UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE VERTEX PHARMACEUTICALS, INC., SECURITIES LITIGATION.	Consolidated Civil Action No. 03-11852-PBS

MEMORANDUM AND ORDER

February 18, 2005

Saris, U.S.D.J.

I. INTRODUCTION

This case involves a securities class action against defendants Vertex Pharmaceuticals Incorporated ("Vertex") and certain officers and directors of Vertex[1] on behalf of persons who acquired publicly traded securities of Vertex between March 9, 1999 and September 24, 2001 (the "Class Period"). Plaintiffs allege that defendants failed to disclose toxicity problems in their leading drug candidate, VX-745, involving adverse effects on the central nervous system ("CNS"), in a timely manner, and

[1] The individual defendants are: Joshua S. Boger, Chief Executive Officer and Chairman of the Board during the Class Period; Andrew S. Marks, Patent Counsel during the Class Period; Vicki L. Sato, President during the Class Period; John J. Alam, M.D., Senior Vice President of Drug Evaluation and Approval during the Class Period; and Mark Murcko, Chief Technology Officer and Chair of the Scientific Advisory Board during the Class Period.

that senior management knew prior to September 2001 that VX-745 was not a marketable drug. They allege that defendants made false and misleading statements with regard to the drug and Vertex's drug development process, in violation of §10(b) and §20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b), 78t(a), and Rule 10b-5 promulgated by the Securities and Exchange Commission (SEC), 17 C.F.R. §240.10b-5. Defendants move to dismiss plaintiffs' Consolidated Amended Complaint under Federal Rule of Civil Procedure 12(b)(6), arguing that the complaint does not meet the heightened pleading requirements of the Private Securities Litigation Reform Act (PSLRA), 15 U.S.C. §78u-4(b), which establishes specific pleading requirements for fraud claims under the Securities Exchange Act of 1934.[2] After hearing, the motion is **ALLOWED**.

II. FACTUAL BACKGROUND

Drawing all inferences in favor of the plaintiffs, the amended complaint alleges the following facts (unless otherwise cited), many of which the defendants dispute.

Vertex is a biotechnology company based in Cambridge, Massachusetts with more than 700 employees worldwide. Throughout the Class Period, Vertex claimed a unique drug development

[2] Defendant Marks also moves to dismiss the complaint on the ground that he is not a "controlling person" within the meaning of § 20(a)(Docket No. 66). Because the complaint is dismissed on other grounds, that argument need not be considered here.

process that accelerated the usually lengthy period from drug discovery to commercialization. In 1997, Vertex began developing a compound called VX-745, a p38 mitogen activated protein (MAP) kinase inhibitor targeted for the treatment of inflammatory and neurological diseases.

Plaintiffs allege that defendants should have predicted before clinical testing began that VX-745 would cross the blood-brain barrier, based on the drug's chemical structure – in particular its molecular weight and lipophilicity (ability to dissolve in oily organic compounds called lipids). The blood-brain barrier is a selective filter that regulates the transport of certain molecules from the blood to the brain, and protects the brain from substances in the blood that would cause undesirable effects in the brain. See Principles of Pharmacology: The Pathophysiologic Basis of Drug Therapy 85 (David E. Golan, et. al. eds., 2005). Plaintiffs state that the likelihood that a given drug candidate will cross the blood-brain barrier and enter the CNS (which includes the brain and spinal cord; see id. at 72) increases the risk that the drug candidate will be dangerous.

In the standard drug development process, new drug candidates are tested *in vitro* (outside of any living organism) and on animals before human testing begins, during "preclinical

testing." See Michelle Meadows, The FDA's Drug Review Process: Ensuring Drugs are Safe and Effective (2002), at http://www.fda.gov/fdac/features/2002/402_drug.html. The role of the Food and Drug Administration ("FDA") begins when a drug sponsor submits an Investigational New Drug Application ("INDA"), which includes the results of the preclinical testing of the drug and other relevant information. Id. Based on this data, the FDA decides whether it is reasonably safe to move forward to testing of the drug on humans. Id.

