sponsor must demonstrate that the carcinogenic mechanism is not relevant to humans to obtain FDA approval. ER-122 (SAC ¶ 70). Attempting to make such a showing, Defendants hypothesized that the carcinogenic mechanism in lorcaserin was a hormone called prolactin (the "Prolactin Hypothesis"). ER-3.

The SAC and TAC further allege that Arena and its executives intentionally suppressed the FDA's reaction to the Rat Study. In what Defendants themselves called a "highly unusual" step, the FDA required Arena to submit bimonthly reports

[1] Plaintiff's opening brief recites the relevant allegations in detail. *See* Br. at 9-12 ("Defendants Conduct the Lorcaserin Rat Study").

on its tests of the Prolactin Hypothesis. ER-112 (SAC ¶¶ 15-16); ER-123-24 (SAC ¶¶ 75-79). When Defendants reported that the incidence and proportion of female rats with cancerous tumors had increased at all doses, the FDA requested a meeting. ER-113 (SAC ¶ 20); ER-124 (SAC ¶ 83). At that meeting, the FDA imposed several conditions on continuation of the clinical trials, including that Defendants inform participants of the cancer risk. ER-113 (SAC ¶ 21); ER-124 (SAC ¶ 83); ER-117 (SAC ¶ 41). Defendants' final report to the FDA concluded that lorcaserin does not cause the sustained and robust increase in prolactin that had been observed of drugs that cause cancer in rats but not in humans. ER-4.

Throughout this period, Defendants unfailingly disclosed the positive results of their human clinical trials, leading investors to believe that these results satisfied *all* of the FDA's safety concerns with lorcaserin. Br. 12-18. And when they occasionally mentioned animal studies, Defendants made unqualified positive statements like, "We have favorable results on everything that we've compiled so far," ER-151 (SAC ¶ 190) (quoting ER-263). *See also, e.g.*, ER-139-40 (SAC ¶ 144) (quoting ER-387-88). It is undisputed that Defendants *never mentioned* the Rat Study's cancer finding or the FDA's serious expressions of concern.

Plaintiff alleges that Arena and its executives intentionally concealed the cancer findings of the Rat Study and the FDA's reaction to those results knowing that these facts would be material to investing decisions *in light of Defendants' other*

representations to investors. As Plaintiff has explained, Arena's stock price depended on investor perceptions about whether and when the FDA would approve lorcaserin, its main product. *See* Br. at 33-35. These perceptions depended in turn on investor beliefs about the FDA's satisfaction with the safety of lorcaserin. *See* Br. at 35-36. The importance of the results of the Rat Study and the FDA's concerns to these perceptions were manifest. Br. at 37.

Like many others who have committed securities fraud, Defendants acted to prevent shareholder flight. *See, e.g., Warshaw v. Xoma Corp.*, 74 F.3d 955, 959-60 (9th Cir. 1996); *In re Immune Response Sec. Litig.*, 375 F. Supp. 2d 983, 1020 (S.D. Cal. 2005). When investors learned of the Rat Study, Arena's stock price fell 40 percent in one day. ER-116 (SAC ¶¶ 36-37); ER-129 (SAC ¶¶ 114-15); ER-165 (SAC ¶ 254). And when the FDA Advisory Panel recommended against approval of lorcaserin a few days later, the stock fell another 47 percent. ER-116 (SAC ¶¶ 38-39); ER-165 (SAC ¶ 256).

B. Defendants Admit to Having Intentionally Suppressed Information about the Rat Study's Cancer Findings and the FDA's Reaction.

Defendants readily acknowledge that they knew about the cancer findings of the Rat Study and the FDA's response. Indeed, Defendants claim to have been so intimately familiar with the Rat Study and the FDA's concerns that they each "'had a legitimate scientific reason to believe that the final Rat Study data, including the

[Prolactin Studies], was sufficient to address the FDA's safety concerns.'" Appellees' Br. at 32 (quoting ER-7); *see also id.* at 10.

Defendants likewise acknowledge that neither they nor anyone else publicly disclosed the results of the Rat Study or the FDA's response, which they claim would have been impractical. *Compare* Appellees' Br. at 8 ("Arena, like other pharmaceutical companies, disclosed data from these 'pivotal' Phase III human trials.") *with id.* at 53-54 (claiming that "Arena could not have disclosed the Rat Study results without also disclosing" millions of additional pages).

