FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

TODD SCHUENEMAN, on behalf of himself and all others similarly situated; WILLIAM SUTLIFF; JEAN SUTLIFF; ARENA INVESTORS GROUP; ANTHONY CARAVELLA, *Plaintiffs*, and CARL SCHWARTZ, *Plaintiff-Appellant*, v. ARENA PHARMACEUTICALS, INC.; JACK LIEF; ROBERT E. HOFFMAN; DOMINIC P. BEHAN; WILLIAM R. SHANAHAN; CHRISTY ANDERSON, *Defendants-Appellees*, v. CHRIS GEORGAKOPOULOS; LARRY SPROWL; MAXAT AMANKOSSOV; DAVID PRINCE; FORD L. WILLIAMS; JOHN LEE; BABAK GHAYOUR, *Movants.*	No. 14-55633 D.C. No. 3:10-cv-01959-CAB-BLM OPINION

Appeal from the United States District Court
for the Southern District of California
Cathy Ann Bencivengo, District Judge, Presiding

Argued and Submitted May 4, 2016
Pasadena, California

Filed October 26, 2016

Before: Harry Pregerson, Jay S. Bybee,
and N. Randy Smith, Circuit Judges.

Opinion by Judge Bybee

SUMMARY*

Securities Fraud

The panel reversed the district court's dismissal of a putative securities class action in connection with defendants' public statements about their weight-loss drug, lorcaserin.

The district court held that the plaintiffs did not adequately plead scienter because defendants and the FDA were engaged in a good-faith scientific dispute regarding the cause of cancer in lab rats that were given the drug.

The panel held that a strong inference of scienter was properly pleaded under Federal Rule of Civil procedure 9(b)

* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

and the Private Securities Litigation Reform Act because when the defendants touted the safety and likely FDA approval of lorcaserin, they referred to animal studies supporting their FDA application. Once they raised the animal studies, they were obligated to disclose the cancer studies on rats.

COUNSEL

Peter K. Stris (argued), Dana Berkowitz, and Victor O'Connell, Stris & Maher LLP, Los Angeles, California; Laurence D. King and Mario M. Choi, Kaplan Fox & Kilsheimer LLP, San Francisco, California; Robert N. Kaplan and Jeffery P. Campisi, Kaplan Fox & Kilsheimer LLP, New York, New York; for Plaintiff-Appellant.

John C. Dwyer (argued), Cooley LLP, Palo Alto, California; Koji F. Fukumura, Mary Kathryn Kelley, and Ryan E. Blair, Cooley LLP, San Diego, California; for Defendants-Appellees.

OPINION

BYBEE, Circuit Judge:

Lead plaintiff Carl Schwartz filed a putative federal securities class action against Defendants Arena Pharmaceuticals, Jack Lief, Dominic Behan, William Shanahan, and Christen Anderson[1] in connection with public statements made about Arena's weight-loss drug, lorcaserin. At various times, Defendants all made positive public statements about lorcaserin's safety and the likelihood of FDA approval. On certain occasions, Defendants claimed that lorcaserin was not carcinogenic and referred to supporting "animal studies." When Arena filed its application with the FDA, the FDA's advisory panel published a briefing document that disclosed, for the first time, that Arena had been in a "highly unusual" back-and-forth with the FDA regarding the results of cancer studies on rats (the "Rat Study"). For years, Arena knew that the rats receiving lorcaserin were getting cancer. And the FDA wanted evidence that it was not a threat to humans. The market was surprised by the undisclosed Rat Study, and Arena's stock dropped significantly. Schwartz filed suit after news of the Rat Study broke. After further study, the FDA ultimately signed off on lorcaserin, and the product is now on the market.