If the FDA approves testing in humans and the INDA is approved by a local Institutional Review Board (IRB), a panel of scientists and non-scientists that oversees clinical research, Phase I clinical trials can begin. Id. Phase I testing of a drug is usually performed on healthy volunteers, and is intended to determine a drug's side effects and how the drug is metabolized and excreted. Id. If Phase I studies do not reveal unacceptable toxicity, Phase II studies may be initiated. Id. (Toxicity is a measure of the deleterious effect of a particular substance on a organism. See Principles of Pharmacology at 719.) Phase II studies are focused on whether a drug is effective, and provide preliminary data on how a drug works in patients with a particular condition. See Meadows, supra. Phase III studies begin if effectiveness is shown in Phase II, and are more extensive than Phase II studies, usually involving more patients and a

longer study period. Id.

After Phase III trials, when a drug sponsor is ready to seek approval from the FDA to market its new drug in the United States, it submits a formal request called a New Drug Application ("NDA"). Id. The NDA must include all human and animal data on a drug, as well as other relevant information. Id. Phase IV clinical studies are undertaken after a drug has been approved, and may explore new uses for a drug, drug dosages, or long term effects of the drug. Id.

In September 1997, Vertex entered into an agreement with Kissei Pharmaceutical Co., Ltd. ("Kissei") for the development and commercialization of drugs to treat inflammatory and neurological diseases. Vertex announced in 1998 that the two companies planned to begin clinical development of VX-745 the following year, after completion of preclinical studies.

Vertex announced on March 9, 1999, that VX-745 was entering Phase I clinical trials. From that date until late in 2001, Vertex continually reported on the success of VX-745. On November 2, 1999, Vertex announced the initiation of an "exploratory" 28-day Phase II clinical trial of VX-745 on ten patients with rheumatoid arthritis.

In May 2000, Vertex announced a collaboration with Novartis Pharma AG to develop and commercialize drugs directed at targets in the kinase protein family. Under the agreement, Novartis

promised an initial payment of $15 million to Vertex, as well as $200 million in research funding over six years. The agreement provided that the collaboration could be terminated by either party if the party could demonstrate that a compound covered by the agreement would not be a viable drug candidate. (Defendants point out, however, that the agreement excluded VX-745.)

On January 4, 2001, Vertex issued a press release announcing the start of a Phase II clinical trial of VX-745 for rheumatoid arthritis.

Vertex entered into negotiations with Aurora Biosciences Corporation ("Aurora") in March 2000. On July 18, 2001, Vertex completed a merger with Aurora, a transaction valued at $529 million.

Vertex announced its intention to suspend clinical development of VX-745 on September 24, 2001, citing adverse findings in nonclinical animal tests – specifically, that VX-745 had been found to cross the blood-brain barrier into the central nervous system. In a press release, the company stated that the nonclinical animal tests in which the adverse findings were made "were conducted as part of standard nonclinical safety evaluations in support of long term human clinical studies." The press release went on to say that while "[n]o neurological side effects associated with the drug ha[d] been observed in clinical trials ... Vertex voluntarily made the decision ... to suspend

the trial." Vertex shares fell drastically in response to this news.

On December 3, 2002, the SEC announced that insider trading charges had been filed against Defendant Marks, the highest ranking attorney at Vertex. The SEC alleged that Marks learned of the planned suspension of VX-745 on September 20, 2001, and sold all of his Vertex stock on that day. Marks pled guilty to these charges. Plaintiffs allege that defendants Sato and Alam also received illegal insider trading benefits of approximately $3 million.

According to plaintiffs, Vertex's decision to suspend testing of VX-745 was based on test results that were known to defendants before commencement of clinical testing in March 1999. Thus, the defendants ignored indications that VX-745 was dangerously toxic and unmarketable for more than two years while continuing to move the drug through clinical testing and make misleading positive statements to the public.

A. Confidential Witnesses

Plaintiffs support their allegation that defendants knew about problems with VX-745 in 1999 by reference to confidential witnesses ("CWs").[3]

[3] CW5 was not included in the original complaint or in the first amended complaint submitted by plaintiffs. On September 15, 2004, plaintiffs moved to amend the complaint a second time, with CW5 and certain other new allegations (listed where relevant)

1. ***CW1***

CW1 was employed by Vertex and conducted small animal tests on VX-745 during the Class Period, but more senior scientists analyzed the test results. According to CW1, "at around the time of the VX-745 preclinical studies, there were concerns within Vertex that the compound would never ... achieve FDA approval." CW1 also states that "those privy to the analysis of the data from the preclinical testing of VX-745 believed that the compound would demonstrate a toxicity problem during clinical trials," and that "[s]ome scientists at Vertex expressed the concern to management that VX-745 would not [achieve FDA approval]." CW1 is certain that these concerns were raised before Vertex submitted an INDA to the FDA, which must have occurred before the initiation of clinical trials in March 1999.