In an attempt to justify their conduct, Defendants halfheartedly imply that two disclosures adequately conveyed the essential information about the Rat Study and the FDA's reaction. First, Defendants observe that the patient consent form for the clinical trials was "'updated to include the tumor findings in rats'" and claim that it "was publicly available during the Class Period." Appellees' Br. at 35 n.17 (quoting SER-97); *see also id.* at 10. As noted above, the FDA permitted clinical trials of lorcaserin to continue on the condition that Defendants warn participants about the risks identified in the Rat Study. ER-117 (SAC ¶ 41). There is no evidence in the record that the patient consent form was available online, and it was certainly not available on the website of either Arena or the FDA. *Cf.* Appellees' Br. at 35 n.14. Defendants wisely do not press their unsupported suggestion that an obligatory reference to tumors in a form that they claim could be downloaded somewhere on

the Internet adequately informed the market about the Rat Study. *Cf.* ER-130 (SAC ¶ 116) ("Yesterday we were completely blindsided by preclinical carcinogenicity data from the two year lorcaserin animal study.").

Second, Defendants claim to have warned investors that "[t]he FDA approval process is fraught with uncertainty." Appellees' Br. at 7 (citing ER-207-09; ER-224-228; ER-334-339; ER-356-59). Defendants note, for example, that they disclosed that "[o]btaining approval of an NDA can be a lengthy, expensive and uncertain process" and that "[r]egulatory approval of an NDA . . . is not guaranteed." *Id.* It is well settled, however, that generic warnings do not suffice when Defendants know of specific dangers. *See* Br. at 48-49 n.184 (citing *In re Prudential Secs. Inc. P'Ships Litig.*, 930 F. Supp. 68, 72 (S.D.N.Y. 1996) ("The doctrine of bespeaks caution provides no protection to someone who warns 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.")); *see also Provenz v. Miller*, 102 F.3d 1478, 1489 (9th Cir. 1996) ("There is a difference between knowing that any product-in-development may run into a few snags, and knowing that a particular product has already developed problems so significant as to require months of delay.") (quoting *In re Apple Computer Sec. Litig.*, 886 F.2d 1109, 1115 (9th Cir. 1989)).

Far from warning investors of the risks inherent in the results of the Rat Study, Arena specifically represented in every quarterly and annual report for almost two

years: "To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our drug candidates, *except lorcaserin*." ER-140-41 (SAC ¶ 148) (quoting ER-205; ER-209); ER-209; ER-228; ER-359; ER-410; ER-422; ER-432; ER-443; ER-458; ER-476 (emphasis added).

C. Plaintiff's Particularized Factual Allegations Regarding the Circumstances of Defendants' Statements and Omissions Give Rise to a Strong Inference that Defendants Knew the Suppressed Information Was Material to Investors.

The SAC and TAC also contain extensive factual allegations giving rise to a cogent and compelling inference that Defendants knew that the cancer findings of the Rat Study and the FDA's reaction were material to investors.

Defendants' principal response is that it is unrealistic to expect pharmaceutical companies like Arena to disclose all information material to the prospects of a drug candidate like lorcaserin. Appellees' Br. at 53-54. According to Defendants, Plaintiff seeks "nothing short of the complete and full disclosure of all interim results, all FDA questions and communications, and every page of a company's NDA (here, more than 4 million pages) . . . . A pharmaceutical company's SEC filings could be thousands of pages long, deluging the market." *Id.* at 53-54. Defendants continue:

> [H]ere Arena could not have disclosed the Rat Study results without also disclosing, at a minimum, each bi-monthly update sent to the FDA, the mouse, monkey, and human studies, and each of the six Prolactin studies so an investor could consider the Rat Study in context. This

> would defeat the purpose of the federal securities laws by overwhelming potential investors in an avalanche of information.

Id.

Defendants' professed concern about overwhelming the market with material information is unfounded, insincere, and ignores black-letter securities law. After "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." Br. at 45; *id.* at 45 n.170 (citing *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 987 (9th Cir. 2008); *In re Elan Corp. Sec. Litig.*, 553 F. Supp. 2d 187, 208 (S.D.N.Y. 2008)). To borrow this Court's words:

> Had Defendants released no [] reports, their failure to mention the [Rat Study] might have misled no one. But once Defendants chose to tout the company's [study results,] they were bound to do so in a manner that wouldn't mislead investors as to what [they] consisted of.

Berson, 527 F.3d at 987.

Defendants recognize as much. They acknowledge that any duty they had to disclose material information must have arisen from other affirmative disclosures. Appellees' Br. at 53 n.25 (citing *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1322 (2011) ("Even with respect to information that a reasonable investor might consider material, companies can control what they have to disclose . . . by controlling what they say to the market."); *Sec. Police and Fire Prof'ls of Am. Ret. Fund v. Pfizer, Inc.*, No. 10-cv-3105 (SDW), 2013 WL 1750010, at *7 (D.N.J. Apr.