The district court dismissed the First, Second, and Proposed Third Amended Complaints, holding that Arena and the FDA were engaged in a good-faith scientific dispute

[1] Lief, Behan, Shanahan, and Anderson were, during the Class Period, Arena's CEO, Chief Scientific Officer, Chief Medical Officer, and VP of Clinical Development, respectively.

regarding the cause of the rat cancer and that, therefore, scienter was not adequately pleaded. Schwartz filed this timely appeal. We conclude that Schwartz has properly pleaded scienter, and we reverse.

I. BACKGROUND

A. *Arena Pharmaceuticals and Lorcaserin*

Arena is a bio-pharmaceutical company that developed (and eventually marketed) a weight-loss drug called lorcaserin. Lorcaserin is a "serotonin agonist," and functions in some ways similar to the notorious drug, "Fen-Phen." Given the disastrous health consequences of Fen-Phen, the FDA gives close scrutiny to serotonin agonists when it comes to potential cardiovascular problems, and lorcaserin's safety was of obvious importance to investors for the same reason. Prior to approving a drug, the FDA requires extensive clinical studies (testing on humans) and nonclinical studies (testing on animals and in labs). Clinical testing is done in three phases. Each phase of clinical testing attempts to gather more information on drug safety and efficacy in human subjects, and each phase requires a larger and larger population size.

Between September 2006 and July 2009, Arena conducted two Phase III clinical tests with lorcaserin—known as the "BLOOM" (Behavioral modification and Lorcaserin for Overweight and Obesity Management) and "BLOSSOM" (Behavioral modification and Lorcaserin Second Study for Obesity Management) tests. They involved thousands of patients who used lorcaserin for up to two years. At the same time, Arena was conducting the Rat Study—a nonclinical study in which lorcaserin was given to lab rats to test lorcaserin's carcinogenicity. The animal tests are run so that

the FDA can see whether there is a risk of humans developing cancer from the drug. If the rats develop cancer, the burden is then on the drug developer to show the FDA that the carcinogenic mechanism is not relevant to humans. This is generally done in one of two ways: (a) demonstrating that the biological mechanism causing the cancer is unique to rats (or at least not present in humans), or (b) showing that there is a sufficiently large safety threshold to make risk to humans irrelevant (e.g., the cancer-causing dosage levels for rats is significantly higher than human prescription-level dosages).

By February 2007, the Rat Study's initial results indicated that lorcaserin was causing mammary tumors, brain cancer, skin cancer, and nerve sheath cancer in the rats. In May 2007, Arena reported these results to the FDA. Arena believed that the cause of the carcinogenic mechanism was the hormone prolactin, a theory it deemed the "Prolactin Hypothesis." Prolactin is a hormone that has been linked to cancer in rats. The FDA did not halt the clinical studies, but requested follow-up testing and bi-monthly updates on whether the rats taking lorcaserin experienced increased prolactin levels.[2] Arena complied and submitted "initial readings" of the ongoing Rat Study.

In April 2008, Defendants Shanahan, Behan, and Anderson sat down with the FDA to discuss these and other matters. Once again, the FDA did not put the BLOOM and BLOSSOM studies on hold, instead insisting that Arena

[2] The FDA's regulations permit this sort of request. *See* 21 C.F.R. § 312.32(c)(1)(v)(3) (giving FDA regulatory flexibility in demanding interim safety reports). Arena's CEO, Jack Lief, however, later called this request "highly unusual and not part of the normal process with the FDA." He also referred to it as "an out-of-process type of procedure."

submit a draft of the final Rat Study report as soon as possible. The FDA permitted the human testing to continue because:

> 1) the updated informed consent forms included the nonclinical [Rat Study] findings; 2) [it] learned that drug exposure in rats was nearly twice as high as predicted, which increased the safety margin to clinical exposure; 3) preliminary data showed a modest increase in serum prolactin levels after a single dose in male rats . . . ; 4) [it] acknowledged that the interim tumor incidence data would change (e.g., might be less worrisome) . . . ; 5) only with continued clinical study was it possible to assess whether long-term dosing with lorcaserin increased serum prolactin levels in humans; 6) only with continuation of clinical dosing would [it] obtain an accurate assessment of lorcaserin's weight-loss efficacy and safety in diabetics; and 7) given that lorcaserin is non-genotoxic, [it] believed that cancer risk was low under the conditions of use in the ongoing clinical trials . . . .[3]

In February 2009, Arena put together the final report, concluding that follow-up studies substantiated the connection between prolactin and the cancer.

