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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

IN RE XENOPORT, INC. SECURITIES LITIGATION	No. C-10-03301 RMW ORDER GRANTING MOTION TO DISMISS FIRST AMENDED COMPLAINT **[Re Docket No. 47]**

Defendant XenoPort, Inc. ("XenoPort") and individual defendants Ronald W. Barrett (Chief Executive Officer), William J. Rieflin (President), David A. Stamler (Chief Medical Officer), and David R. Savello (Senior Vice President of Development) move to dismiss all claims asserted against them in plaintiff's First Amended Complaint for Violation of the Federal Securities Laws ("FAC"). On October 28, 2011, the court held a hearing to consider defendants' motion. Having considered the papers submitted by the parties and the arguments of counsel, and for the reasons set forth below, the court grants defendants' motion to dismiss.

I. BACKGROUND

Plaintiff brings this class action on behalf of all purchasers of XenoPort stock between May 7, 2008 and February 17, 2010 (the "Class Period"), seeking to pursue remedies under the Securities Exchange Act of 1934, 15 U.S.C. § 78(a) *et seq.* FAC ¶ 1. XenoPort is a pharmaceutical company that focuses on developing medications that use the body's natural nutrient transport mechanisms to

improve the therapeutic benefits of existing drugs. *Id.* ¶ 2. During the Class Period, one of XenoPort's most advanced drug candidates was Horizant (gabapentin encarbil), a modified form of the generic drug gabapentin. *Id.* Horizant was also referred to as XP13512, or "512" for short. XenoPort developed Horizant as a potential treatment for Restless Leg Syndrome. *Id.*

Plaintiff alleges that defendants are liable for false and misleading statements about Horizant that inflated XenoPort's stock price during the Class Period. Specifically, on a May 7, 2008 conference call with analysts, Dr. Barrett discussed the company's Horizant toxicology studies:

> **Katherine Xu** - *Credit Suisse - Analyst*
>
> Ron, could you give us a summary of the long-term tox studies of gabapentin, what we know and what you know, and also an update potentially on your long-term tox studies for the 512 compound?
>
> **Ron Barrett** - *XenoPort, Inc. - CEO*
>
> Sure. With regard to gabapentin, this is a molecule that has a remarkable preclinical safety profile. Doses in the studies with gabapentin went up to 2 grams per day in rodents and also a very high level in the monkey studies, and really the only chronic toxicology finding that was in those studies was hyaline droplet formation in the kidneys that led to kidney damage. And that's a known effect of molecules in the chemical structure class of gabapentin, where the drug binds the alpha-2-microglobulin and forms these droplets in the kidneys. That is a male Wistar rate [sic] phenomenon. It doesn't occur in other species and has been deemed to be not relevant to human toxicology.
>
> In terms of carcinogenicity, the one finding in the gabapentin studies was pancreatic acinar cell tumors in male Wistar rates [sic] at the highest dose. And, again, the work was done to get the FDA comfortable that this did not represent a significant risk to humans. It was found only in rats, only in male rats, and not in other -- in mice.
>
> With regard to our package, we've done a full clinical or preclinical safety package that included long-term tox as well as two-year carcinogenicity studies in two species. And what we've indicated is that the safety profile is very similar if not identical to gabapentin, that we have not uncovered any issues that we believe will affect the NDA timing nor the probability of successful NDA approval from the preclinical tox side.

FAC ¶ 27; Dkt. No. 48 Exh. C at 6-7.[1] Plaintiff emphasizes Dr. Barrett's statement that "the safety profile [of Horizant] is very similar if not identical to gabapentin." FAC ¶ 27. Plaintiff alleges that Dr. Barrett's statements on the conference call were false because XenoPort's studies had revealed that Horizant causes cancer in both male and female rats, whereas cancer caused by gabapentin was observed only in male rats. *Id.* ¶¶ 28, 32-33.

[1] As discussed below, the court takes judicial notice of certain documents as requested by the parties.

On March 16, 2009, XenoPort filed a new drug application ("NDA") for Horizant with the U.S. Food and Drug Administration ("FDA"). FAC ¶ 32. On April 9, 2009, XenoPort stated in a SEC filing that Dr. Barrett, Mr. Rieflin, and Dr. Savello had each received between 85% and 90% of their respective maximum 2008 corporate bonuses, based on their high achievement target levels. *Id.* ¶¶ 43-46. The filing specifically noted "Dr. Barrett's key role in the company's successful completion of the Phase 3 clinical trial program for the company's lead product candidate [Horizant], and the related filing of the new drug application with the U.S. Food and Drug Administration." *Id.* ¶ 44. On July 8, 2009, XenoPort announced the pricing of a secondary public offering, selling shares of common stock at $19 per share, which ultimately generated over $40 million in proceeds for the company. *Id.* ¶ 34.