22, 2013) ("Defendants did not make an affirmative statement about the [clinical] data, and therefore did not put the subject of the clinical data 'in play.'"). They also quote *Brody v. Transitional Hospitals Corp.* for the proposition that "'to be actionable under the securities laws, an omission . . . must affirmatively create an impression of a state of affairs that differ in a material way from the one that actually exists.'" Appellees' Br. at 27 (quoting *Brody*, 280 F.3d 997, 1006 (9th Cir. 2002)). That is precisely what Plaintiff alleges occurred in this case.[2]

Indeed, Defendants' *own belated disclosures* illustrate that they knew how to clearly and succinctly communicate the risk of regulatory delay or denial associated with the results of the Rat Study. *See* Br. at 49-50. After the FDA rejected the Lorcaserin Application, Defendants filed a quarterly report with the Securities and Exchange Commission stating:

> 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]*.

[2] Defendants claim they had no duty to disclose the Rat Study cancer findings because they "had nothing to do with" the human trials, which "are what the FDA 'used in evaluating [a drug's] overall risks and benefits.'" Appellees' Br. at 53 n.25 (quoting ER-53). It is disingenuous for Defendants to assert that the results of the Rat Study "had nothing to do with" the FDA's evaluation of lorcaserin's "overall risks and benefits," Appellees' Br. at 53 n.25, when a clean long-term nonclinical carcinogenicity study on rats is required for FDA approval. *See also* Br. at 12-18.

ER-105 (Third Quarter 2010 Form 10-Q) (emphasis added).

Public companies – including pharmaceutical research and development companies – routinely disclose scientific and other technical data. These firms are not exempt from the securities laws simply because most investors are not scientists, accountants, or other professionals trained to understand the intricacies of their businesses. *Compare* Br. at 57 ("[I]f 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.") *with* Appellees' Br. at 54 ("Especially in the pharmaceutical industry, public companies must make frequent judgments about where to draw the line on disclosure issues because they cannot know in advance what the FDA may later consider important in conducting its risk/benefit analysis of a drug.").

Here, Defendants assert that tens of thousands if not millions of pages of jargon would be necessary for investors to consider the results of the Rat Study "in context," Appellees' Br. at 53, but evidently no such disclosures were necessary to "contextualize" the results of the human studies. This Court should assess Defendant's factual claims "in context," and permit this case to proceed.

II. Rather than Defend the *Pleading* Dismissal, Defendants Merely Rehash the Same *Merits Position* Mistakenly Adopted by the District Court.

As explained above, Defendants do not seriously dispute the sufficiency of Plaintiff's factual allegations of scienter. Instead, Defendants counter Plaintiff's allegations with allegations of their own: that they reasonably believed that the results of the Rat Study were "favorable," that they were ignorant of the FDA's serious concerns, and that they were "as surprised and disappointed" as stockholders when the FDA rejected lorcaserin. *See* Appellees' Br. at 28-42.

Defendants' argument falls short on two levels. First, Defendants' beliefs about whether investors *should* care about the results of the Rat Study and the FDA's reaction are irrelevant: Plaintiff need only credibly allege that Defendants knew that investors *would* care about that information. Second, Defendants' argument fails on its own terms because facts already in the record make clear that Defendants could not plausibly have held the beliefs they now profess. And despite Defendants' evident wish to skip ahead to summary judgment, this Court cannot simply disregard Plaintiff's factual allegations before any formal discovery.

A. Defendants' "Reasonable Beliefs" About Whether Investors *Should* Care About Suppressed Information Are Not Relevant to Whether Defendants Knew That Investors *Would* Care.

Defendants argue that they "were as surprised and disappointed as Arena stockholders by the temporary disagreement with the FDA in September 2010 over the interpretation of the results of the Rat Study and the Prolactin Studies."

Appellees' Br. at 51. According to their brief, Defendants reasonably believed that the results of the Rat Study were "favorable." *Id.* at 28 ("Defendants were reasonable in viewing the results of the Rat Study and the Prolactin Studies as favorable."). Moreover, Defendants claim that they reasonably expected the FDA to agree with their interpretation of the Rat Study and the Prolactin Studies. *Id.* at 32 (The FDA never formally "disclose[d] its interpretation of the Rat Study and the Prolactin Studies until it published the September 2010 briefing document.").

