

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

In re VERTEX PHARMACEUTICALS, INC. )	Master File No. 03 11852 PBS
SECURITIES LITIGATION )	
_____ )	CONSOLIDATED AMENDED
This Document Relates To: )	COMPLAINT FOR VIOLATION OF THE
_____ )	FEDERAL SECURITIES LAWS
ALL ACTIONS. )	
_____ )	<u>DEMAND FOR JURY TRIAL</u>

## INTRODUCTION AND OVERVIEW

1. This is a securities class action on behalf of persons who purchased or otherwise acquired the publicly traded securities of Vertex Pharmaceuticals Incorporated (“Vertex” or the “Company”) between March 9, 1999 and September 24, 2001 (the “Class Period”), against Vertex and certain of its officers and directors for violation of the federal securities laws.

2. Vertex, headquartered in Cambridge, Massachusetts, is a biotechnology company focused on the discovery, development and commercialization of breakthrough drugs for a range of serious diseases. Vertex claimed to have developed a process that allowed Vertex to identify drug candidates more efficiently, and more accurately, than other processes. Throughout the Class Period, Vertex used its VX-745, a compound Vertex told the public could be developed into a drug to fight inflammatory disease, to show how successful its process was.

3. In fact, during the Class Period, defendants artificially inflated the price of Vertex stock by issuing false and misleading statements regarding its development of Vertex compound VX-745. Defendants’ misrepresentations and omissions also mislead the public about Vertex’s ability to identify, test and develop new drug candidates with greater efficiency and speed than its competitors, repeatedly emphasizing that their “accelerated drug design approach,” which yielded “productivity gains,” defendants bragged that their process “holds the potential to have a huge impact on the overall efficiency of drug discovery.”

4. A number of former employees, referred to as confidential witnesses (“CWs”) referenced in this Complaint, have informed plaintiffs that the scientists conducting preclinical small animal studies in VX-745, informed senior management, including defendant Joshua S. Boger (“Boger”), that the scientists knew VX-745 would not survive clinical trials due to its high level of toxicity. This toxicity impacted the central nervous system and arose from the fact that VX-745

crossed the blood-brain barrier. Yet defendants did not disclose even this fact to the public. Yet when these results were reported to management – including defendant Boger, who according to witnesses, personally managed the development of VX-745 – management elected to continue the compound’s development anyway. One senior scientist involved in the VX-745 program told a witness that he knew VX-745 was going to fail during the tests on small animals in the preclinical phase. Ultimately, he left the Company over this disagreement with senior management. Nevertheless, clinical studies conducted on humans were performed, despite the Company’s knowledge that the compound had been shown to be unsafe in animal tests.

5. The Class Period begins on March 9, 1999, when defendants announced that the VX-745 was entering clinical trials. Defendants crowed about the productivity gains of its drug design system throughout 2000, and in December 2000, Kissei Pharmaceutical Co., Ltd. (“Kissei”) made a \$1 million milestone payment to the Company relating to the testing of the second generation of kinase inhibitors. In January 2001, the Company announced the commencement of dose-ranging Phase II clinical trials of VX-745 to treat rheumatoid arthritis. At the same time, defendants were selling its ability to develop drugs quickly to induce other drug companies to invest in, or collaborate with, Vertex.

6. Additionally, beginning as early as March 26, 2000, Vertex entered into negotiations with Aurora Biosciences Corp. (“Aurora”) covering possible collaboration. By April 2001, these negotiations culminated in a merger when Vertex announced that it would acquire Aurora in a stock-for-stock transaction. The announcement specifically referenced Vertex’s drug delivery system. On July 18, 2001, Vertex announced that it had successfully completed the acquisition of Aurora in a merger valued at \$529 million.

7. On May 9, 2000, Vertex announced that it had reached a collaborative agreement with Novartis Pharma AG (“Novartis”) to develop and commercialize small molecule drugs in the kinase protein family – the same family of drugs as the VX-745. Under the agreement, Novartis agreed to make pre-commercial payments to Vertex of up to \$800 million, subject to certain milestones and conditions. Novartis’ initial payment of \$22.5 million turned Vertex’s second quarter loss into a profit. Yet as analysts noted, such agreements put tremendous pressure on Vertex to produce drugs quickly: “As the pressure to generate increasing numbers of commercially viable drugs more quickly, Novartis-Vertex ... [has] entered into long term, high stakes collaborations that rely heavily on Vertex’s ... discovery engines.” The Novartis deal provided if Novartis (or Vertex) could demonstrate that “by reason of scientific developments” that existed on the effective date, that it was likely that a kinase inhibitor compound covered by the agreement would not be a viable candidate, then the agreement could be terminated by either party. Thus, Vertex had a strong incentive to portray VX-745, one of its leading kinase inhibitors, as succeeding – since Novartis could seek to use any failure to terminate its agreement.

8. By August 2001, the Company had made the decision to suspend its development of VX-745, something it did not reveal to the public until September 24, 2001. In the interim, defendant Andrew S. Marks (“Marks”) directed his broker to unload all of his shares and options in Vertex stock. Defendant Marks was the highest ranking lawyer on Vertex’s staff from June 2001 to September 2001 and was frequently consulted on matters other than patent issues. Defendant Marks ultimately sold 20,900 shares of Vertex, reaping a total of \$476,765, and he has now pled guilty to insider trading, thus admitting that the withdrawal of VX-745 from the market was material, and inside information not circulable to the public. Moreover, defendant Marks did not trade alone.

Defendants Vicki L. Sato (“Sato”) and John J. Alam (“Alum”) also reaped illegal insider benefits of roughly \$3 million.

9. On September 24, 2001, Vertex announced to the public what its scientific development team had known for years: VX-745 was not safe. The Company stated, “[t]he decision to suspend clinical development of VX-745 is based directly on adverse effect findings within nonclinical (animal) tests.” Defendants admitted for the first time that “Nonclinical tests have indicated that VX-745 crosses from the blood into the CNS [central nervous system].”

10. The decision to suspend testing of the drug was not based on the results of the Phase I clinical testing being conducted at that time. Rather, the suspension was based on toxicity from animal test results – which test results, according to confidential witnesses, were known *before* the commencement of clinical testing in early 1999. Delaying making this news public, however, not only permitted Vertex to receive milestone payments on VX-745 from Kissei, but, as importantly, allowed it to continue to sell the myth of its enhanced drug delivery process and sign collaborative deals with other drug companies, and, finally, acquire Aurora.

11. In short, the following was known or recklessly ignored by each of the defendants during the Class Period:

(a) That VX-745 crossed the blood-brain barrier, and this caused increased risk of toxicity in the central nervous system;

(b) That as a result of early animal preclinical testing Vertex’s senior scientist concluded that VX-745 would not survive toxicity testing in the clinical stages;

(c) That once clinical testing of VX-745 had commenced, defendants continued the preclinical testing of VX-745, a direct result of their rushed testing to maintain the fiction of an accelerated but safe drug delivery system;

(d) That defendants purposefully delayed the announcement of renewed long-term preclinical studies of VX-745 in animals until announcement of study results to avoid connection of the need for the renewed studies with the October 2000 disclosure of defendants' problems with the Vertex first-generation drug candidate selection process; and

(e) That the announcement of the unsuitability of VX-745 as a drug candidate was similarly delayed until two months after completion of the merger with Aurora.