On February 17, 2010, XenoPort received a Complete Response letter from the FDA, stating its determination that it could not approve the Horizant NDA in its current form. FAC ¶ 37; Dkt. No. 48 Exh. K. After the market closed, XenoPort issued a press release stating they had received the Complete Response letter and that "the FDA indicated that a preclinical finding of pancreatic acinar cell tumors in rats was of sufficient concern to preclude approval of Horizant for [Restless Leg Syndrome] at this time." FAC ¶ 37. The following morning, before the market opened, XenoPort held a conference call with analysts. *Id.* ¶ 38. On the call, Dr. Barrett explained that XenoPort had observed cancer in female rats in its Horizant studies:

> **Steve Yoo** - *Leerink Swann - Analyst*
>
> Okay. Just to clarify, it was only seen in male Wistar rats, right, XP512 carc signal?
>
> **Ron Barrett** - *XenoPort, Inc. - CEO*
>
> In our study because 512 is -- produces higher exposures than gabapentin, it was an equivocal signal seen in the highest dose in female rats. It was more prevalent in the male rats.
>
> **Steve Yoo** - *Leerink Swann - Analyst*
>
> So it was more prevalent in the female rats than male rats for the 512 study?
>
> **Ron Barrett** - *XenoPort, Inc. - CEO*
>
> No, the opposite. It was clear in male. It was equivocal in females at the highest dose, which produces exposures that exceed those for which gabapentin was tested in four of them.

Id. ¶ 38; Dkt. No. 48 Exh. E at 7.

On February 17, 2010, XenoPort's stock had closed at $19.60 per share. FAC ¶ 36. During the Class Period, the stock price had reached a high of $24.75, on September 17, 2009. *Id.* ¶ 35. On February 18, 2010, after XenoPort's press release and conference call, XenoPort's stock opened at $6.91 per share. *Id.* ¶ 39. Pre-market stock price reports indicate that the plunge in XenoPort's stock price had occurred by 8:17 AM – before the conference call began at 8:30 AM. Dkt. No. 48 Exhs. O, P; FAC ¶ 39.

Horizant was ultimately approved by the FDA on April 6, 2011. FAC ¶¶ 28, 53.

II. ANALYSIS

A. Requests for Judicial Notice

Defendants and plaintiff have submitted separate requests for judicial notice concerning documents quoted or referenced in the FAC, XenoPort's stock prices, FDA guidance, and SEC filings by XenoPort. Dkt. Nos. 49, 52. Because these are all types of information that may be considered on a motion to dismiss, the parties' requests are granted. *See* Fed. R. Evid. 201; *Branch v. Tunnell*, 14 F.3d 449, 454 (9th Cir. 1994), *overruled on other grounds by Galbraith v. Cnty. of Santa Clara*, 307 F.3d 1119 (9th Cir. 2002) ("[D]ocuments whose contents are alleged in a complaint and whose authenticity no party questions, but which are not physically attached to the pleading, may be considered in ruling on a Rule 12(b)(6) motion to dismiss."); *Brodsky v. Yahoo! Inc.*, 630 F. Supp. 2d 1104, 1111-12 (N.D. Cal. 2009) ("[H]istoric stock prices are subject to accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned."); *Mack v. S. Bay Beer Distribs.*, 798 F.2d 1279, 1282 (9th Cir. 1986), *criticized on other grounds by Astoria Fed. Sav. & Loan Ass'n v. Solimino*, 501 U.S. 104 (1991) (finding a court may take judicial notice of matters of public record, including records and reports of administrative bodies); *In re CNET Networks, Inc.*, 483 F. Supp. 2d 947, 953-54 (N.D. Cal. 2007) (finding a court may take judicial notice of public filings on a motion to dismiss).

Defendants oppose plaintiff's request on the grounds that plaintiff is improperly trying to go beyond the complaint to remedy deficient allegations. However, the Federal Rules of Evidence provide "[a] court *shall* take judicial notice if requested by a party and supplied with the necessary

information." Fed. R. Evid. 201(d) (emphasis added). Plaintiff's request concerns information that is properly the subject of judicial notice – indeed, the same kinds of information for which defendants have requested notice. Thus, the court takes judicial notice of Exhibits A through U attached to the declaration of John C. Dwyer, Dkt. No. 48, and exhibits A through D attached to the declaration of Samuel K. Rosen, Dkt. No. 53.