Defendants thus profess to have been "reasonably" oblivious to any increased likelihood that the FDA would reject the Lorcaserin Application based on the Rat Study and the FDA's response, or that their positive representations to investors were incomplete and misleading. In support of their position, Defendants repeatedly point out that the FDA approved lorcaserin in 2012, proving them "right" in the end. *See, e.g.*, Appellees' Br. at 3, 23-24, 39, 41-42.[3]

To be clear: Defendants' position is not, in any way, a defense of the district court's dismissal of this case. As Plaintiff has explained at length, Defendants are

[3] It is worth noting that Arena withdrew its request for approval of lorcaserin in the European Union ("EU") in May 2013 after the EU equivalent of the FDA rejected lorcaserin because of the Rat Study. *See* ER-100 (attaching "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"); *see also* European Medicines Agency, *Withdrawal of the Marketing Authorisation Application for Belviq (lorcaserin)*, http://www.ema.europa.eu/docs/en_GB/document_library/Medicine_QA/2013/05/WC500143811.pdf.

liable for securities fraud if they misrepresented information that they knew *investors* would consider material to the prospects for FDA approval of lorcaserin in 2010. *See, e.g.*, Br. at 41 ("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.") (emphasis added); *id.* at 42 ("Defendants committed securities fraud by intentionally depriving *investors* of the opportunity to evaluate for themselves the significance of [the Rat Study and the FDA's reaction].") (emphasis added). Even if Defendants firmly believed that the Rat Study and the FDA's reaction had no effect on the prospects for regulatory approval of lorcaserin, they could not deprive investors of the opportunity to form a different opinion.

B. In Any Event, Plaintiff – Without the Benefit of Any Formal Discovery – Has Uncovered Overwhelming Evidence That Defendants Did Not Hold the Beliefs That They Now Assert.

Defendants' assertions that they were "reasonably" ignorant of the negative implications of the Rat Study, the gravity of the FDA's concerns, and the probability that the FDA would reject the Lorcaserin Application in 2010 are also incompatible with the extensive evidence already in the record.[4]

[4] Plaintiff's opening brief recites the relevant allegations in detail. *See* Br. at 42-45 ("Plaintiff Alleged Facts Giving Rise to a Strong Inference of Scienter in the Second and Proposed Third Amended Complaints").

Defendants' arguments about the weight of evidence are unquestionably premature. *See, e.g.*, *In re Amylin Pharms., Inc. Sec. Litig.*, No. 01CV1455 BTM (NLS), 2002 WL 31520051, at *8 (S.D. Cal. May 1, 2003) ("At a later stage, the issue of the reasonableness of defendants' belief in their statements will arise again; for now, the complaint has pled fraud with adequate particularity."); *Yanek v. Staar Surgical Co.*, 388 F. Supp. 2d 1110, 1132 (C.D. Cal. 2005) (denying motion to dismiss where defendants argued that they believed issues would not threaten FDA approval); *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974), *overruled on other grounds by Davis v. Scherer*, 468 U.S. 183 (1984) ("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."). Nonetheless, as explained next, Defendants' particular factual claims are especially ironic in light of the existing record:

1. Defendants Did Not Believe That the Results of the Rat Study Were "Favorable."

Defendants do not actually try to establish the "favorability" of the Rat Study in their brief. *Cf.* Appellees' Br. at 28-31. Rather, they observe that the findings of the Rat Study – that lorcaserin causes tumors in rats – were not necessarily catastrophic because they might not be relevant to humans. *Id.* at 28-29 ("As the TAC alleges, 'in order to demonstrate *that the tumors observed in the Rat Study were irrelevant to human risk*, [Arena] would have to demonstrate either a safety margin . . . or a rodent-specific mechanism.'") (emphasis altered).

At most, Defendants might have "reasonably believed" that the FDA would treat the results of the Rat Study as irrelevant. *See id.* at 28-29; *id.* at 29. But that proposition does not help Defendants. When a doctor tells a patient that he has "favorable results on everything that we've compiled so far," as Defendant Anderson told Arena investors, the doctor has not found a tumor that might be benign. *See* ER-151 (SAC ¶ 190) (quoting ER-263). Likewise, when a pharmaceutical executive expresses "confidence" in FDA approval "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 Defendant Lief told Arena investors, investors do not think that the company must first convince the FDA to ignore the animal studies. ER-144 (SAC ¶ 160) (quoting ER-315).