CW1 also reports that it was "a common feeling among co-workers that the Company rushed compounds through the testing process in order to meet milestones or deadlines with Vertex partners, particularly Kissei and Novartis."

2. ***CW2***

CW2 worked at Vertex as an analytical scientist after the Class Period, from the middle of 2002 until the end of 2003. CW2

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included in the proposed second amended complaint. Plaintiffs claim that they did not find CW5 until September 2004. Defendants oppose this motion. The Court denies the motion to amend as futile.

did not work on VX-745, but states that scientists involved in drug modeling at Vertex told CW2 that other scientists who had been involved in the early testing of VX-745 "knew during the preclinical phase that VX-745 would not pass clinical trials." CW2 was told that these scientists "predicted that the compound might be effective but would not be able to withstand the rigors of clinical trials," and informed management of their views. CW2 also stated that one scientist left the company in June 2003 after a dispute with Vertex's president of research, John Thomson, over VX-745. That scientist told CW2 that "the scientists who modeled and performed preclinical analyses knew that the compound would not succeed and would result in a waste of millions of dollars by Vertex." The scientist described the initial problems with VX-745 as having occurred during in vitro analyses and analyses with plasma, conducted during preclinical small animal testing.

3. ***CW3***

CW3 was a scientist at Vertex "during the latter half of the Class Period" who "possessed knowledge of Vertex's testing procedures." In CW3's view, "preclinical studies could not continue on a compound designated for specific treatment ... once Phase I clinical studies began because of both cost and regulatory prohibitions." Thus, "CW3 believed that animal testing should have been completed long before VX-745 was enrolled for

clinical trials."

According to CW3, a toxicity study on VX-745 was performed by an outside company and was completed before Vertex began investing in clinical studies.

4. ***CW4***

CW4 worked at Aurora and was employed by Vertex after its merger with Aurora in July 2001, two months before the end of the Class Period. CW4 reports that Aurora employees were unhappy that they had not been told about the progress of VX-745 and problems associated with it. CW4 knew of "rumors that Vertex ... deliberately kept Aurora personnel from knowing anything about the status of drug development."

5. ***CW5***

CW5 worked at Vertex from mid-2000 to mid-2001 as a senior research scientist in the United Kingdom office. CW5 "worked closely with staff scientists involved with the in vitro testing of VX-745." CW5 states that by mid-2001, "there were several indications of overestimation of activity for VX-745 from preclinical data that was either misinterpreted or the subject of overpositive interpretation." CW5 also alleges that in mid-2001, the UK staff discussed VX-745 studies conducted in 1998 and 1999, and the fact that "Vertex gave overpositive interpretation" of the data.

CW5 also states that "[p]reliminary indications of CNS action in preclinical in vivo animal tests would include convulsions, seizures, and death in mice or rats." According to CW5, "Vertex may have focused more on efficacy and did not closely assess other preliminary indications of CNS action." CW5 states that "seeing potential for CNS neuronal effects in small animal studies should have presented a big question for Vertex." It is somewhat unclear from CW5's statement on this subject whether Vertex ignored preliminary indications of CNS effects, or whether Vertex noted these indications but failed to test further.

B. Alleged False or Misleading Statements

Plaintiffs allege eleven false or misleading statements by the defendants:

(1) On March 9, 1999, Vertex issued a press release announcing the initiation of Phase I clinical trials of VX-745 as a candidate for treatment of inflammatory and neurological diseases. The press release quoted defendant Sato as stating that "[t]he rapid development of VX-745 from discovery to Phase I clinical trial initiation reflects Vertex's accelerated drug design approach as well as the strength of our collaboration with Kissei." The press release also touted the company's drug development process more generally.

(2) On November 2, 1999, Vertex issued a press release stating

that the company had begun a pilot Phase II trial of VX-745. The press release again noted Vertex's unique drug design system.