B. Plaintiff's Section 10(b) Claim

To state a claim under Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, 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 plaintiff's injury. *DSAM Global Value Fund v. Altris Software, Inc.*, 288 F.3d 385, 388 (9th Cir. 2002) (citation omitted). In their motion, defendants challenge the sufficiency of plaintiff's allegations on every element except for reliance.

1. Falsity

Under the Private Securities Litigation Reform Act ("PSLRA"), a complaint must specify each statement alleged to have been misleading and the reason or reasons why the statement is misleading. 15 U.S.C. § 78u-4(b)(1). Plaintiff alleges that Dr. Barrett's statement about Horizant having a safety profile "very similar if not identical to gabapentin" is false because there are differences between Horizant and gabapentin, including that Horizant was observed to cause cancer in female as well as male rats. FAC ¶¶ 3, 27-31, 33. Defendants argue that, while plaintiff may have established that Horizant's safety profile is not "identical" to gabapentin's, plaintiff has failed to plead that the results were not "very similar" as Dr. Barrett stated. Defendants argue that the FDA considered the results "similar," that Dr. Barrett was comparing more than the rat carcinogenicity studies, and that Horizant was tested at higher levels of exposure than gabapentin, so there was no way to know whether gabapentin would also cause cancer in female rats at the same level. Plaintiff responds that, while Horizant and gabapentin may be "similar," the alleged differences are sufficient to show they are not "very similar if not identical."

Dr. Barrett's statement must be understood in context. In response to an analyst's question about both compounds, he first addressed the findings for gabapentin. Then, instead of directly

describing any of Horizant's study results, Dr. Barrett stated that its "safety profile is very similar if not identical to gabapentin." Drawing all reasonable inferences in plaintiff's favor, Dr. Barrett's statement would suggest to listeners that Horizant is "very similar if not identical to gabapentin" particularly with respect to the findings that Dr. Barrett had mentioned.[2] In describing gabapentin, Dr. Barrett drew attention to the fact that the toxicology and carcinogenicity findings were limited to male rats, including saying that cancer "was found only in rats, *only in male rats,* and not in other -- in mice." FAC ¶ 27 (emphasis added). A reasonable interpretation of Dr. Barrett's statement is that Horizant is similar to gabapentin in that adverse results were observed only in male rats. Thus, the court finds the FAC sufficiently alleges that Dr. Barrett's statement was misleading.

2. Scienter

Under the PSLRA, "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)(A). For liability under Section 10(b), a plaintiff must show the defendant acted with scienter, "a mental state embracing intent to deceive, manipulate, or defraud." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 319 (2007). In the Ninth Circuit, scienter may be met by a showing of "deliberate recklessness," which requires "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." *Zucco Partners, LLC, v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009). For a complaint to survive, the inference of scienter must be "cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs*, 551 U.S. at 324. A court must therefore consider "plausible nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff." *Id.* at 323-24. The ultimate question is

[2] Defendants made essentially that point when they argued, in an earlier motion, that Dr. Barrett's statements constituted a disclosure that Horizant causes cancer in rats. Dkt. No. 24 at 5-6, 17. Dr. Barrett did not explicitly state that Horizant causes cancer in rats. Rather, Dr. Barrett said gabapentin causes cancer in rats, and Horizant was "very similar if not identical."

"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." *Id.* at 323.

Plaintiff primarily makes two sets of allegations to support scienter. First, plaintiff alleges that defendants were motivated to artificially inflate XenoPort's stock price to assure the completion of a secondary offering at $19 per share, with the aim of increasing their compensation under XenoPort's corporate bonus plan. FAC ¶ 42. However, plaintiff's allegations concern defendants' 2008 bonuses, as reported in an April 2009 SEC filing, whereas the secondary public offering was announced in July 2009.[3] The secondary offering therefore does not explain why the bonuses support an inference of scienter. Most of the performance objectives on which defendants' bonuses were based are internally focused and would not be affected by stock price, such as preclinical and clinical development milestones, research and development objectives, and internal business and financial objectives. FAC ¶¶ 43-44. Moreover, "routine business objectives, without more, cannot normally be alleged to be motivations for fraud." *Lipton v. Pathogenesis Corp.*, 284 F.3d 1027, 1038 (9th Cir. 2002). Similarly, courts have held that corporate bonuses, even those explicitly tied to financial performance or stock price, have only limited probative value as to scienter. *In re Syncor Int'l Corp. Sec. Litig.*, 239 Fed. Appx. 318, 321 (9th Cir. 2007) (unpublished); *In re Downey Sec. Litig.*, 2009 U.S. Dist. LEXIS 83443 at *41-42 (C.D. Cal. 2009). To support an inference of scienter, there must be "[a] strong correlation between financial results and stock options or cash bonuses," which requires allegations "indicating how intimately the bonuses were tied to the company's financials." *Zucco*, 552 F.3d at 1004-05. Such allegations are absent here.