Like their claim that the results of the Rat Study were "favorable," Defendants' remaining "scientific" arguments about the implications of the Rat Study were contrived for this litigation. Defendants devote five pages of their brief to factual assertions and specific objections to Plaintiff's characterization of the results of the Rat Study and the Prolactin Studies. *See* Appellees' Br. at 28-32. For example, Defendants claim that the Prolactin Studies "unequivocally showed a 3.4-4.2-fold increase in prolactin in male rats and a 2-fold increase in prolactin in female rats." *Id.* at 30. And in a 227-word footnote, Defendants excoriate Plaintiff's "disregard for the scientific process." *Id.* at 30 n.15.

The contemporaneous documents, however, contradict Defendants' claims. Defendants now represent to this Court that the Prolactin Studies "unequivocally" showed an increase in prolactin, but in 2010 they told the FDA that "mammary tumors were primarily prolactin negative" and that "[t]here was no correlation between incidence of mammary gland prolactin stain and the incidence of pituitary gland prolactin stain in females at all dose levels." *See* Lead Plaintiff's Reply Memorandum of Points and Authorities in Support of Lead Plaintiff's Motion to Amend Second Consolidated Class Action Complaint, Dkt. No. 75 (Dec. 27, 2013), at 4. And while Defendants complain that Plaintiff misstates the definitive results of the Prolactin Studies, the contemporaneous evidence in the record confirms that the results were undeniably equivocal. *See* ER-62-63 (TAC ¶¶ 66-67).[5]

[5] *See also, e.g.*, Dec. 20 Blair Decl., Ex. BF (ECF No. 74-2, at 4) (stating that in female rats treated with lorcaserin "serum prolactin appeared to ***decrease*** while haloperidol consistently ***increased*** serum prolactin levels in both male and female rats suggesting that increased haloperidol is a very potent stimulator of prolactin release."); (ECF No. 74-2, at 12) (stating "[n]o definitive conclusions could be drawn as to the effect of lorcaserin on prolactin levels due to high variability of the assay data . . . [and] the use of overiectomized rats, however, led to a reduction in prolactin level that did not increase following lorcaserin administration."); (ECF No. 74-2, at 13) (stating lorcaserin did not increase prolactin in low-hormone replacement group); (ECF No. 74-2, at 15) (stating "Lorcaserin had no effect on . . . the number of prolactin secreting cells in the pituitary and mammary gland."); King Decl., Ex. C (ECF No. 61-4, at 8) (stating in multiple studies, haloperidol and dexfenfluramine increased serum prolactin while lorcaserin did not).

With all due respect to opposing counsel and the district court, none of us is a scientist. And it is not productive to debate the implications of the Rat Study and the Prolactin Studies without the benefit of discovery or expert assistance – just as it was inappropriate for the district court to summarily credit Defendants' assertions. Defendants concede that the results of the Rat Study were *at best* irrelevant, and that when the market learned of their existence Arena stock fell 40 percent. Plaintiff looks forward to learning more about Defendants' scientific views – both in 2010 and in 2014 – through the formal discovery process.

2. Defendants Understood the Seriousness of the FDA's Concerns about the Rat Study.

Defendants object to Plaintiff's contention that the FDA "repeatedly expressed concerns" about the Rat Study and the Prolactin Studies on the grounds that the FDA never formally "disclose[d] its interpretation of the Rat Study and Prolactin Studies until it published the September 2010 briefing document." Appellees' Br. at 32. That is a non-sequitur. As explained above, Defendants concede that the FDA required Arena to demonstrate that the results of the Rat Study were *irrelevant* to human risk to obtain approval of lorcaserin. *See, e.g.*, Appellees' Br. at 28-29. It is hard to imagine a more compelling expression of "serious" concern.

Plaintiff has also alleged that the FDA repeatedly and specifically conveyed its concerns about the implications of the Rat Study to Defendants. The FDA

required Defendants to conduct additional tests to substantiate the Prolactin Hypothesis, ER-3; took the "highly unusual" step of directing Defendants to submit bimonthly updates on their results, ER 112 (SAC ¶¶ 15-16); ER-123-24 (SAC ¶¶ 75-59); requested a meeting to discuss the results of the Rat Study and their implications for humans, ER-113 (SAC ¶ 21); ER-124 (SAC ¶ 83); and required as conditions of allowing the clinical trials to continue that Defendants disclose to human participants the risks identified in the Rat Study, ER-117 (SAC ¶ 41), and submit a draft report of the final results of the Rat Study as soon as it was available, ER-125 (SAC ¶ 88).