[3] From the record before us, there is no evidence that the FDA said anything further to Defendants about the Rat Study until September 2010.

On March 12, 2009, less than one month after Arena put together the final Rat Study report for the FDA, CEO Jack Lief told investors that Arena was confident about lorcaserin's approval. That confidence was "based on the Phase II data, the Phase I data, *the preclinical studies that was [sic] done, [and] all the animal studies that have been completed*." (Emphasis added.) A May 2009 SEC filing, signed by Lief, similarly 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*." (Emphasis added.) In a shareholder call on September 18, 2009, Christen Anderson, Vice President of Clinical Development, represented that Arena "ha[d] favorable results *on everything that we've compiled so far*." (Emphasis added.) During a shareholder call on November 10, 2009, Lief stated that "at [that] time [they] ha[d] *all of the data in hand* that [would] be included" in the soon-to-be-submitted application. (Emphasis added.) Arena's Chief Scientific Officer, Dominic Behan, told investors that "[a]s you can see from the data, we believe that lorcaserin is a game changer." And when discussing the upcoming Advisory Committee meeting, Arena's Chief Medical Officer, William Shanahan, said, "we're not expecting any surprises associated with the panel."

In December 2009, Arena submitted its final application (which included all study data and the Rat Study conclusions) to the FDA. The FDA scheduled an Advisory Committee meeting to consider whether lorcaserin should be recommended for FDA approval. In preparation for this meeting, Arena hired Dr. Gary Williams, a world-renowned

toxicologist (specializing in carcinogenicity) to answer questions for the Committee.[4]

On September 14, 2010, the FDA published Arena's and the FDA's briefing documents on the FDA's website. In its briefing documents, the FDA disclosed the existence of the Rat Study and concerns about lorcaserin's possible carcinogenicity for the first time. Investors and analysts were "caught off guard," "surprised," and "completely blindsided" by the "unforseen," "[un]disclosed," "significant concern" about "pre-clinical cancers in rats." Arena's stock took a plunge, declining in value by 40% in a single day.

At a later meeting with the Advisory Committee, Arena interpreted the data to support the safety of lorcaserin. Arena explained that the Rat Study showed that (a) the dosage rates for rats getting cancer were 82 times higher than human exposure, thus creating an acceptable safety margin, and (b) the *timing* of prolactin increases substantiated the Prolactin Hypothesis and that the *amount* of prolactin increase should not be the focus of the inquiry.

The FDA Advisory Committee disagreed, initially. It believed that in order to prove the Prolactin Hypothesis, the studies needed to show robust and sustained increases in prolactin levels in the rats, which the data did not show. Advisory Committee members recognized that there was a difference of opinion among its members regarding how to

[4] Dr. Williams would explain that the *timing* of prolactin increase relative to rat mammary development substantiated the Prolactin Hypothesis and that the *amount* of prolactin increase (which turned out to be pretty insubstantial in the Rat Study) should not be the focus of the inquiry.

translate the data to apply to humans, but ultimately voted 9 to 5 against recommending lorcaserin for approval. A month later, the FDA denied the application and requested that Arena provide further independent pathological review of the Rat Study.

An independent panel of pathologists later uniformly concluded that Arena had overreported the incidents of tumors to the FDA. Moreover, after Arena submitted a new application, the FDA Advisory Committee found that there was a high-enough safety margin for the drug *and* that the Prolactin Hypothesis was a "plausible" explanation for the rat cancer. The FDA approved lorcaserin in June 2012, and it is currently on the market.