Defendants argue that the bonuses alleged here not only do not support an inference of scienter but support an opposing inference of good faith because the bonuses were paid in stock. It would be nonsensical, defendants argue, for them to accept their bonuses in the very stock whose price they had allegedly artificially inflated, particularly because plaintiff has not alleged that any

[3] With respect to Dr. Barrett, plaintiff argues this is irrelevant because Dr. Barrett "received a bonus based on one offering that relied on fraudulently inflated stock prices." Dkt. No. 51 at 16 n. 8. Plaintiff apparently refers to the SEC filing's mention of "the completion of a $40 million registered direct financing," on which Dr. Barrett's bonus was partially based. FAC ¶ 44. However, plaintiff does not allege any details of this financing that would allow the court to infer any connection between it and Dr. Barrett's alleged misrepresentation.

defendants disposed of those shares while their price was still inflated. Courts have held that investments in the company's stock during the class period undermine an inference of scienter. *See Zack v. Allied Waste Indus., Inc.*, 2005 WL 3501414 at *14 (D. Ariz. 2005), *aff'd*, 275 F. Appx. 722 (9th Cir. 2008); *In re Allergan Inc. Sec. Litig.*, 1993 WL 623321 at *22 (C.D. Cal. 1993). Plaintiff does not dispute that the bonuses were paid in stock but points out that the shares appear to have been fully vested. Thus, plaintiff argues, the bonus shares could have been sold immediately but defendants simply chose not to. However, since plaintiff has not articulated a reason defendants would knowingly hold on to allegedly inflated shares, the fact that the shares were vested does not undermine defendants' argument that receiving and keeping stock is inconsistent with scienter.

Plaintiff in his opposition also points for the first time to evidence of stock sales by certain defendants: Dr. Savello's sale of approximately 45% of his XenoPort stock on May 12, 2008, five days after the alleged misrepresentation, and later dispositions of XenoPort shares by Drs. Barrett and Savello. Suspicious stock sales can give rise to an inference of scienter, but only "when they are dramatically out of line with prior trading practices at times calculated to maximize the personal benefit from undisclosed inside information." *Metzler Inv. GmbH v. Corinthian Colleges, Inc.*, 540 F.3d 1049, 1066-67 (9th Cir. 2008). Such a showing typically requires large sales amounts and corroborative sales by other defendants. *Id.* at 1067 (finding no scienter where two defendants sold less than half their holdings and third defendant sold nothing at all). Dr. Savello's sale, while arguably large, is uncorroborated by sales by any other defendants, including defendants who were actually on the May 2008 conference call. The later dispositions of stock all involved small percentages and appear to be shares withheld to pay taxes in connection with acquisitions of additional shares. *See* Dkt. No. 53 Exh. D. Thus, plaintiff's new evidence of alleged insider trading is insufficient to support an inference of scienter. Defendants' stock transactions, as a whole, are at best equivocal on the issue of scienter.

Plaintiff's second set of scienter allegations relies on the "core operations" inference: that based on the small size of the company, the significant role each defendant played as a member of XenoPort's executive circle, and the importance of Horizant to the company during the Class Period, scienter may be inferred as to each defendant. FAC ¶¶ 48, 50. Under *Tellabs*, core operations

allegations are considered as part of a holistic review of all of the allegations in the complaint. *South Ferry LP, #2 v. Killinger*, 542 F.3d 776, 784 (9th Cir. 2008). However, the core operations inference standing alone will generally not support a strong inference of scienter absent "additional detailed allegations about the defendants' actual exposure to information." *Id.* at 784-85. Here, plaintiff alleges only generally that defendants' were aware of the concealment of the cancer indications in female rats, without specific details about what information each defendant was exposed to. In addition, plaintiff does not allege that individual defendants other than Dr. Barrett and Mr. Rieflin were on the May 2008 conference call, so they were not directly exposed to the alleged misrepresentation. As to Dr. Stamler, plaintiff relies solely on a core operations inference, as there are no allegations that he received a bonus. *See* Dkt. No. 51 at 20 & n.11.