12. The announcement on September 24, 2001 of the termination of the VX-745 drug development program caused Vertex's stock price to drop to as low as \$17.74 from its Class Period high of \$97.25, on record volume of over 9.8 million shares. Defendants' scheme resulted in the artificial inflation of Vertex stock throughout the Class Period and caused millions of dollars in damages to members of the class.<sup>1</sup>

#### **JURISDICTION AND VENUE**

13. The claims asserted herein arise under §§10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. §§78j(b) and 78t(a), and Rule 10b-5. Jurisdiction is conferred by §27 of the Exchange Act, 15 U.S.C. §78aa. Venue is proper here pursuant to §27 of the Exchange Act. Acts and transactions giving rise to the violations of law complained of occurred here.

#### **THE PARTIES**

14. Plaintiff City of Dearborn Heights General Governmental Employees' Retirement System purchased shares of Vertex common stock and was damaged thereby.

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<sup>1</sup> Share and per share amounts have been adjusted to reflect Vertex's August 2000 2-for-1 stock split.

15. Plaintiff Terry Sivesind acquired shares of Vertex common stock and was damaged thereby.

16. Defendant Vertex claims to be a biotechnology company focused on the discovery, development and commercialization of breakthrough drugs for a range of serious diseases. Vertex is headquartered in Cambridge, Massachusetts and has major research sites in San Diego, California and Oxford, U.K. The Company employed roughly 700 people during the Class Period and had between nine and twelve drugs in development at that time.

17. (a) Defendant Sato was, during the Class Period, President of the Company. During the Class Period, Defendant Sato sold 20,000 of her Vertex shares for proceeds of \$965,100.

(b) Defendant Boger was, during the Class Period, Chairman of the Board and Chief Executive Officer of the Company.

(c) Defendant Alam was, during the Class Period, Senior Vice President, Drug Evaluation and Approval. During the Class Period, Alam sold 31,495 of his Vertex shares for proceeds of \$2,004,776.

(d) Defendant Mark Murcko (“Murcko”) was, during the Class Period, Chief Technology Officer and Chair of the Scientific Advisory Board of the Company.

(e) Defendant Marks was, during the Class Period, Patent Counsel of the Company. During the Class Period, Marks sold 20,900 of his Vertex shares for proceeds of \$476,765.

18. The individuals named in ¶17 are the “Individual Defendants.” They are liable for the false statements pleaded herein at ¶¶41, 43, 51, 54, 60, 62, 65 and 70, as those statements were each “group-published” information for which they were collectively responsible. The Individual Defendants, by reason of their stock ownership and positions with Vertex and their day-to-day

involvement with Company affairs, were controlling persons of Vertex. Vertex was a company of just 700 employees with only twelve drug candidates during the Class Period. Each individual defendant can be presumed to have known the state of testing of VX-745, its leading candidate. Vertex controlled each of the Individual Defendants. These controlling persons are liable under §20(a) of the Exchange Act.

19. In addition to having actual knowledge of the falsity of their statements, each of the defendants had the motive and the opportunity to perpetrate the fraudulent scheme and course of business described herein. During the Class Period, defendants sought to complete a stock-for-stock merger with Aurora, valued at approximately \$592 million. Because the merger was critical to the Company's position and continued ability to continue to fund its operations and continue as a "going concern," defendants sought to complete the merger *prior* to the disclosure of the critical material information, to assure the highest Vertex share price possible. Moreover, the success of the highly visible VX-745 was critical to Vertex's ability to achieve certain milestones in its agreement with Kissei and maintain the fiction that it had developed an exceptionally accelerated and effective drug delivery system. Finally, the insider selling of defendants Marks, Sato and Alam – including Marks' guilty plea of insider trading – further support the already strong inference of scienter on the part of these defendants.

#### **CONFIDENTIAL SOURCES**

20. Information provided by certain confidential witnesses confirms that defendants knew, or were reckless in not knowing, not only that VX-745 crossed the blood-brain barrier, but also that it was toxic. These witnesses confirm that preclinical small animal tests of VX-745 in early 1999, revealed the very problems that eventually caused the Company to announce that it was discontinuing its development of the drug two years later on September 24, 2001. Defendants

misled the public about the prospects and success of VX-745. These confidential witnesses are referred to as “CWs” throughout this Complaint to protect them from retaliation or harassment. Where appropriate, plaintiffs may also provide a generic job description in situations where a specific job title would identify the witness.

21. **CW1**

(a) CW1 worked at Vertex for over five years and throughout the Class Period. CW1 conducted small animal testing for Vertex during the Class Period. CW1 was responsible for performing the tests that were the basis for blood-brain barrier studies of VX-745, among other drugs.

(b) CW1 described the process by which Vertex engaged in testing of its compounds. Results of small and large animal studies were reported to Yao Ming Wang, who reported to the lead scientist responsible for the VX-745 project, who in turn reported directly to executive management, including defendant Boger. Boger managed the development of VX-745. CW1 confirmed that VX-745 was the leading market candidate for Vertex during its development.

(c) CW1 explained that for a compound to become a drug (meaning that it passes Food and Drug Administration (“FDA”) requirements), it must have certain properties, and meet certain standards, a complex group of values set forth in an Investigational New Drug application, or an “IND.” An IND includes all preclinical information. Once submitted, the FDA has 30 days to reject the application. If there is no notification of rejection, this is considered a green light to proceed with Phase I clinical trials. Toxicity data from analysis of preclinical testing was a necessary component of the Vertex IND for VX-745.

(d) CW1 recalled that at around the time of the VX-745 preclinical studies, there were concerns within Vertex that the compound would never be “druggable,” (*i.e.* would never

achieve FDA approval). Based on CW1's communications with co-workers, 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. At that time, some scientists at Vertex expressed the concern to management that VX-745 would not be druggable. The issue was not one of effectiveness, but one of safety. This information was kept tight-lipped by the scientists and upper management.

(e) According to CW1, it was also 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. In the case of VX-745, CW1's co-workers expressed the belief that quick decision making led to its demise. Indeed, CW1 summarized CW1's view that Vertex's management was focusing on the business of making drugs when they were supposed to be doing science and making the best drugs it could.

## 22. CW2

(a) CW2 worked at Vertex from mid-2002 through 2003 as an analytical scientist. Due to CW2's position with Vertex, CW2 possessed intimate knowledge of the Company's testing procedures.

(b) Vertex had a "modeling" group – a group of scientists that analyzed the structure of molecules in order to predict the behavior of compounds under development. Once the modeling group found a compound with a molecular structure with desirable properties, it was then evaluated by management as a candidate to move forward in preclinical studies.

(c) Due to CW2's position, CW2 was in contact with personnel from the modeling group and with scientists involved in data analysis from Vertex internal preclinical studies. Some of those scientists informed CW2 that the scientists involved with the early testing of VX-745

knew during the preclinical phase that VX-745 would not pass clinical trials. CW2 was informed that scientists involved in VX-745's early development predicted that the compound might be effective but would not be able to withstand the rigors of clinical trials. CW2 was certain that by the time small animal testing for toxicity occurred in the preclinical phase, the scientists involved did not believe the compound was viable and informed management. However, management did not listen to those scientists.