B. *The Suit*

After the FDA posted the briefing documents online and Arena's stock plummeted, Schwartz filed suit alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5. The district court dismissed the First Amended Complaint (FAC) without prejudice for failure to plead scienter. The court first held that the FAC failed to plead sufficient details permitting the court to infer that the Defendants had knowledge about the Rat Study or the FDA's concerns. Second, the court held that reading the FAC holistically, it was more plausible that, assuming they did know about the results, the Defendants "reasonably believed the results to be *positive*" and thus they did not act with deliberate recklessness regarding the omissions.

Schwartz filed a Second Amended Complaint (SAC) in May 2013, adding details regarding the Defendants and their

personal knowledge of the Rat Study and allegations from numerous confidential informants regarding Arena's financial health. The district court dismissed the SAC, holding that the case boiled down to a scientific dispute between Arena and the FDA regarding the safety of lorcaserin. The court then invited a proposed Third Amended Complaint (TAC) to give Schwartz the opportunity to plead facts to "show this case to be about more than a difference of scientific opinion."

Schwartz proffered a TAC, but the district court denied leave to amend saying that amendment would be futile. In the district court's view, the strongest inference from the alleged facts was that Arena experienced an unexpected scientific disagreement with the FDA, and that because there was a reasonable basis to believe that the data supported the Prolactin Hypothesis, the Defendants did not make their omissions with scienter. Schwartz filed a timely appeal.[5]

II. ANALYSIS

Schwartz's theory is simple. At the same time Defendants touted the safety and likely approval of lorcaserin, they referred to the animal studies supporting the FDA application. But once they raised the animal studies, Defendants were obligated to disclose the Rat Study's existence to the market. Failure to do so, in Schwartz's view, demonstrates scienter. Recognizing that this is a close case, we agree. First, we set out the background legal principles

[5] We review de novo the grant of a motion to dismiss, *Nat'l Elevator Indus. Pension Fund v. VeriFone Holdings, Inc. (In re Verifone Holdings, Inc. Sec. Lit.)*, 704 F.3d 694, 700–01 (9th Cir. 2012), as well as denials of leave to amend based on futility, *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 1007 (9th Cir. 2009).

governing private securities fraud claims. Second, we apply these standards to conclude that Schwartz has adequately alleged scienter.

A. *Background Legal Principles*

Under Section 10(b) of the Securities Exchange Act of 1934 (15 U.S.C. § 78j(b)) and SEC Rule 10b-5 (17 C.F.R. § 240.10b-5),[6] Schwartz must allege "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Lloyd v. CVB Financial Corp.*, 811 F.3d 1200, 1206 (9th Cir. 2016) (quoting *Erica P. John Fund, Inc. v. Halliburton Co.*, 563 U.S. 804, 810 (2011)). Only scienter is at issue in this appeal.

Ordinarily, when we review a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), we accept a plaintiff's allegations as true "and construe them in the light most favorable" to the plaintiff, *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 989 (9th Cir. 2009), dismissing the complaint only if it fails "to 'state a claim to relief that is plausible on its face.'" *Id.* (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). But because Schwartz here alleges that Defendants fraudulently violated

[6] Schwartz has also raised a claim under Section 20(a) of the Securities Exchange Act of 1934, for controlling-person liability. Such claims hinge on an underlying violation of section 10(b). *Zucco*, 552 F.3d at 990. Accordingly, because we reverse the district court and hold that Schwartz has sufficiently pleaded scienter on his section 10(b) claim, we similarly reverse, without analysis, the district court's dismissal on the section 20(a) claim. *Id.*

federal securities laws, the equation is altered by the "dual pleading requirements of Federal Rule of Civil Procedure 9(b) and the [Private Securities Litigation Reform Act (PSLRA), 15 U.S.C. § 78u-4]." *Zucco*, 552 F.3d at 990.