Defendants admit many of these facts. *See, e.g.*, Appellees' Br. at 33 (FDA required Arena to "'substantiate its view 'with data on prolactin levels,'"); *id.* at 34 ("[I]n September 2007 the FDA requested that Arena send bi-monthly updates regarding the interim results of the Rat Study, and Arena did so"); *id.* at 35 (FDA made detailed notations about the Rat Study and Prolactin Studies in connection with April 2008 meeting with Arena); *id.* at 35 n.17 (FDA noted that "[i]nvestigator brochure and patient informed consent documents were updated to include the tumor findings in rats").

Despite those facts and admissions, Defendants ask this Court to conclude that there were no "'red flags' from the FDA during the Class Period . . . ." Appellees' Br. at 33. Specifically, Defendants claim that "[a]t all times before April 2008, the FDA viewed Arena's position that the mammary tumors in the Rat Study were

caused by the Prolactin Mechanism as 'reasonable' and 'plausible,'" *id.*, that the FDA's request for interim results shows at most "the 'give and take' between the FDA and a pharmaceutical company that 'is the essence of the . . . license application process,'" *id.* at 34, and that "[t]he FDA's reasons for permitting the Phase III trials to continue in April 2008 are precisely the same reasons why Arena believed it had demonstrated both a safety margin and a rat-specific mechanism upon completion of the Rat Study and the Prolactin Studies," *id.* at 35.

To be sure: this litigation could possibly vindicate Defendants. But it was inappropriate for the district court to credit Defendants' factual assertions *before any formal discovery* had taken place. Defendants concede that they knew they had to demonstrate the results of the Rat Study were irrelevant to human risk to obtain approval of lorcaserin, and that the FDA rejected lorcaserin in 2010 because it was not convinced. Plaintiff looks forward to learning more about Defendants' interactions with the FDA through the formal discovery process.

3. Defendants Prepared for the Possibility that the FDA Might Not Approve the Lorcaserin Application in 2010.

Perhaps most to the point, Arena and its executives *behaved* as though they did not like the results of the Rat Study, were concerned about the FDA's response, and generally feared that the FDA might not approve the Lorcaserin Application in 2010. The SAC and TAC allege a course of conduct that overwhelmingly suggests that Defendants deliberately fostered an unduly optimistic impression of the

prospects for FDA approval of lorcaserin in 2010 so that they could give themselves extra time to convince the FDA that their drug was safe.

As Plaintiff has explained, Defendants quickly and specifically announced the results of human clinical trials and linked them to the prospects for regulatory approval, but never mentioned the Rat Study. *See* Br. at 45-56. Defendants also told investors that all studies were encouraging and that there were no obstacles to regulatory approval, again omitting the results of the Rat Study and the FDA's requirement that Defendants prove irrelevance to human risk. *See* Br. at 15-18.

At the same time, Defendants took steps to ensure that Arena would remain solvent for at least two more years if the FDA did not approve lorcaserin in 2010. Br. at 53. Arena suspended purchases and fired 31 percent of its workforce, measures that employees understood were related to uncertainty about the prospects of the Lorcaserin Application. Br. at 18. Arena also raised $190 million through stock issuances and a four-year loan, or enough to fund its operations through 2012. Br. at 19. To put it mildly, viewed holistically, these allegations give rise to a cogent and compelling inference of intent to mislead.[6]

[6] Defendants' piecemeal attack on Plaintiff's circumstantial allegations is unpersuasive. *See* Appellees' Br. at 42-51. For example: Defendants dismiss confidential witness statements as irrelevant by asserting an unreasonably narrow view of what is relevant. *See, e.g., id.* at 46 (dismissing witnesses who worked in Arena's purchasing department and reported directive to suspend unnecessary purchases because they "had no basis to opine on the Rat Study or the Prolactin Studies"). Defendants' description of Plaintiff's fundraising allegations as "a

III. Defendants' Miscellaneous Arguments Lack Merit.

In their brief, Defendants address four other issues that this Court must confront. As explained below, Defendants are wrong on each of those four subjects.

A. Defendants' Benevolent Paternalism Justification for Fraud Runs Counter to Black-Letter Securities Law.

Defendants cloak their failure to disclose the results of the Rat Study in the mantle of benevolent paternalism. In Defendants' view, investors cannot properly evaluate the implications of scientific data for the value of a pharmaceutical company. Appellees' Br. at 54. As such, Defendants claim the prerogative to suppress such information for investors' own good:

> [C]onsider a hypothetical investor who sold his or her Arena holdings based on his or her interpretation of the first report to the FDA about the interim Rat Study results, only to see Arena's stock price zigzag based on each subsequent interim report in the ongoing study, the final Rat Study results, the Prolactin studies, and then watch it rise significantly when the FDA approved lorcaserin.