(d) CW2 recalled that one of the scientists who had worked on VX-745 ultimately left the company in June 2003 because of tension between himself and senior management over his position with regard to VX-745. That scientist was involved in a direct dispute with Vertex's president of research, John Thomson, who reported directly to defendant Boger. The disagreement centered around VX-745. The scientist told CW2 directly 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.

(e) CW2 stated that this scientist described the initial problems with VX-745 as having occurred during *in vitro* analyses and analyses with plasma, conducted during the small animal testing in the preclinical testing.

23. **CW3**

(a) CW3 was employed during the latter half of the Class Period as a scientist at Vertex. In this position, CW3 possessed knowledge of Vertex's testing procedures.

(b) CW3 reported that Vertex used an outside company for clinical trials of its compounds. However, Vertex performed pKa studies of kinase inhibitor compounds under development, including VX-745. These studies are part of the small animal studies done just after the *in vitro* phase and are performed long before clinical trials even begin. First, the pKa group

determines the effects of a compound on the brain, kidneys and liver. The next step is the toxicity study, which in the case of VX-745 was performed by an outside company. According to CW3, the toxicity study was completed before Vertex began investing in clinical trials. Toxicity studies are rigorous and expensive and usually take six months to a year to ensure that once human testing begins in Phase I clinical studies, no one is hurt and no unnecessary risks are taken.

(c) CW3 believed that pKa studies for VX-745 were done on mice and rats at Vertex, but an outside company tested larger animals in more advanced pKa studies. CW3 stated that in CW3's view, preclinical studies could not continue on a compound designated for specific treatment (*e.g.*, rheumatoid arthritis) once Phase I clinical studies began because of both cost and regulatory prohibitions. In short, CW3 believed that animal testing should have been completed long before VX-745 was enrolled for clinical trials.

24. **CW4**

(a) CW4 was hired by Aurora and employed by Vertex following its merger with Aurora through the end of the Class Period. CW4 dealt with instrumentation for equipment in the Aurora research and development department.

(b) CW4 reported that Aurora employees largely felt they had been kept in the dark about progress and problems with VX-745. CW4 had heard rumors that Vertex in Cambridge deliberately kept Aurora personnel from knowing anything about the status of drug development.

## **SUBSTANTIVE ALLEGATIONS**

### **Vertex Began Developing VX-745 in 1997**

25. Defendants stated that Vertex discovered the 3-D structure of p38 MAPK in 1996. Mitogen-activated protein ("MAP") kinases are key enzymes involved in the amplification of cellular responses to stimuli. The enzyme p38 MAP kinase ("p38 MAPK") is a specific member of

the MAP kinase family, associated with the onset and progression of inflammation. Vertex told the public that through its study of these enzymes it sought to develop a drug to fight inflammation.

26. According to the Company, Vertex computer modeling and testing suggested the design of VX-745 as a potential inhibitor of enzyme p38 MAPK. Defendants then undertook the development of VX-745. The development of VX-745 thus conferred two potential benefits on the Company, (1) if successful, it would validate its ability to target and develop drug candidates; (2) it would provide Vertex with a marketable drug. At all times during the Class Period, therefore, the p38 MAPK inhibitor program was one of defendants' most important technological programs, critical to the valuation and success of the Company.

27. In September 1997, the Company and Kissei entered into a collaborative agreement for the p38 MAP kinase program for the development and commercialization of novel, orally active drugs for the treatment of inflammatory and neurological diseases. Under the terms of the agreement, Kissei agreed to pay the Company up to \$22 million, composed of a \$4 million license payment paid in September 1997, \$11 million of product research funding over three years and \$7 million of development and commercialization milestone payments. By December 31, 1998, Vertex had recognized \$11 million from this agreement as revenue.

28. Kissei's investments in Vertex's drug development resulted in a substantial increase in the Company's revenue in 1996 and 1997. For example, according to the Company's 1997 Form 10-K, Vertex's revenue in 1996 was \$18.6 million, and by the end of 1997 it was \$43.8, a 235% increase. Thus, Kissei's interest in Vertex, and the Company's purported superior drug discovery and development processes, were a cornerstone of the Company's ability to attract other companies willing to collaborate with Vertex and enable Vertex to grow. Indeed, by 1999 Vertex had nine drug candidates under development. The success or failure of any single drug candidate was critical to

Vertex's success in selling its drug development process to future investors. Thus, Vertex had a strong financial incentive to report that the VX-745 was progressing toward development as a viable drug.

29. The success of VX-745 was not only important to the Company's ability to collect revenue by achieving certain milestones, but would serve to validate Vertex's purported superior drug development process and encourage other collaborative agreements.

30. Indeed, in announcing the Kissei agreement on September 11, 1997, the Company noted:

"This agreement is another endorsement of our approach to drug discovery and in particular recognizes the value created to date by our research to design inhibitors of p38 MAP kinase," commented Dr. Joshua Boger, Chief Executive Officer of Vertex.

31. Within a year, Vertex obtained its \$2 million milestone payment from Kissei and affirmed the progress of VX-745. On July 7, 1998, the Company issued a press release entitled "Vertex and Kissei Select VX-745 as Lead p38 MAP Kinase Inhibitor Targeting Inflammatory and Neurological Diseases; Vertex Receives \$2.0 Million Milestone Payment from Kissei." The press release noted, "VX-745, now in preclinical development, has the potential to treat inflammatory diseases and neurological diseases." It further stated that "Vertex and Kissei plan to begin clinical development of VX-745 in 1999, following successful completion of preclinical studies."

32. Indeed, defendant and CEO Boger, in a July 7, 1998 Company press release, crowed that "[t]he addition of VX-745 to our pipeline reflects the power of our integrated technology platform to establish quickly lead candidates in highly competitive, novel areas." Similarly, defendant Sato, in a March 9, 1999 company press release, boasted, "[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." From at least March 9, 1999 through the end of the Class Period, defendants promoted the success of VX-745. Yet defendants

did not reveal what was known to them from the preclinical testing: VX-745 crossed the blood-brain barrier in levels toxic to animals. Vertex only disclosed this toxicity in September 2001 – long after it had known about it and only two months after it had completed its acquisition of Aurora.

### **Crossing the Blood-Brain Barrier Implicates Increased Risk of Toxicity**

33. Unless introduced directly into the central nervous system, the concentration of a given drug in the central nervous system that results from oral or parenteral administration will often be lower than otherwise found in the blood. The reason for this differential concentration is the blood-brain barrier, a boundary surrounding the periphery of the brain. This boundary acts as a barrier or filter, restricting the flow of many substances into the central nervous system from the circulatory system.

34. The blood-brain barrier significantly impedes entry from blood to brain of virtually all molecules. Only molecules that are small and lipophilic or those that enter the brain through active transport can cross this barrier. Thus, lipid-soluble molecules are at greatest risk of crossing the blood-brain barrier. Lipid-soluble molecules with a molecular weight in the range of 400-600 mass units are transported readily through the blood-brain barrier. Molecules that do not cross the blood-brain barrier do not enter the central nervous system.