(3) On March 1, 2000, defendant Boger was interviewed on CNNfn's *Market Coverage* about Vertex's drug development process. In that interview, Boger stated that the company was equipped to bring a drug from discovery to market faster than under the traditional model, and that two or three drugs within the company pipeline would likely be on the market in "a couple of years."

(4) A Vertex press release issued on October 23, 2000 announced the selection of four new drug candidates by the company. It quoted Boger as stating that the new candidates "are strong evidence of the productivity gains we have been able to achieve in drug discovery." The press release noted that two of the new candidates stemmed from the company's p38 MAP kinase research program, which had also developed VX-745. It stated that these "second-generation" candidates were distinct from "first generation" inhibitors, such as VX-745, and that the new drug candidates had been chosen using stringent criteria for selection among various leading candidates. The press release described VX-745 as "Vertex's most advanced p38 MAP kinase inhibitor ... [now] in Phase II clinical development in collaboration with Kissei for the treatment of rheumatoid arthritis."

(5) A November 27, 2000 article in *Dow Jones Newswires* reported that Boger had announced the company's aim to have two or three

drugs ready for INDA filings each year by 2005. Boger noted that this goal was possible because of the company's unique drug discovery program targeting particular protein families.

(6) On January 4, 2001, Vertex announced the commencement of a three-month Phase II clinical trial of VX-745 for rheumatoid arthritis in approximately 135 adult patients.

(7) Vertex released an "Outlook for 2001" on January 9, 2001. The release listed positive developments within the company in 2000 and predicted continued success in the future. It pointed to Vertex's p38 MAP kinase program in particular, and noted advancement in two drugs, including VX-745.

(8) An article in *Bull Int Inform Droit et Pharmacie* on February 1, 2001 referred to the Phase II trials set to begin on VX-745.

(9) A Vertex press release on February 22, 2001 announced that the company had reported its 2000 fourth quarter and full year financial results. The release quoted Boger's statement that "in 2000, Vertex's drug discovery and development enterprise progressed to a new level of product creation capability and downstream revenue opportunity."

(10) Vertex issued a press release entitled "Vertex Pharmaceuticals Reports First Quarter 2001 Financial Results" on April 24, 2001. The press release quoted Boger as stating that "[i]n the first quarter of 2001, we continued to make clear

progress on the clinical front," and noting that VX-745 Phase II clinical trials had been initiated.

(11) Vertex reported 2001 Second Quarter and First Half financial results in July, and issued a press release about the results on July 26, 2001. The press release again made positive statements about the company's progress in 2001, and noted the potential of VX-745 for treating disease.

Plaintiffs claim that the listed statements were false and misleading because defendants were aware when the statements were made that VX-745 was toxic and would not be profitable. Plaintiffs argue that in these statements Vertex failed to advise investors that VX-745 preclinical tests had been deficient, instead implying that preclinical work had been successfully completed because clinical testing could begin. Plaintiffs also suggest that statements referring to the effectiveness of Vertex's drug development process were misleading due to the failure of VX-745, and that discussion of the second-generation kinase inhibitor drugs was an attempt to conceal problems with first-generation drugs such as VX-745.

III. DISCUSSION

A. Motion to Dismiss Standard

For purposes of this motion, the Court takes as true "the well-pleaded facts as they appear in the complaint, extending

plaintiff every reasonable inference in his favor." Coyne v. City of Somerville, 972 F.2d 440, 442-43 (1st Cir. 1992) (citation omitted); In re Cabletron Sys., Inc. 311 F.3d 11, 22 (1st Cir. 2002) (applying standard in PSLRA case).

B. Pleading Requirements

"The PSLRA's pleading standard is congruent and consistent with the pre-existing standards" in the First Circuit, which has been "notably strict in applying the [Federal Rule of Civil Procedure] 9(b) standard in securities fraud actions." Greebel v. FTP Software, Inc., 194 F.3d 185, 193 (1st Cir. 1999).

Where a securities fraud action is based on allegations of misleading statements or omissions, the alleged statements must be "misleading to a material degree." Cabletron, 311 F.3d at 27-28 (citation omitted). In addition, the PSLRA requires that a complaint "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. §78u-4(b)(1).

The PSLRA also requires a securities fraud complaint to "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). This "scienter" requirement "alters the

usual contours of a Rule 12(b)(6) ruling because, while a court continues to give all reasonable inferences to plaintiffs, those inferences supporting scienter must be strong ones." Cabletron, 311 F.3d at 28 (citing Greebel, 194 F.3d at 201).