Rule 9(b) imposes "a heightened pleading requirement, which requires that a party 'state with particularity the circumstances constituting fraud.'" *Nat'l Elevator Indus. Pension Fund v. VeriFone Holdings, Inc. (In re Verifone Holdings, Inc. Sec. Lit.)*, 704 F.3d 694, 701 (9th Cir. 2012) (quoting Fed. R. Civ. P. 9(b)). Under the rule, however, the "heightened pleading standard" only applies to the circumstances of the fraud and not to the defendant's state of mind. *ESG Capital Partners, LP v. Stratos*, 828 F.3d 1023, 1031–32 (9th Cir. 2016). The PSLRA, however, ups the ante by requiring that "'the complaint . . . specify each statement alleged to have been misleading, [and] the reason or reasons why the statement is misleading,'" *VeriFone*, 704 F.3d at 701 (quoting 15 U.S.C. § 78u-4(b)(1)(B)) (alteration in original), and by requiring that the allegations give "rise to *a strong inference* that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A) (emphasis added). These "heightened pleading requirements for securities fraud cases . . . present no small hurdle for the securities fraud plaintiff." *VeriFone*, 704 F.3d at 701.

Schwartz's burden, therefore, is to allege sufficiently particular facts to demonstrate a strong inference of scienter—a mental state that not only covers "intent to deceive, manipulate, or defraud," *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 48 (2011) (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 319 (2007)), but also "deliberate recklessness," *Zucco*, 552 F.3d at 991

(quotation marks omitted).[7] We have defined "deliberate recklessness" as more than "*mere* recklessness or a motive to commit fraud." *Id.* (emphasis added). Instead, deliberate recklessness is "an *extreme* departure from the standards of ordinary care . . . 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." *Id.* (emphasis added) (internal quotation marks omitted); *accord Ottmann v. Hanger Orthopedic Grp., Inc.*, 353 F.3d 338, 343 (4th Cir. 2003). "A complaint will survive," the Supreme Court has instructed, "only if 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." *Tellabs*, 551 U.S. at 324. All in all, though not impossible, this "is not an easy standard to comply with—it was not intended to be—and plaintiffs must be held to it." *Eminence Capital, LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1052 (9th Cir. 2003) (per curiam).

Of particular importance to Schwartz's theory is the idea that the securities laws "do not create an affirmative duty to disclose any and all material information." *Matrixx*, 563 U.S. at 44. Instead, "companies can control what they have to disclose under these provisions by controlling what they say to the market." *Id.* at 45. But "once defendants cho[o]se to tout" positive information to the market, "they [are] bound to do so in a manner that wouldn't mislead investors," including

[7] Although the Supreme Court has never decided "whether reckless behavior is sufficient for civil liability under § 10(b) and Rule 10b-5," *Tellabs*, 551 U.S. at 319 n.3, "[e]very Court of Appeals that has considered the issue has held that a plaintiff may meet the scienter requirement by showing that the defendant acted intentionally or recklessly . . . ." *Id.*

disclosing adverse information that cuts against the positive information. *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 987 (9th Cir. 2008). Three cases are particularly relevant here: *Matrixx*, *Berson*, and *In re AstraZeneca Sec. Lit.*, 559 F. Supp. 2d 453 (S.D.N.Y. 2008).

In *Matrixx*, the makers of Zicam, Matrixx Initiatives, began receiving complaints from doctors saying that patients were losing their sense of smell when using Zicam to treat the common cold. 563 U.S. at 31. A research doctor, Dr. Linschoten, drew Matrixx's attention to studies linking zinc (the main active ingredient in Zicam) to loss of smell. *Id.* at 32. Matrixx told Dr. Linschoten that it had hired a consultant to review Zicam. A second researcher, Dr. Jafek, soon thereafter published an abstract noting about a dozen patients who had all lost their sense of smell after using Zicam. *Id.* at 32–33. When Drs. Linschoten and Jafek prepared a presentation on Zicam and loss of smell, Matrixx told Dr. Jafek not to use Zicam's name in the presentation. *Id.* at 33. Shortly thereafter, several product liability suits were filed by plaintiffs complaining of damage to their sense of smell. *Id.*