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general motive to raise capital" is misleading, *see id.* at 47, as Plaintiff specifically alleged that after issuing only $2 million of stock in all of 2008, Defendants raised $190 million over fourteen months, or exactly enough money to fund Arena for two additional years, Br. at 19. And Defendants' invocation of the "significant economic downturn" in 2009 as an excuse for its budget cuts and layoffs, Appellees' Br. at 49, is exactly backwards. There is no reason to believe that Arena would suffer in a downturn. To the contrary, when other investment opportunities are scarce, research and development firms thrive. *See, e.g.*, Rochelle Garner, *Research, Development Funds Ride Out Recession*, BLOOMBERG NEWS (July 25, 2010).

Id. In other words, it was proper to withhold information that would have caused Arena stockholders to act unwisely.

To be clear: Defendants urge this Court to abandon nearly a century of federal securities law. "Disclosure, and not paternalistic withholding of accurate information, is the policy chosen and expressed by Congress." *Basic v. Levinson*, 485 U.S. 224, 234 (1988); *see also In re Apollo Group, Inc. Sec. Litig.*, 509 F. Supp. 2d 837, 840 (D. Ariz. 2007) (rejecting argument that Defendants owed a duty "not to disclose the contents of [a] report in order to prevent market overreaction" because "[s]uch paternalism finds no place in the federal securities laws"). The purpose of the securities laws is "to protect investors by promoting and requiring a full disclosure of information thought to be necessary to persons desiring to make informed investment decisions." *Sec. Adm'r v. College Assistance Plan (Guam), Inc.*, 700 F.2d 548, 550 (9th Cir. 1983).

Defendants evidently contemplate "full disclosure" of the results of the Rat Study and the Prolactin Studies with horror. Lay investors would have acted based on their own, untrained interpretations of scientific data. *See* Appellees' Br. at 54. The price of Arena stock would have "zigzag[ed]" chaotically, and some investors might have made choices that they later regretted. *Id.* But these are not harms that the securities laws recognize. *See, e.g., Steiner v. Tektronix, Inc.*, 817 F. Supp. 867 (D. Ore. 1992) ("Federal securities laws are intended to provide investors with full

disclosure of stock information and protection against fraud, not to insulate them from stock market fluctuations.").

The securities laws, however, *do* protect investors from Defendants' "altruism." As Defendants acknowledge, Arena's stock price would have fluctuated with "the first report to the FDA about the interim Rat Study results . . . each subsequent interim report in the ongoing study, the final Rat Study results, [and] the Prolactin studies . . . ." Appellees' Br. at 54.[7] In other words, investors would have considered that information *material* in evaluating Arena stock. *Matrixx*, 131 S. Ct. at 1318 (omitted fact material if there is "a substantial likelihood that disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available").

Concealing material information to manipulate investors' behavior is a paradigmatic example of securities fraud. *See, e.g.*, *Warshaw*, 74 F.3d at 959-60 (complaint sufficiently alleged that defendant pharmaceutical company's representations "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"); *Sec. Adm'r*, 700 F.2d at 550. Indeed, Defendants'

[7] This acknowledgement further undermines Defendants' stated fear of "overwhelming [investors] in an avalanche of information." Appellees' Br. at 54. There is no such thing as an "avalanche of *material* information." *Cf. General Electric Co. by Levit v. Cathcart*, 980 F.2d 927 (3d Cir. 1992).

professed motive to prevent investors from "overreact[ing]" to the Rat Study or the Prolactin Studies comes strikingly close to an outright admission of liability. *See In re Apollo Group, Inc.*, 509 F. Supp. 2d at 840.[8]

B. Defendants' Waiver Argument Is Frivolous.

Defendants assert in the introduction of their brief that "Plaintiff affirmatively disavowed in writing before the district court the precise theory of fraud that is now the centerpiece of his Appeal – i.e., that Arena knew that the Rat Study would derail or delay FDA approval." Appellees' Br. at 2 (citing SER-149). That contention is plainly meritless.[9]

Over two years ago, Defendants urged the district court to dismiss Plaintiff's First Amended Complaint on the grounds that their misrepresentations and

[8] For a moment, let us accept Defendants' invitation to "consider a hypothetical investor," Appellee's Br. at 54, who had the benefit of the material information that was suppressed. Contrary to Defendants' suggestion, that "hypothetical investor" would have fared significantly better than his flesh-and-blood counterparts. The reason is simple. *See* Br. at 34-35. Delay in FDA approval meant that lorcaserin was both more expensive to develop (because Arena had to undertake additional studies) and less profitable (because Arena lost years of sales) than the market anticipated. *Id.* Consistent with basic economic precepts, the expectation that the FDA would approve lorcaserin in 2010 artificially inflated the price of Arena stock until the moment the FDA disclosed the results of the Rat Study.