1. ***Misleading Nature of Statements***

As a preliminary matter, a plaintiff in a securities fraud action must "provide factual support for the claim that the statements or omissions were fraudulent, that is, facts that show exactly why the statements or omissions were misleading." Aldridge v. A.T. Cross Corp., 284 F.3d 72, 78 (1st Cir. 2002)(citing Greebel, 194 F.3d at 193-94).

Plaintiffs provide no facts to support their allegation that statements 3, 5, and 9 are misleading. These statements make no mention of VX-745, and instead consist mainly of general endorsements of Vertex's drug development process. Statement 3 also includes a prediction by defendant Boger that Vertex would bring two or three drugs to market in the next two years. In Statement 5, Boger states Vertex's goal of bringing two or three drugs per year to the regulatory stage by 2005. Statement 9 makes vague assertions about the success of the company in 2000, such as "[w]e made progress across our product pipeline" and "Vertex's drug discovery and development enterprise progressed to a new level of product creation capability and downstream revenue opportunity."

Plaintiffs make no allegations that the problems with VX-745 had such extensive company-wide effects that these statements were false or misleading. See Pirraglia v. Novell, Inc., 339 F.3d 1182, 1189 (10th Cir. 2003)(holding that PSLRA pleading requirement was not satisfied as to general company statements about positive customer demand, where plaintiffs "allege no facts showing that customer demand ... was so low as to render these vague statements false or misleading"). Plaintiffs' claims as to statements 3, 5, and 9 therefore fail the PSLRA pleading requirements, and the discussion below refers only to the remaining statements.

2. ***Materiality Requirement***

A statement or omission is material if it "would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." Basic, Inc. v. Levinson, 485 U.S. 224, 231-32 (1988) (quoting TSC Indus., Inc. v. Northway, Inc., 426 U.S. 438, 449 (1976)). "[T]he materiality of a statement or omission is a question of fact that should normally be left to a jury rather than resolved by the court on a motion to dismiss." Baron v. Smith, 380 F.3d 49, 53 (1st Cir. 2004) (quoting Cabletron, 311 F.3d at 34). Thus, this Court must consider only whether the complaint presents a "plausible jury question of materiality." Id.

If, as plaintiffs allege, defendants were aware by March

1999 that VX-745 would not be marketable, that information would have "been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available," Basic, 485 U.S. at 231-32, given Vertex's aggressive promotion of the drug in press releases and other statements. See In re Sepracor, Inc. Sec. Litig., 308 F. Supp. 2d 20, 28 (D. Mass. 2004) (finding materiality requirement satisfied as to company's positive statements about animal testing of a drug where defendants failed to disclose cardiac side effects of the drug and FDA had stated "zero tolerance" policy for cardiac side effects). The materiality requirement is therefore satisfied in this case.

3. ***Scienter Requirement***

The Supreme Court has defined scienter as "a mental state embracing intent to deceive, manipulate, or defraud." Ernst & Ernst v. Hochfelder, 425 U.S. 185, 193 n.12 (1976). Under the PSLRA, the complaint must allege with particularity facts that present a "*strong* inference of scienter" – "a mere reasonable inference is insufficient to survive a motion to dismiss." Greebel, 194 F.3d at 197. Scienter need not be demonstrated by direct evidence, and can "extend to a form of extreme recklessness that is 'closer to a lesser form of intent.'" Cabletron, 311 F.3d at 38 (quoting Greebel, 194 F.3d at 199). However, "'catch-all' allegations which merely assert motive and

opportunity, without something more, fail to satisfy the PSLRA." Cabletron, 311 F.3d at 39 (quoting Greebel, 194 F.3d at 197 (internal citation omitted)). The First Circuit has not defined a particular formula for pleading scienter, instead relying on a "case by case fact-specific" approach. Aldridge, 284 F.3d at 82 (citing Greebel, 194 F.3d at 196).

The amended complaint alleges the following facts related to scienter:

(1) Vertex had a strong financial incentive to produce positive reports about VX-745 due to the company's collaborative agreements with Kissei and Novartis, and the merger with Aurora. Success with VX-745 would help make the collaborations profitable, allow the Aurora merger to be completed, and generally validate the company's drug development process.