### **Lipophilicity and VX-745**

35. The likelihood that a given drug candidate will cross the blood-brain barrier increases the risk that that candidate would be dangerous. The central nervous system is a complex vulnerable system, and exposing it to new molecules creates the risk of death or permanent impairment. (For this reason, when defendants ultimately announced the failure of VX-745, Vertex made very clear in a September 25, 2001 press release that the second generation drugs did *not* cross the blood-brain

barrier.) As discussed below, scientists can predict early on whether or not a compound or molecule will cross the blood-brain barrier by testing its lipophilicity.

36. The design of a target molecule for a desired pharmacologic effect typically requires careful consideration of the desired absorption, distribution, metabolism and excretion (“ADME”) profile. Consideration of an appropriate ADME profile is usually accomplished by both *in vitro* and animal studies during the preclinical development stage. *In vitro* studies include determination of physical properties that affect absorption, such as drug crystal form, particle size, polymorphism, and hydration. Chemical properties must also be considered. Of all of the physicochemical properties, lipophilicity is extremely important, since it greatly influences *in vivo* distribution, metabolism and excretion.

37. In cases where the molecular weight of the molecule is in the range of 400-600 mass units, the finding of a high positive value for lipophilicity is predictive of the ability of the molecule to cross the blood-brain barrier.

38. Pharmaceutical scientists on their own staff, trained either in Medicinal Chemistry or Pharmaceutics, can usually make a qualitative prediction of the ability of a molecule to cross the blood-brain barrier by inspection of the chemical structure. Calculated values can be obtained in a few seconds.

39. Based on this simple estimation method, it was reasonable to predict that VX-745 would cross the blood-brain barrier. Indeed, defendants here have admitted that they knew VX-745 crossed the blood-brain barrier. This admission applies to each defendant. Despite this, defendants did not tell the investing public that VX-745 crossed the blood-brain barrier until September 24, 2001 when Vertex pulled the compound from clinical testing.

## FRAUDULENT SCHEME AND COURSE OF BUSINESS

40. Throughout the Class Period defendants sought to persuade the market and its collaborating drug company partners that Vertex's drug identification and delivery methods were superior to other methods. Defendants touted VX-745 as the chief illustration of the Company's ability. In fact, as defendants knew or recklessly ignored, in early 2000, through preclinical animal tests, defendants learned VX-745 was toxic. Although VX-745 crossed the blood brain barrier and had been shown to be toxic in preclinical small animal tests, defendants continued to develop the compound, taking it through Phase I and Phase II testing, and made materially false and misleading statements and omitted other material facts concerning the drug status and development. The defendants did so in order to (i) continue to promote Vertex's alleged superior drug identification and delivery system and thereby keep its earlier collaboration agreements and enter new ones, such as the \$800 million Novartis in May 2000; (ii) receive funding that allowed it to develop a second generation of kinase inhibitors, so that when Vertex was eventually forced to remove VX-745 from development it could do so substantiating the second generation and make it appear that Vertex's superior drug delivery system was still intact; and (iii) use Vertex's artificially inflated stock to acquire Aurora – a company that would enable Vertex to develop viable drug products.

41. **The March 9, 1999 false and misleading statements:** Nine months later, on March 9, 1999, the Company issued a press release entitled "Vertex Announces Start of Clinical Trial with VX-745 as New Drug Candidate Targeting Inflammatory and Neurological Diseases." The press release stated in part:

*Vertex Pharmaceuticals Incorporated announced today the initiation of a Phase I clinical trial with VX-745, a novel, orally administered investigational drug targeting p38 mitogen-activated protein (MAP) kinase, a human enzyme involved in the regulation of inflammatory responses. VX-745 has the potential to treat inflammatory diseases such as asthma, Crohn's disease and rheumatoid arthritis, and neurological diseases such as stroke.*

*“The 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,”* commented Dr. Vicki Sato, Senior Vice President and Chief Scientific Officer of Vertex. “The Phase I trial is the first step in what we expect will be a series of clinical trials for VX-745 in inflammatory diseases. This trial will assess the compound’s safety and help to determine the dose range for subsequent studies.”

\* \* \*

*“Vertex has demonstrated its ability to integrate information on innovative molecular targets for the rapid discovery and advancement of lead drug development candidates such as VX-745. At Vertex, the average time from project initiation to selection of a lead drug development candidate has been a little more than three years, which is faster than pharmaceutical industry averages,”* stated Dr. Joshua Boger, Chairman, President and CEO of Vertex. “This track record gives us confidence that we can maintain a stream of innovative drug candidates going into the clinic.”

42. **Reasons the March 9, 1999 statements were false and misleading:** Nowhere within the March 9th press release did Vertex advise investors that certain additional preclinical studies were deficient or certain new preclinical studies needed to be performed. Instead, defendant Boger assured investors of Vertex’s rapid and sophisticated approach to drug discovery and advancement of candidates into the clinic. By heralding the Vertex approach as unique within the industry, the implication was that Vertex had appropriately dealt with the preclinical testing phase for VX-745 and had eliminated potential risks, concealing the need for further preclinical studies thereby.

43. **The November 2, 1999 false and misleading statements:** On November 2, 1999, the Company issued a press release entitled “Vertex Begins Pilot Phase II Clinical Trial of VX-745, p38 MAP Kinase Inhibitor for the Treatment of Inflammatory Disease.” The press release stated in part:

*Vertex Pharmaceuticals Incorporated announced today that it has begun an exploratory Phase II trial of the investigational drug VX-745, the Company’s orally*

administered p38 mitogen-activated protein (MAP) kinase inhibitor, in patients with rheumatoid arthritis. VX-745 is being developed by Vertex Pharmaceuticals in the United States and Europe for the treatment of inflammatory diseases.

***“This trial will provide further information about the potential for VX-745 in the treatment of rheumatoid arthritis, and help us to design larger studies aimed at evaluating the safety and efficacy of the drug,”*** said Dr. Vicki Sato, Senior Vice President of Research and Development and Chief Scientific Officer of Vertex. “With VX-745 entering Phase II, we now have six drug candidates in Phase II clinical development targeting a range of medically under-served diseases. We look forward to further developing and advancing our product pipeline.”

\* \* \*

***The exploratory Phase II trial announced today is a 28-day study designed to test the tolerability and pharmacokinetics of VX-745 in ten patients with rheumatoid arthritis.*** The study is being conducted in Europe. The trial will also assess the pharmacodynamic activity of VX-745, and clinical disease activity markers will be monitored.

\* \* \*

The Company has nine drug candidates in clinical development to treat viral diseases, inflammation, cancer, autoimmune diseases and neurological disorders. ***Vertex has created its pipeline using a proprietary approach, information-driven drug design, that integrates multiple technologies in biology, chemistry and biophysics aimed at increasing the speed and success rate of drug discovery.***

44. **Reasons the November 2, 1999 statements were false and misleading:** With the November 2, 1999 press release, defendants effectively told the market that preclinical work for VX-745 been successfully completed, the associated risks minimized, and that the VX-745 had quickly progressed to the Phase II milestone. While the defendants pointed to the need for clinical assessment of tolerability and pharmacodynamics, ***at no point did they discuss the need to revisit the preclinical phase.*** Indeed, defendants instead pointed to the virtues of their drug development model, stating that “Vertex has created its pipeline using a proprietary approach, information-driven drug design, that integrates multiple technologies in biology, chemistry and biophysics aimed at increasing the speed and success rate of drug discovery.” In fact, as the CWs have reported, Vertex

management knew by early 1999 that VX-745 was not a viable drug candidate. However, revealing this would have jeopardized Vertex's negotiations with other collaborative investors such as Novartis and Kissei.