[9] Defendants know as much. Not only do they fail to specify the portion of the Supplemental Excerpts of Record they purport to rely upon, *see* Appellees' Br. at 2, but they also do not pursue their waiver argument in the body of the brief at all, *cf.* Appellees' Br. at 28-56.

omissions were forward-looking statements protected by the "safe harbor" provision the PSLRA. *See* SER-148 (citing Defs' Mem. at 22-25). In opposition, Plaintiff explained that Defendants' misrepresentations about the Rat Study and the FDA's concerns were not "inherently forward-looking" simply because they misled the market about the prospects for FDA approval of lorcaserin. *See* SER-149.

As Plaintiff wrote, Defendants' material false and misleading statements and omissions concerned "present or historical facts that were demonstratively false and misleading at the time Defendants made [them]." SER-149 (citing *In re Amylin Pharms., Inc. Sec. Litig.*, No. 01CV1455 BTM (NLS), 2002 WL 31520051, at *9 (S.D. Cal. Oct. 10, 2002)); *see also id.* at n.14 (distinguishing cases holding that predictions of FDA approval are not actionable on grounds that "Defendants knew of and failed to disclose the observations of the Rat Study and the FDA's concerns about them"). In short, Plaintiff articulated "the precise theory of fraud that is now the centerpiece of his Appeal." Appellees' Br. at 2.[10]

[10] Even if Plaintiff had "affirmatively disavowed" his present theory of relief in unrelated proceedings concerning a long-defunct complaint, he did not forfeit any rights here. This Court reviews the allegations in the SAC to determine whether they "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 554, 570 (2007).

C. The Control Person Claim Must Be Revived.

The district court dismissed Plaintiff's claim under Section 20(a) of the Exchange Act on the sole grounds that Plaintiff had failed to plead a primary violation of Section 10(b). ER-7; *see* Appellees' Br. at 55. For the reasons described here and in Plaintiff's opening brief, Plaintiff adequately pleaded a violation of Section 10(b). Thus, this Court should reinstate the control person claim as well. *See Arthur Children's Trust v. Keim*, 994 F.2d 1390, 1396 (9th Cir. 1993) ("[T]he determination of who is a controlling person . . . is an intensely factual question.").

D. At a Minimum, Plaintiff Should Be Given Leave to Amend.

If it affirms the November 4 Order dismissing the Second Amended Complaint, then this Court should reverse the March 20 Order denying Plaintiff's motion for leave to amend. Br. at 58. Defendants offer no reason to believe that "the pleading could not possibly be cured by the allegation of other facts." *Lopez v. Smith*, 203 F.3d 1122, 1130 (9th Cir. 2000). Though it is true that "[t]he district court previously identified specific deficiencies in both the CAC and the SAC and gave Plaintiff the opportunity to correct them," Appellees' Br. at 55, that opportunity was meaningless because the district court's directions were plainly incorrect. *See, e.g.*, ER-15 (footnote 9) (granting leave to amend SAC 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").

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: December 5, 2014

/s/ Peter K. Stris
Peter K. Stris
Dana Berkowitz
Victor O'Connell
STRIS & MAHER LLP
725 S. Figueroa St., Ste. 1830
Los Angeles, CA 90017
Telephone: (213) 995-6800
Facsimile: (213) 261-0299

Additional Counsel for Lead Plaintiff/Appellant

Robert N. Kaplan
Jeffrey P. Campisi
KAPLAN FOX& KILSHEIMER LLP
850 Third Avenue, 14th Floor
New York, NY 10022
Telephone: (212) 687-1980
Facsimile: (212) 687-7714

Laurence D. King
Mario M. Choi
KAPLAN FOX & KILSHEIMER LLP
350 Sansome Street, Suite 400
San Francisco, CA 94104
Telephone: (415) 772-4700
Facsimile: (415) 772-4707

Lead Counsel for Lead Plaintiff/Appellant

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 6,813 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: December 5, 2014

/s/ Peter K. Stris
Peter K. Stris
Counsel for Appellant

CERTIFICATE OF SERVICE

I hereby certify that, on December 5, 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: December 5, 2014

/s/ Peter K. Stris
Peter K. Stris
Counsel for Appellant