(2) VX-745 was the leading market candidate for Vertex during its development.

(3) Before clinical trials began in early 1999, some scientists within Vertex predicted, based on negative indications in preclinical small animal testing, that the drug would have toxicity problems during clinical trials and would never achieve FDA approval.

(4) Some of these scientists expressed their concerns to Vertex management, but they were ignored. One scientist left Vertex several years later because of his disagreement with the company

over VX-745.

(5) Defendant Marks used his knowledge about the problems with VX-745 to earn $475,765 in September 2001, and has pled guilty to charges of insider trading. Plaintiffs allege that defendants Sato and Alam also made money through insider trading.

(6) Vertex stated that the decision to suspend testing of VX-745 in September 2001 was based on adverse findings in animal tests.

(7) The toxicity study on VX-745 was completed before clinical trials were begun. Based on normal procedure at Vertex, animal testing for VX-745 should have been completed before the initiation of clinical trials.

The question is whether these allegations are sufficient to create a strong inference of scienter.

Plaintiffs allege that based on general practices within Vertex, animal testing of VX-745 was probably mostly completed before the drug was enrolled for clinical trials in March 1999.[4]

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[4] It should be noted that under FDA policy, long-term animal testing may continue after clinical studies have begun. See Center for Drug Evaluation and Research Handbook; Long-Term Testing, available at http://www.fda.gov/cder/handbook/longterm.htm. ("Long-term testing in animals ranges in duration from a few weeks to several years. Some animal testing continues after human tests begin to learn whether long-term use of a drug may cause cancer or birth defects.") The Court may take judicial notice of this policy, as a matter of public record. See Watterson v. Page, 987 F.2d 1, 3 (1st Cir. 1993) (noting that court may take judicial notice of public records on a Rule 12(b)(6) motion); Lamers Dairy Inc. v. U.S. Dept. of Agr., 379 F.3d 466, 471 n.8 (7th Cir. 2004)("This court may take judicial notice of reports of administrative

Vertex itself has stated that the suspension of clinical testing of VX-745 in September 2001 was based on adverse data from animal rather than clinical tests. In combination, when all inferences are made in favor of the plaintiffs, these points suggest that defendants were aware of some problems with VX-745 from animal testing earlier than September 2001, perhaps by March 1999.

However, the allegation that the defendants were aware that preclinical testing demonstrated a toxicity problem with VX-745 by March of 1999 is not in itself sufficient to demonstrate scienter. The fact that a drug has a certain toxicity level does not necessarily doom the drug's commercial prospects. As defendants point out, many drugs currently on the market are toxic depending on dosage levels and concentrations. Defendants note that other drugs (such as Lipitor and Zocor) have been found in animal studies to have toxic effects on the CNS in certain dosages, yet have been approved by the FDA. See Def.'s Exh. I, J. Thus, defendants' knowledge of some toxicity in VX-745 in 1999, without more, is insufficient to indicate "a mental state embracing intent to deceive, manipulate, or defraud." Ernst, 425

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bodies."); In re Wellbutrin SR/Zyban Antitrust Litigation, 281 F.Supp.2d 751(E.D.Pa. 2003)(taking judicial notice of FDA report posted on the official FDA website).

U.S. at 193 n.12.

Defendants' significant financial incentives to delay release of adverse information about VX-745, particularly the upcoming merger with Aurora on July 18, 2001, strengthen the scienter inference. While motive evidence alone is insufficient to satisfy the scienter requirement, unusually strong financial incentives may be relevant when considered in combination with other factors. See Aldridge, 284 F.3d at 83 ("When financial incentives to exaggerate earnings go far beyond the usual arrangements of compensation based on the company's earnings, they may be considered among other facts to show scienter.") (citation omitted).

Overall, however, these factors (financial motive and the likely timing of animal testing) do not create a strong inference of scienter. The tipping point for satisfaction of the scienter requirement is the addition of the allegations by cooperating confidential witnesses that Vertex management knew early on that VX-745's toxicity problems were significant enough to preclude successful clinical trials of the drug. These witnesses allege that the company's rosy statements about the progress of VX-745 in clinical trials were fraudulent because management knew from lead scientists that the drug was likely not viable.