Notwithstanding this information, Matrixx continued to make public statements promoting its belief in Zicam's market growth in the upcoming months. *Id.* at 33–34. In all of its public statements, Matrixx failed to mention either the researchers' concerns or the pending lawsuits over the loss of smell. *Id.* at 33–34, 45–47. Moreover, once investment analysts reported that the FDA was looking into the issue, Matrixx put out press releases saying that the allegations were "unfounded and misleading," and that "[i]n no clinical trial" had the kind of zinc in Zicam caused "a single report of lost or diminished [smell]." *Id.* at 34. Within days, Good Morning America highlighted Dr. Jafek's findings. *Id.* at 35.

The defendants then told the SEC it had put together a panel of doctors and scientists to review Zicam. *Id.* Because of the volatility in Matrixx's stock price, the plaintiffs filed suit. *See id.* at 36.

Matrixx argued that in order to meet the deliberate recklessness standard of scienter, the plaintiffs would have to plead that the defendants "knew of statistically significant evidence of causation" of loss of smell. *Id.* at 48–49. In other words, Matrixx argued it was not required to divulge the information because the information was not strong enough to raise alarm bells. The Supreme Court rejected that argument, noting that there was a strong inference of deliberate recklessness based on Matrixx's (1) telling Dr. Linschoten that it was having an outside consultant review the matter; (2) getting a panel of physicians and scientists to review Dr. Jafek's presentation; (3) demanding that Dr. Jafek remove Zicam's name from the presentation; and (4) suggesting that studies had been done that had not been done. *Id.* at 49. Matrixx was obligated to disclose the issue given its positive statements to the market and the fact that it had "received information that plausibly indicated a reliable causal link between Zicam and [loss of smell]." *Id.* at 45.

In *Berson*, the defendant, Applied Signal Technology, had publically discussed the value of its "backlog"—defined as "the dollar value of the work it ha[d] contracted to do but ha[d]n't yet performed"—to investors. 527 F.3d at 984. However, Applied Signal failed to disclose that "four stop-work orders" had been issued by its clients, leading to a significant risk that the "stopped work" would be "cancelled altogether" and that the company would never actually earn the money from those backlogged orders. *Id.* We explained that, generally, Applied Signal had no obligation to discuss

the backlog at all: "Had [Applied Signal] released no backlog reports, their failure to mention the stop-work orders might not have misled anyone." *Id.* at 987. "But," we continued, "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 that backlog consisted of." *Id*.

In contrast, the defendants in *AstraZeneca* were developing a blood thinner, Exanta, to compete with the existing gold-standard drug, Warfarin. 559 F. Supp. 2d at 457. The defendants released numerous press releases, made SEC filings, and held teleconferences touting the likely approval of the drug and its safety profile. *Id.* at 458–62. However, as an Advisory Committee meeting approached, the FDA published a briefing document online that disagreed with the safety profile of the drug and took an overall negative view of it. *Id.* at 462. When the stock price dropped, the plaintiff filed suit. But the district court dismissed the complaint on scienter grounds. *Id.* at 472. The court noted that the collective statements of the defendants had disclosed risks of injury associated with the drug in public statements, and that, in the end, the FDA simply had a different interpretation of the safety profile. *Id.* at 470–71. Thus, because there were no allegations "to indicate that the [public] statements made did not reflect the honest belief of the authors," the court held there was no strong inference of deliberate recklessness. *Id.* at 471–72.