Taken as a whole, plaintiff's complaint reflects little more than an ordinary company trying to achieve typical business objectives and incentivizing its executives through a bonus program. Beyond the alleged misrepresentation itself, plaintiff presents no unusual or suspicious circumstances, and there is little to link most of the defendants to the misrepresentation in the first place. The alleged misrepresentation seems to boil down to an argument about whether Horizant and gabapentin were "very similar" or merely "similar." Such a distinction does not create a highly unreasonable omission that would put defendants on notice of the danger of misleading investors. Thus, the allegations, taken collectively, do not give rise to a cogent inference that any defendant acted with either deliberate recklessness or fraudulent intent.

Even as to Dr. Barrett, for whom the inference of scienter is somewhat stronger, defendants have offered plausible nonculpable explanations that make the opposing inference of innocence more compelling. According to Dr. Barrett, XenoPort had performed "a full clinical or preclinical safety package that included long-term tox as well as two-year carcinogenicity studies in two species." FAC ¶ 27. Although neither side has indicated the full extent of these studies, Dr. Barrett's statement shows they were not limited to carcinogenicity nor to rats. It is plausible that the finding of cancer in female rats did not stand out as a prominent difference between Horizant and gabapentin in Dr. Barrett's mind when he compared their study results as a whole, and that this was the perspective from which he was speaking on the conference call. In addition, defendants argue

that no direct comparison could be made between the female rat cancer caused by Horizant and any gabapentin study results. Dr. Barrett explained that cancer had been observed in female rats exposed to the highest dose of Horizant, "which produces exposures that exceed those for which gabapentin was tested." FAC ¶ 38. This provides another explanation how Dr. Barrett could have honestly considered the two drugs' safety profiles "very similar if not identical" while fully aware of the female rat results.

Thus, plaintiff has failed to allege facts giving rise to a strong inference of scienter, and his Section 10(b) claim must be dismissed. Because the failure to allege scienter is fatal to plaintiff's claim, the court does not address the issues of materiality and loss causation.

C. Plaintiff's Section 20 Claim

Section 20(a) makes liable those who directly or indirectly control a person who is directly liable for a violation of the Securities and Exchange Act, unless the controlling person acted in good faith and did not directly or indirectly induce the acts constituting the violation. 15 U.S.C. § 78t(a). To establish "control person" liability, a plaintiff must show that a primary violation was committed and that the defendant directly or indirectly controlled the violator. *Paracor Fin., Inc. v. Gen. Elec. Capital Corp.*, 96 F.3d 1151, 1161 (9th Cir. 1996). Because plaintiff has failed to plead a direct violation of Section 10(b) as discussed above, plaintiff's Section 20 claim must also be dismissed.

D. Leave to Amend

Defendants urge the court to dismiss the complaint without leave to amend, citing *In re Vantive Corp. Sec. Litig.*, 283 F.3d 1079, 1097 (9th Cir. 2002) ("Leave to amend need not be granted when an amendment would be futile."). Plaintiff did not request leave to amend in his papers or at the hearing. Although plaintiff introduces certain new facts in his opposition relating to defendants' stock sales, the court does not find that these facts would remedy the failure to allege scienter. Plaintiff also introduced a new theory at the hearing: that XenoPort's original NDA presented Horizant to the FDA as a new drug unrelated to any existing drug, and that XenoPort resubmitted its NDA and ultimately gained FDA approval by relying on the studies for gabapentin and admitting that Horizant was not as novel a drug as originally presented. The court notes that this is now the third time plaintiff has significantly reformulated his ever-changing theory of the case. However,

even if allowed to amend, plaintiff has not shown how this theory is tied to any representation made to investors, nor has plaintiff shown that he could allege facts suggesting that defendants acted with scienter in submitting the original NDA. Moreover, plaintiff's new theory is at odds with the allegation that defendants misrepresented that Horizant was *more similar* to gabapentin than it actually was. Plaintiff confirmed at the hearing that that representation is the asserted fraud on the market. Because plaintiff has not shown what new facts or theories he would plead that might render his complaint viable, the court finds it appropriate to dismiss the complaint with prejudice. *See Vantive*, 283 F.3d at 1098.

III. ORDER

For the foregoing reasons, the court grants defendants' motion to dismiss. The First Amended Complaint is dismissed without leave to amend.

DATED: 12/12/2011

RONALD M. WHYTE
United States District Judge