(a) ***Confidential Sources***

In Cabletron, the First Circuit set forth the applicable

particularity standard under the PSLRA where allegations in a complaint are supported by confidential sources. 311 F.3d at 28-30. The court rejected a per se rule that anonymous sources must be named, noting that the PSLRA "was designed to erect barriers to frivolous strike suits, but not to make meritorious claims impossible to bring." Id. at 30 (citations omitted). Adopting Novak v. Kasaks, 216 F.3d 300 (2d Cir. 2000), as a model, the court laid out a case-by-case test:

> The approach we take, similar to Novak, is to look at all of the facts alleged to see if they 'provide an adequate basis for believing that the defendants' statements were false.' Novak, 216 F.3d at 314. This involves an evaluation, inter alia, of the level of detail provided by the confidential sources, the corroborative nature of the other facts alleged (including from other sources), the coherence and plausibility of the allegations, the number of sources, the reliability of the sources, and similar indicia.

Cabletron, 311 F.3d at 29-30. The court noted, "there is no one-size-fits-all template. Sufficient evidence of one type might reduce or eliminate the need for evidence in other categories, without thwarting the legislative intent behind the PSLRA." Id. at 32. Thus, "courts will allow private securities fraud complaints to advance past the pleadings stage when some questions remain unanswered, provided the complaint as a whole is sufficiently particular to pass muster under the PSLRA." Id. (citations omitted).

In Cabletron, the First Circuit found that the particularity

requirement was satisfied by the confidential witnesses' allegations. Id. at 30. The court noted the witnesses' "personal knowledge" and "strong basis of knowledge" of the facts alleged, their "specific descriptions of the precise means through which [the fraud] occurred," their "consistent accounts" which "reinforce one another and undermine any argument that the complaint relies unduly on the stories of just one or two former employees, possibly disgruntled," and the independent evidence corroborating their statements. 311 F.3d at 30-31.

Plaintiffs' allegations in this case do not satisfy this standard. Most significantly, none of the CWs claims to have personal knowledge of the most important facts they allege. Only CW1 worked at Vertex during the entire duration of the Class Period. CW2 arrived at Vertex after the Class Period, and CW3, CW4, and CW5 were at Vertex only during the latter half of the Class Period.

Although CW1 conducted small animal tests during the Class Period, none of CW1's allegations stem directly from CW1's own observations. Instead, in claiming that the defendants knew about defects in VX-745, CW1 cites "some scientists at Vertex" and "those privy to the analysis of the data," and refers to "a common feeling among co-workers."

CW2 similarly does not rely on personal observations. CW2 heard about problems with VX-745 from a scientist who left the

company in June 2003 (almost two years after the drug's suspension) due to disagreements over VX-745. CW2 also reports information from drug modeling scientists who learned of the allegations from *other* scientists involved in early VX-745 testing.

CW3 discusses Vertex's testing procedures *in general* rather than VX-745 testing in particular. Most glaringly, CW4 refers only to "rumors" among Aurora personnel. Mere rumors cannot reasonably satisfy the requirement that the facts alleged "provide an adequate basis for believing that the defendants' statements were false." Cabletron, 311 F.3d at 29 (quoting Novak, 216 F.3d at 314).

CW5 "worked closely" with scientists involved in VX-745 testing at the end of the Class Period, but claims no first-hand knowledge of the testing that plaintiffs claim produced the adverse results. Instead, CW5 describes discussions of 1998-99 data by "UK staff" in mid-2001, just months before Vertex suspended VX-745 testing. In a sense, CW5 therefore undercuts plaintiffs' allegations as to the timing of management's knowledge.

CW5 does state that convulsions, seizures, and death in mice and rats occurred in VX-745 small animal tests, but provides no context for these results. Moreover, CW5's statement that scientists in 2001 believed Vertex "gave overpositive

interpretation of earlier in vitro tests" is vague, and implies negligence rather than the "extreme recklessness" necessary to demonstrate scienter. Cabletron, 311 F.3d at 38.

The lack of detail provided by the CWs is also notable. Specific dates are mostly lacking, and the language used is very vague. CW1, for example, describes "concerns within Vertex" that VX-745 would never achieve FDA approval, but does not discuss the underlying scientific data that supported this view. Similarly, CW2 notes that scientists "knew during the preclinical phase that VX-745 would not pass clinical trials" without further detail. CW3 and CW4 make no specific statements as to adverse test results for VX-745.