B. *Analysis*

Applying these principles, we conclude that Schwartz has alleged scienter with sufficient particularity to survive a motion to dismiss. There is no question that Schwartz has alleged that Defendants knew that the Rat Study existed. *See*

Matrixx, 563 U.S. at 31–32 (defendants made aware of negative studies); *Berson*, 527 F.3d at 984 (defendants knew of stop-work orders). Similarly, Schwartz has alleged that Defendants knew that the FDA's request for bi-monthly reports and follow-up studies was "highly unusual" and "out-of-process." But in full knowledge of this, Defendants went ahead and told investors about their confidence in lorcaserin's approval being based on "the *preclinical* studies that [were] done, [and] *all the animal studies that have been completed*." (Emphasis added.) The public was assured that lorcaserin's "long-term safety and efficacy" (and thus the likelihood of its imminent approval) were "demonstrated" through "long-term preclinical toxicity and carcinogenicity studies." These "preclinical, animal studies" were done, according to Arena, "to help [Arena] and regulatory authorities assess the potential risk that drug candidates may be toxic or cause cancer in humans."

Defendants may not have had a duty to disclose the Rat Study had they not been representing that animal studies supported lorcaserin's safety and therefore its likelihood of being approved. "[C]ompanies can control what they have to disclose under these provisions by controlling what they say to the market." *Matrixx*, 563 U.S. at 45. But here, to paraphrase our holding in *Berson*, "once defendants chose to tout [lorcaserin's likely approval by referencing allegedly positive animal and preclinical studies], they were bound to do so in a manner that wouldn't mislead investors as to [potentially negative information within their possession]." *Berson*, 527 F.3d at 987. Arena's failure to inform the market about the risk of non-approval or delayed approval based on the FDA's "concerns" about the Rat Study was "an extreme departure from the standards of ordinary care . . . [that] present[ed] a danger of misleading buyers or sellers that

[was] either known to [Arena] or [was] so obvious that [Arena] must have been aware of it." *Zucco*, 552 F.3d at 991 (internal quotation marks omitted).

Arena did more than just express its confidence in lorcaserin's future. It affirmatively represented that "all the animal studies that [had] been completed" supported Arena's case for approval. And at the time these statements were made by various Arena officials in 2009, Arena knew that the animal studies were *the* sticking point with the FDA. Contrary to Arena's representations to investors, it was not true that the "preclinical, animal studies" demonstrated the "long-term safety and efficacy" of lorcaserin or "the potential risk that [it] may be toxic or cause cancer in humans." It was also not true that Arena had "all of the data in hand" or that "everything that [they had] compiled so far" was "favorable." These statements were representations about lorcaserin that Arena could not, in fact, support at the time they were made. Arena was free to express confidence in FDA approval. It might have represented that Arena was working through some requests from the FDA and was confident the data would vindicate lorcaserin. But what it could not do was express confidence by claiming that all of the data was running in lorcaserin's favor. It was not.

To be sure, as Defendants point out, there is not any specific allegation about the *content* of the FDA's concerns with the Rat Study prior to the publication of the briefing document. But as Arena's 2010 disclosure, following the FDA's announcement, makes crystal clear:

> [W]e conducted long-term carcinogenicity preclinical studies of lorcaserin. The FDA identified in the [Complete Response Letter

> ("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 [Application]*.

(Emphasis added.) In other words, it seems quite clear that Arena understood that the FDA did not entirely agree with Arena's views of the Rat Study. Indeed, FDA documents note that "[Arena] was made aware of [the FDA's] *concerns*" and was asked to "*defend* continuation" of the clinical testing in light of the "nonclinical tumor/cancer data." (Emphasis added.) Defendants obviously felt the need to respond by complying with the follow-up test requests. And they obviously felt the need to hire a pre-eminent expert to make the case that the Prolactin Hypothesis was supported. Defendants' own response to the issue contributes to an inference of scienter here. *Cf. Matrixx*, 563 U.S. at 49–50 (defendant's decision to "convene[] a panel of physicians and scientists" in response to undisclosed allegations of negative health effects from the defendants' product contributed to a "'cogent and compelling' inference that [the defendant] elected not to disclose the reports of adverse events not because it believed they were meaningless but because it understood their likely effect on the market"). This further buttresses our conclusion that Schwartz has adequately alleged scienter.