45. **The March 1, 2000 False and Misleading Statements:** On March 1, 2000, defendant Boger was interviewed by John Metaxas, anchor of CNNfn's *Market Coverage*:

METAXAS: Do you think there will be any acceleration in your ability to bring a drug from discovery to market? I mean, as I understand it, that process traditionally takes about 10 years.

BOGER: Yes. I think by focusing on drugs and gene family, we also gained synergies in development as well and I think that results in both faster time in the market and I think the tools that we develop in these gene families will be useful in bringing more certainty to the development process as well.

\* \* \*

BOGER: I think our chemo genome strategy in looking at target and drug families is the wave of the future in the way drugs are going to be discovered and developed in the future.

\* \* \*

METAXAS: Where in the pipeline are some of your pipeline products right now?

BOGER: Our pipeline is very strong in the mid stage of clinical development and significant patient testing. And our next drugs to the market are a couple of years away, but we have two or three possibilities there in that time frame.

46. **Reasons the March 1, 2000 Statements Were False and Misleading:** In this interview, defendant Boger told the public that Vertex had the capability of bringing two to three drugs to market in the next two years, while the traditional processes took ten years. This was false in that Vertex's drug development process was not "more certain," but indeed was more rushed and less thorough. It was misleading in that Boger did not tell the public that Vertex's leading drug candidate, VX-745, had in fact failed in preclinical testing, calling into question the process Vertex used to identify and target compounds.

47. On May 9, 2000, Vertex announced its collaboration with Novartis. The Company issued a press release entitled “Vertex and Novartis Establish Discovery Alliance Targeting Protein Kinases – Agreement Pioneers New Model for Drug Discovery and Early Development.” The press release stated in part:

Vertex Pharmaceuticals Inc. and Novartis Pharma AG today announced that they have formed an alliance to discover, develop, and commercialize small molecule drugs directed at targets in the kinase protein family. Over the course of the collaboration, Novartis could, subject to milestones and other conditions, make pre-commercial payments to Vertex of \$800 million, based on the successful discovery and full development of eight compounds.

Under the terms of the agreement, Novartis will provide Vertex with a \$15 million initial payment and further research funding of \$200 million over 6 years, and Vertex will have responsibility for drug discovery and clinical proof-of-concept testing of drug candidates.

48. On July 6, 2000 a *Reuters* report entitled “Vertex sees Q2 EPS profit instead of forecast loss,” stated in part:

Vertex Pharmaceuticals Inc. on Thursday forecast that it would turn a second-quarter profit instead of the loss Wall Street expected due to revenues from alliances with major drug companies.

\* \* \*

The company said that it received \$22.5 million from Novartis Pharma AG in the second quarter as part of the alliance Vertex and Novartis signed in May 2000.

Vertex will recognize about \$18.5 million of this amount, including a \$15 million initial payment, as second quarter revenue.

Over the course of the collaboration, Novartis could make payments to Vertex of up to \$800 million, based on the successful discovery and full development of eight compounds.

49. At the same time, Vertex sought to privately place over \$200 million in notes to institutions. A September 12, 2000 article in *BioWorld Today* entitled “Vertex Plans \$200M Offering, \$175M Note Redemption,” stated in part:

With seven potential products in Phase II trials, Vertex Pharmaceuticals Inc. said it plans to fuel their development by offering \$200 million in convertible subordinated notes to institutional buyers – and will call for redemption next month of \$175 million worth of convertible subordinated notes issued earlier.

The private placement was extremely successful. On September 13, 2000, the Company announced that it had sold \$300 million of Convertible Subordinated Notes, due September 2007, through a Rule 144A offering to qualified institutional buyers.

50. Analysts responded by upgrading Vertex’s stock, focusing on the Company’s alleged drug development capabilities. In a September 28, 2000 “Research Alert,” Chase H&Q analyst David Molowa said Vertex’s technology platform “positions the company to be one of the leaders in the post-genomic area of drug discovery.” He stated: “With valuations in the biotechnology industry – Vertex included – at historical highs, standard valuation methods are obsolete, in our opinion.... *Nevertheless, we believe Vertex’s drug discovery capabilities and rich pipeline should provide continued momentum for the stock over the next 12 months.*”

51. **The October 23, 2000 False and Misleading Statements:** On October 23, 2000, the Company issued a press release entitled “Vertex Expands Product Pipeline with Selection of Four New Drug Candidates Targeting Viral Infections, Autoimmune and Inflammatory Diseases, and Cardiovascular Disorders.” The press release stated in part:

Vertex Pharmaceuticals Incorporated announced today the expansion of its product pipeline with *the selection of four new drug candidates with the potential to treat viral infections, autoimmune diseases, cardiovascular disorders and inflammation.* The selection of these candidates reflects the successful completion of Vertex research programs focused on the discovery of second-generation, small molecule inhibitors of IMPDH, p38 MAP kinase, and interleukin-1 beta converting enzyme (ICE). *Each drug candidate that has been selected is now undergoing formal preclinical development in preparation for the start of clinical studies.* Two or more of the newly selected drug candidates are expected to enter Phase I clinical studies in 2001.

*“These new drug candidates are strong evidence of the productivity gains we have been able to achieve in drug discovery,”* said Joshua Boger, Ph.D, Chairman, President, and CEO of Vertex. *“They represent the leading edge of our*

***accelerated research output from our integrated drug discovery platform and our chemogenomics approach.*** We believe that our increased speed and success in translating genomic discoveries into product candidates will create enhanced commercial and business development opportunities for Vertex, allowing us to expand our pipeline and create value for shareholders.”

\* \* \*

#### New Drug Candidates Targeting p38 MAP Kinase

***Vertex announced today the selection of VX-954 and VX-702 as new drug development candidates from the Company’s p38 MAP kinase research program.*** P38 MAP kinase is an enzyme that regulates the production of interleukin-1 beta, interleukin-6 (IL-6) and tumor necrosis factor alpha, which are involved in acute and chronic inflammatory response. Inhibition of p38 MAP kinase may be an effective strategy for slowing the progression of acute and chronic inflammatory reactions. As part of a collaboration with Vertex, Kissei Pharmaceutical Co., Ltd. holds an option to develop VX-954 and VX-702 in Japan and other Far East countries. Vertex’s p38 MAP kinase inhibitors have the potential to treat a range of inflammatory and cardiovascular diseases. ***Vertex’s most advanced p38 MAP kinase inhibitor, VX-745, is in Phase II clinical development in collaboration with Kissei for the treatment of rheumatoid arthritis.***

\* \* \*

***The drug candidates announced today represent classes of compounds that are distinct from first-generation inhibitors designed by Vertex that are now in clinical development. Each was chosen from among several lead candidates that met stringent criteria for selection, including potency, bioavailability, half-life, ease-of-synthesis, and preclinical indicators of safety. Each drug candidate has demonstrated a therapeutic effect in two or more models of disease activity.***

“The five drug candidates we have advanced this year reflect a sustained ramp-up in drug discovery productivity, and provide us the opportunity to pursue multiple indications based on common mechanisms of action,” said Vicki Sato, Ph.D., Senior Vice President of Research and Development and Chief Scientific Officer.... “This puts Vertex on track to double the size of our product development pipeline, increasing the number of products in development from eight to approximately 16 by the end of next year.”