Plaintiffs' other allegations do not significantly corroborate the CWs' claims. Plaintiffs note that the merger of Aurora and Vertex was completed only two months before Vertex's suspension of clinical development of VX-745, and that this transaction, as well as Vertex's deal with Kissei, provided a significant incentive for Vertex to keep negative information about VX-745 out of the media for as long as possible. While these transactions suggest a possible motive for the actions alleged by plaintiffs and provide some evidence of scienter, they do not independently corroborate plaintiffs' allegations.

Overall, even when taken together, the CWs' statements fail to satisfy the particularity standard for confidential witnesses

under the PSLRA, and plaintiffs therefore provide an inadequate basis for a strong inference of scienter.

Allegations that some Vertex scientists expressed concern to management during the preclinical phase that VX-745 would not pass clinical trials because of toxicity may be sufficient, under some circumstances, to support a strong inference of scienter. In Sepracor, for example, the Court held that evidence that the defendant company knew about cardiac problems in a drug's animal studies but did not disclose them satisfied the scienter requirement, even without a description of the underlying scientific details. 308 F. Supp. 2d at 31. In that case, however, the inference of scienter was buttressed by the fact that the FDA had expressed a "zero tolerance" policy as to cardiac side effects in antihistamines. Id. The Court particularly emphasized the relevance of this point in relation to scienter, highlighting that it was relying "heavily" on defendants' silence as to the cardiac problems in the face of the "zero tolerance" FDA policy. Id. Moreover, the FDA had previously warned the company that the animal studies showing cardiac and liver damage were issues that had to be resolved. Id. at 26.

In contrast, here plaintiffs present no evidence that the level of toxicity present in VX-745 violated a clear-cut FDA policy. The existence of scientific disagreement within a company

as to the potential viability of a drug in development, without more details about the substance of the debate, cannot provide the necessary strong showing of scienter. See In re Medimmune, Inc. Sec. Litig., 873 F. Supp. 953, 966 (D. Md. 1995) (noting that "[m]edical researchers may well differ ... in the interpretation of test results," and that such disagreement does not support an inference of scienter by a drug company).

This case stands in contrast to caselaw finding fraud claims viable based on a company's rosy prognosis of a drug's prospects combined with its failure to disclose adverse warnings from the FDA. See, e.g., In re Biogen Sec. Litig., 179 F.R.D. 25, 36 (D. Mass. 1997)(holding that a jury could reasonably find scienter where CEO of drug company made positive comments about drug trial without disclosing, among other things, FDA's concerns about the trial); In re Transkaryotic Therapies, Inc. Sec. Litig.; 319 F.Supp.2d 152, 160 (D.Mass. 2004)(denying motion to dismiss where drug company made optimistic statements about drug's efficacy while failing to disclose FDA's serious concerns as to efficacy); In Re Amylin Pharmaceuticals, Inc. Sec. Litig., 2003 WL 21500525, *5, 8 (S.D. Cal. May 1, 2003); In re CV Therapeutics, Inc. Sec. Litig., 2004 WL 1753251 *6-9 (N.D. Cal. Aug. 5, 2004). Here, there were no warnings from the FDA, which received the toxicity data in the defendants' INDA.

Thus, plaintiffs' complaint does not satisfy the PSLRA's

scienter requirement, and defendants' motion to dismiss the §10(b) claim is allowed.

C. Section 20(a) Claim

Under §20(a) of the Securities Exchange Act of 1934, "[e]very person who, directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person...." Because the §10(b) claim in this case is dismissed and "there must be a primary violation for liability under section 20(a)," Aldridge, 284 F.3d at 84, the §20(a) claim must be dismissed as well.

IV. ORDER

The Court **ALLOWS** defendants' motion to dismiss the consolidated amended complaint (Docket No. 68). The Court **DENIES** plaintiffs' motion to supplement the complaint (Docket No. 72) as futile.

S/PATTI B. SARIS
United States District Judge

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Note* This page is not part of the opinion as entered by the court.

The docket information provided on this page is for the benefit of publishers of these opinions.

1:03-cv-11852-PBS Marcano v. Vertex Pharmaceuticals Incorporated et al
Patti B. Saris, presiding
Date filed: 09/27/2003 Date of last filing: 02/18/2005

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