Defendants attempt to avoid this conclusion by noting that all of the relevant statements contained in Schwartz's pleadings came *after* the sit-down meeting with the FDA, and

that the result of that meeting was to permit Arena to go on with the BLOOM and BLOSSOM studies. Moreover, Defendants heard nothing between the time they submitted the final Rat Study report in 2009 and the 2010 disclosure by the FDA. Thus, in Defendants' view, because the last thing they heard from the FDA was "positive," they were free to make the comments they did without disclosing the Rat Study. But the mere fact that the BLOOM and BLOSSOM studies were allowed to continue is insufficient to override the "highly unusual" nature of the procedures invoked by the FDA concerning the Rat Study. Nor can the FDA's silence be taken as tacit approval such that Defendants were relieved from the duty to disclose the Rat Study when they chose to invoke "animal studies" as a grounds for their confidence in lorcaserin's approval.

Defendants contend that this case is really just like *AstraZeneca*: a good-faith scientific disagreement between the FDA and Arena about the meaning of the Rat Study and support for the Prolactin Hypothesis. If it were simply the case that this dispute turned on whether scienter could exist based on the reasonableness of Arena's interpretation of the Rat Study versus the FDA's interpretation, there would be little question Defendants would have the better argument. *See AstraZeneca*, 559 F. Supp. 2d at 471 ("As of the time when the FDA Advisory Committee met . . . , AstraZeneca had its side of the case and the FDA staff had its side. The FDA staff view prevailed before the Advisory Committee. This does not mean that AstraZeneca was not conscientious in advocating the 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."). However, the simple fact that Arena had an explanation for its view of the data does not mean investors would not want

to know that Arena and the FDA were at odds. Arena could have remained silent about the dispute or it could have addressed its discussions with the FDA head-on. But it could not represent that there was no controversy here because all the data was favorable. As Schwartz explains, his "theory of fraud is not that Defendants intentionally misled the market about the objective safety of lorcaserin. Rather, [Schwartz'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." It is the failure to disclose "issues" and "concerns" with the Rat Study and the FDA's interest in the outcome of those studies—not who was ultimately right about the underlying science—that matters. *Cf. Matrixx*, 563 U.S. at 43 ("Given that medical professionals and regulators act on the basis of evidence of causation that is not statistically significant, it stands to reason that in certain cases reasonable investors would as well."). And it sure mattered to investors, who were understandably concerned by the information revealed in the FDA's 2010 briefing documents.[8]

[8] We reject Schwartz's argument, however, that the vague and largely unsubstantiated allegations from confidential informants support a strong inference of scienter. We have cautioned securities plaintiffs that, absent some truly compelling allegations, we will not consider routine business behavior (like firing people or raising capital) to serve as the basis for scienter. *See In re Rigel Pharm., Inc. Sec. Lit.*, 697 F.3d 869, 884–85 (9th Cir. 2012) ("[A]llegations of routine corporate objectives such as the desire to obtain good financing and expand are not, without more, sufficient to allege scienter."). Holding otherwise "would support a finding of scienter for any company that seeks to enhance its business prospects." *Id.* at 884. Although this deprives Schwartz's complaint of allegations about Defendants' motives, "absence of a motive allegation, though relevant, is not dispositive." *Matrixx*, 563 U.S. at 48.

III. CONCLUSION

Rule 9(b) and the PSLRA create a significant barrier for private securities plaintiffs. But it is not an impossible barrier; nor was it meant to be. We "must review all the allegations holistically" to determine whether Schwartz has met the relevant pleading standards. *Matrixx*, 563 U.S. at 48 (internal quotation marks omitted). We conclude that he has.[9]

REVERSED and REMANDED.

[9] Because the district court also dismissed the Section 20(a), controlling-person liability claim on scienter grounds, we reverse on that point as well. *See supra* n.6; *Zucco*, 552 F.3d at 990.