\* \* \*

Vertex has created its pipeline using a proprietary, information-intensive approach to drug design that integrates multiple technologies in biology, chemistry and biophysics, aimed at increasing the speed and success rate of drug discovery.

52. **Reasons the October 23, 2000 Statements Were False and Misleading.** Rather than admit the serious deficiencies in the methods Vertex used to design its first-generation drug development candidates, defendant Sato sought to conceal the defective nature of one or more of the Company's first-generation drug targets by announcing its new second generation of drugs. The Company boasted of the "sustained ramp-up in drug discovery productivity." Vertex explained that its second-generation compounds were actually of a better design, as judged by criteria including "potency, bioavailability, half-life, ease-of-synthesis," and most importantly, "preclinical indicators of safety."

53. The impression of a "rich" pipeline loaded with additional new and improved compounds coupled with communication of the application of more stringent selection criteria was carefully orchestrated to suggest that corrections for past "fast-track" approaches had been made. At the same time, defendants concealed the impact of the prior flawed selection methods on VX-745 or the other first-generation target compounds under development.

54. **The November 27, 2000 False and Misleading Statements:** A November 27, 2000, article in *Dow Jones Newswires* entitled "Vertex Pharma Aims for Two to Three NDAs/Yr By 2005," stated in part:

NEW YORK –(Dow Jones)- *Vertex Pharmaceuticals Inc. (VRTX) aims to have two to three drugs it has developed in investigational new-drug application filings with the regulatory authorities each year by 2005*, Chairman, President and Chief Executive Josh Boger told investors at the Robertson Stephens Medical Conference on Monday.

*This goal*, which includes any submissions made by its research partners, *is a figure "doubling the productivity of an Aventis SA (AVE) or a Novartis AG (NVS) at present,"* said Boger.

*The goal may be lofty, but Boger believes his company can deliver because of its drug-discovery program that targets protein families.*

By focusing on a family, Vertex's researchers can locate several similar genes, accelerate and streamline the design process, and find hundreds of targets, said Boger, adding, "*The short and long of it is to get better drugs faster.*"

\* \* \*

*Vertex's research capabilities underlie the \$800 million deal with Novartis that it signed in May.* The alliance assumes Novartis will select eight compounds for full development after Vertex has conducted "proof in man" studies. But given Vertex's research strategy, *Boger expects many more than eight compounds coming out of the arrangement.*

55. Vertex's stock reacted accordingly. On November 28, 2000, Vertex was at \$73.63, up \$3.75, or 5.4%.

56. **Reasons the November 27, 2000 Statements Were False and Misleading:** The November 27, 2000 statements were false in that VX-745 was not a viable drug candidate. Thus, Boger's claims that Vertex could double the productivity of Aventis or Novartis by 2005 were misleading, in that Boger knew that the drug-discovery program he was touting had failed with regard to VX-745.

57. **The January 4, 2001 False and Misleading Statements:** On January 4, 2001, the Company issued a press release entitled "Vertex Pharmaceuticals Announces Start of Phase II Clinical Trial of VX-745 for Rheumatoid Arthritis." The press release stated in part:

*Vertex Pharmaceuticals Incorporated announced today the commencement of a dose-ranging Phase II clinical trial with VX-745, a small molecule inhibitor of p38 MAP kinase, in patients with rheumatoid arthritis. Vertex is a leader in the discovery and clinical development of p38 MAP kinase inhibitors, which have the potential to be a powerful new class of oral anti-inflammatory medicines that reduce cytokine activity through a novel mechanism of action.*

*"The study announced today is designed to allow us to evaluate the clinical activity of a p38 MAP kinase inhibitor over a three-month dosing period,"* said John J. Alam, M.D., Senior Vice President for Drug Evaluation and Approval.

\* \* \*

In tandem with the development of VX-745 as a lead clinical candidate for the treatment of rheumatoid arthritis, *Vertex significantly broadened its p38 MAP*

***kinase program*** in 2000 by advancing two additional, distinct p38 MAP kinase inhibitors, VX-954 and VX-702, into preclinical development. Vertex Pharmaceuticals holds development and commercial rights in the United States and Europe for its p38 MAP kinase inhibitors. Kissei Pharmaceutical Co., Ltd. of Matsumoto-City, Japan is Vertex's partner for developing p38 MAP kinase inhibitors in Japan and certain Asian countries. ***In December 2000, Kissei made a \$1 million milestone payment to Vertex related to the start of preclinical testing of VX-702.***

The randomized, double-blind, placebo-controlled trial announced today will test two different doses of VX-745 in a total of approximately 135 adult patients. The trial will explore the clinical activity and tolerability of escalating doses of VX-745 when given as monotherapy for three months. ***The trial will enroll patients who have active rheumatoid arthritis and are not responding adequately to their current therapy.*** The trial will evaluate objective clinical response rates, self-reported patient health assessments, and pharmacodynamic markers of drug activity.

***The Company is in the final stages of providing clinical trial material for approximately 35 clinical centers in the United States that are scheduled to begin screening and enrolling patients.*** The trial is expected to be completed in 2001. ***In 2000, Vertex completed a one-month, pilot Phase II clinical trial in patients with rheumatoid arthritis.***

58. **Reasons the January 4, 2001 Statements Were False and Misleading.** Despite the apparent progression of VX-745 beyond the Phase II pilot study and into a “dose-ranging Phase II study,” defendants remained steadfast in their intentions to rapidly progress the “second generation” p38 MAPK inhibitor candidates, VX-702 and VX-954, as quickly as possible. They knew but continued to conceal the fact that the efforts made to design VX-745 were fundamentally flawed because the molecule crossed the blood-brain barrier and that the VX-745 program would need to be terminated once one of the properly designed candidates had completed the preclinical testing stage. Since defendants had failed to progress the other inhibitor candidates beyond the preclinical phase, and since an active p38 MAPK program was critical to the success of the Company, defendants had no choice but to continue to conceal their concerns regarding VX-745.

59. **The January 9, 2001 False and Misleading Statements:** Defendants continued to tout Vertex's drug development program. On January 9, 2001, the Company issued a press release

entitled “Vertex Pharmaceuticals Provides Investors with Outlook for 2001.” The press release stated in part:

“The year 2000 was a pivotal one for Vertex,” stated Joshua Boger, Ph.D., Chairman and CEO of Vertex Pharmaceuticals. “We enhanced our position in the industry by demonstrating the potential of our chemogenomics drug discovery approach, ***broadening and advancing our product pipeline***, signing approximately \$900 million in corporate collaborations and strengthening our financial position by raising more than \$500 million.”

“Vertex’s strategy for 2001 is to utilize emerging genomic information to expand our leadership position in drug discovery, maximizing our product creation opportunities,” stated Dr. Boger. “In the coming year, we intend to use our chemogenomics approach to expand our broad product pipeline by bringing multiple new drug candidates for novel drug targets into preclinical testing. ***We expect that the productivity gains from this approach will be increasingly evident in 2001 and beyond.***”

Dr. Boger continued, “In addition, to fully capture the productivity of our research organization, we will continue to pursue a partnering strategy that balances the risks and rewards of drug discovery, development and commercialization. We also expect to invest significantly in research and development and acquire novel and complementary technologies. ***We believe that these investments in our organization, coupled with the continued clinical advancement of drug candidates in our product pipeline, will ultimately translate into significant value for our shareholders.***”

\* \* \*

Vertex is investing in its IMPDH and p38 MAP kinase programs to accelerate the clinical progress of several drug candidates. ***In 2000, Vertex advanced two drug candidates from these programs – merimempodib (VX-497), an IMPDH inhibitor for the treatment of hepatitis C virus (HC), and VX-745, a p38 MAP kinase inhibitor for the treatment of rheumatoid arthritis.*** The Company expects to conduct additional studies of merimempodib and VX-745 in 2001 and to conduct preclinical development of follow-on compounds.

60. **The February 1, 2001 False and Misleading Statements:** On February 1, 2001, a *Bull Int Inform Droit et Pharmacie* article entitled “Vertex Pharmaceuticals – clinical trials on three compounds,” stated in part:

Vertex Pharmaceuticals is to begin Phase II trials in the US on the p38 MAP kinase inhibitor VX-745 as a treatment for rheumatoid arthritis in patients who do not respond to conventional treatment.

61. **Reasons the January 9, 2001 and February 1, 2001 Statements Were False and**

**Misleading:** Defendant Boger's repeated references to the Company's pipeline and productivity gains were false and misleading, as he knew that VX-745 had failed, but did not reveal it to the public. Yet he nonetheless bragged that the drug candidates in Vertex's pipeline had continued their clinical advancement, and VX-745 was specifically referenced as one such candidate. Similarly, the claim that VX-745 was to begin Phase II trials was false, as the compound had never successfully completed preclinical testing.

62. **The February 22, 2001 False and Misleading Statement:** On February 22, 2001, the Company issued a press release entitled "Vertex Pharmaceuticals Reports Fourth Quarter and Full Year 2000 Financial Results." The press release stated in part:

*"In 2000, Vertex's drug discovery and development enterprise progressed to a new level of product creation capability and downstream revenue opportunity,"* stated Joshua Boger, Ph.D., Chairman and CEO of Vertex Pharmaceuticals. "We advanced our drug design platform by taking a lead in the new field of chemogenomics, which represents the intersection of medicinal chemistry with the human genome. *We made progress across our product pipeline* and strengthened our financial position by raising more than \$500 million in cash. We signed collaborative agreements with potential payments of approximately \$900 million – including a landmark deal with Novartis on the kinase family – illustrating the value that Vertex creates in drug discovery for the Company and its partners."

63. Then, on March 5, 2001, Vertex was forced to admit that one of its candidates had failed. The effect on the Company's stock price was immediate. Thus, insiders knew that any additional negative reports would hammer Vertex stock. A March 5, 2001 *Biotechnology Newswatch* article entitled "Vertex stock falls in wake of Hep C trial results," stated in part:

*News of an unsuccessful Phase II trial of Vertex Pharmaceuticals, Inc.'s hepatitis C drug caused a 13 percent free-fall in the company's stock.*

Shares dropped \$6.88 to \$47.50 in the wake of reports that Vertex planned to boost research and development spending to get VX-497 through the pipeline, resulting in a larger loss for the year.

64. The pressure continued to mount in April, 2001 when a forum was held specifically discussing the Vertex-Novartis deal. Vertex's development of the kinase family was in the public eye. An April 18, 2001 *PR Newswire* article entitled "Novartis – Vertex Drug Discovery Collaboration on Kinases to be Presented at Pharma & Biotech Licensing Conference on June 4-5 in Philadelphia," stated in part:

Many deals are to be presented at the 5th International Pharma & Biotech Licensing & Deal-Making Summit, including "Target Family Deal Making: The Vertex – Novartis Collaboration," presented by Robert Mashal, M.D., of Vertex Pharmaceuticals, announces Strategic Research Institute.

In 2000, Vertex and Novartis entered into a broad-based drug discovery collaboration on kinases. Over the course of the collaboration, Novartis could, subject to milestones and other conditions, make pre-commercial payments to Vertex of \$800 million, based on the successful discovery and full development of eight compounds. The size and scope (> 500 targets) reflect Vertex's approach to drug discovery. The deal's terms, structure, goals, and current status as well as future directions in discovery deal-making at Vertex will be discussed.

65. **The April 24, 2001 False and Misleading Statements:** On April 24, 2001, the Company issued a press release entitled "Vertex Pharmaceuticals Reports First Quarter 2001 Financial Results." The press release stated in part:

-- Vertex Continues to Make Clear Progress in Clinic --

\* \* \*

***"In the first quarter of 2001, we continued to make clear progress on the clinical front,"*** stated Joshua Boger, Ph.D., Chairman and CEO of Vertex Pharmaceuticals. ***"In Vertex-driven programs, we initiated a Phase II clinical trial with VX-745, our p38 MAP kinase inhibitor, in patients with rheumatoid arthritis.***

\* \* \*

Dr. Boger continued, "As we near the one-year anniversary of the signing of our collaboration with Novartis, we are pleased with our progress as we have ramped up our chemogenomics platform targeting the kinase family. ***Our parallel drug discovery platform is performing as we envisioned it would, hiring is on plan, and we are on track to select one or more kinase inhibitors for preclinical development this year.*** In addition, we know that chemogenomics is scalable into other multi-

target gene families of interest, and we believe that the broader application of our strategy could create significant new product and alliance opportunities.”

\* \* \*

#### Pipeline Update

##### Vertex-driven Programs

##### P38 MAP Kinase Program: VX-745

-- In January 2001, Vertex began a dose-ranging multi-center, double-blinded, placebo-controlled Phase II clinical trial with VX-745 in patients with rheumatoid arthritis. Vertex is taking this compound forward through clinical development with its Far East partner, Kissei. Vertex retains U.S. and European commercial rights to VX-745.

66. **Reasons the April 24, 2001 Statements Were False and Misleading:** Defendant Boger’s claims that there was “clear progress” on VX-745 and that Phase II studies were initiated were false and misleading, because Boger and Vertex possessed data which showed the drug to be toxic and not a viable drug candidate. Moreover, defendant Boger used this false statement as a lead-in to his discussion of the Vertex-Novartis deal, making plain that the success of the VX-745 was to presage the success of the \$800 million deal. The pipeline update was similarly false because the drug should not have entered Phase II testing.

#### **MOTIVE: THE AURORA ACQUISITION**

67. On April 30, 2001, the Company issued a press release entitled “Vertex Pharmaceuticals to Acquire Aurora Biosciences: Vertex to Integrate Aurora’s Core Strengths in Cell Assay Development and Ultra High Throughput Screening to Accelerate Drug Discovery in Gene Families.” The press release stated in part:

Vertex Pharmaceuticals Incorporated and Aurora Biosciences Corporation announced today that they have signed a definitive agreement whereby Vertex will acquire Aurora in a stock-for-stock transaction. The fully-diluted equity value of the transaction is approximately \$592 million. *The agreement will unite Aurora’s industry-leading assay development, screening and cell biology capabilities with Vertex’s integrated drug discovery expertise*, creating a comprehensive, scalable platform for systematically accelerating drug candidate output in target-rich gene families. The combination of Vertex’s and Aurora’s technology and expertise is expected to:

- \* increase the flow of novel drug candidates into development,
- \* accelerate the creation of a broad intellectual property estate, and
- \* provide enhanced opportunities for major drug discovery, development and commercial alliances.

Under the terms of the agreement, which have been approved by the Boards of Directors of both Vertex and Aurora, each share of Aurora will convert into shares of newly issued Vertex common stock at a fixed ratio of 0.62 shares of Vertex common stock for each share of Aurora common stock. Based on the closing price of Vertex stock of \$39.25 on April 27, 2001, the fixed exchange ratio implies a price of \$24.34 per Aurora share, a 44 percent premium to the closing price of \$16.85 on April 27, 2001. Vertex will be obligated to issue a total of approximately 14.0 million shares of common stock in exchange for Aurora's outstanding common stock, and Aurora options will be equitably converted to Vertex options. The transaction will be structured as a tax-free share exchange and is intended to be accounted for as a pooling-of-interests. Directors and officers of both companies have agreed to vote their shares in favor of the merger. The merger is subject to approval by both Vertex's and Aurora's shareholders, regulatory approval and other closing conditions, and is expected to close in the third quarter of 2001. The transaction, excluding merger-related expenses, is not expected to materially affect Vertex's previously announced net operating results projections for 2001. As of December 31, 2000, Aurora had approximately \$100 million in net cash.

\* \* \*

“Aurora has developed a compelling suite of technologies that has the potential to accelerate target selection, lead generation and optimization, drug candidate selection and establishment of clinical proof-of-concept across multiple gene families,” said Joshua Boger, Ph.D., Vertex's Chairman and CEO. ***“By integrating Aurora's capabilities within Vertex's chemogenomics platform, we believe we will be able to rapidly expand research into major new gene families, as well as enhance our existing multi-target research programs in the kinase and caspase gene families.*** In addition, we believe that Aurora's proteomics and assay development expertise are broadly applicable in our clinical programs, and will enable us to more rapidly establish the therapeutic profile of our development-stage drug candidates.”

“This merger fulfills a near term goal that we have emphasized over the past six months in our public communications and guidance to the financial community, which is to extend our leadership position in gene family-based drug discovery through internal expansion and complementary acquisitions,” added Dr. Boger.

“Our core strengths in assay development and ultra high throughput screening are an excellent strategic fit with Vertex's chemogenomics platform,” said Stuart J.M. Collinson, Ph.D., Aurora's Chairman, CEO and President, who will join

Vertex's Board of Directors when the merger closes. ***“The agreement with Vertex significantly accelerates our comprehensive drug discovery initiatives and creates new and enhanced partnership opportunities in the years ahead. Together with Vertex, we believe that we can immediately and systematically boost our collective research output in multiple gene families, creating near and long-term value for shareholders.”***

#### Vertex and Aurora: Drug Discovery Advantages in Multiple Major Gene Families

The combined company will have one drug on the market, the HIV protease inhibitor Agenerase(R), and ***12 drug candidates in clinical development targeting the treatment of viral diseases***, cancer, autoimmune and inflammatory diseases, and neurological diseases. The combined company's integrated technology platform will be supported by more than 25 collaborative and licensing agreements with research institutions and major pharmaceutical companies, including American Home Products, Aventis, Bristol-Myers Squibb, GlaxoSmithKline, Eli Lilly, Johnson & Johnson, Merck, Novartis, Pfizer, Pharmacia and Roche.

Vertex has extensive efforts underway to discover and develop small molecule inhibitors for specific targets in the kinase and caspase gene families, and ***the merger is expected to significantly enhance Vertex's drug discovery capabilities in these and other major gene families and target classes***. The merger enables Vertex to integrate Aurora's industry-leading capabilities in the development of cell-based assays and screening instrumentation for use in drug discovery directed at ion channels, g-protein coupled receptors (GPCRs), kinases, proteases and phosphatases, and for use in target validation in a wide range of gene families. Vertex's ongoing drug discovery efforts will also benefit from Aurora's predictive pharmacology and proteomics technologies, which use high-throughput assessments of toxicology and metabolic markers to establish therapeutic proof-of-concept and safety of drug candidates in early clinical testing. Aurora's recent acquisition of PanVera, a specialty supplier of high quality recombinant proteins, provides a further, valuable asset in drug discovery.

68. As a result of defendants' false statements, analysts raised their estimates. A May 21, 2001 *Reuters News* article entitled “RESEARCH ALERT-Robertson raises Vertex rating,” stated in part:

NEW YORK, May 21 (Reuters) – Robertson Stephens on Monday raised its investment rating on shares of biotech company Vertex Pharmaceuticals Inc. to strong buy from buy.

\* \* \*

*“We believe VRTX has one of the broadest clinical pipelines in the industry,”* King and Harr said in a research note. *Vertex has twelve product candidates in clinic development and is aiming for five more this year, they said.*

69. On July 18, 2001, the Company issued a press release entitled “Vertex Pharmaceuticals Announces the Completion of its Acquisition of Aurora Biosciences.” The press release stated in part:

Vertex Pharmaceuticals Incorporated today announced the completion of its acquisition of Aurora Biosciences Corporation. The transaction was completed today after Vertex and Aurora shareholders voted to approve the merger agreement at special meetings held at Vertex’s and Aurora’s headquarters.

The merger is a tax-free stock-for-stock exchange. As a result of the acquisition, Aurora shareholders will receive 0.62 shares of Vertex common stock for each share of Aurora common stock. Cash will be provided for fractional shares. Letters of transmittal regarding the procedures to exchange Aurora common stock for Vertex common stock will be sent to former Aurora stockholders in the near future. Aurora will deregister its common stock with the Securities and Exchange Commission and delist its common stock from the Nasdaq Stock Market.

As a result of the merger, Aurora will operate as a wholly owned subsidiary of Vertex and will continue to carry the Aurora name. Aurora will continue to pursue its strategy of collaborating with new and existing partners in all capacities.

*“Vertex is a leader in small molecule drug discovery. This merger represents a significant step in our strategy to enhance and accelerate the design and development of major new drugs,”* stated Joshua Boger, Ph.D., Chairman and CEO of Vertex Pharmaceuticals. “By integrating Aurora’s capabilities into Vertex’s chemogenomics platform, we will be able to rapidly expand research into major new gene families, as well as enhance our existing multi-target gene family research program in the kinase, caspase and protease gene families. Vertex has a strong track record of creating drug candidates targeting significant unmet medical needs, and the technologies and capabilities gained from this merger will increase our ability to create medically important drugs.”

70. **The July 26, 2001 False and Misleading Statements:** On July 26, 2001, the Company issued a press release entitled “Vertex Pharmaceuticals Reports Second Quarter and First Half 2001 Financial Results.” The press release stated in part:

“Our acquisition of Aurora Biosciences marks a very significant milestone for Vertex,” stated Joshua Boger, Ph.D., Chairman and CEO of Vertex Pharmaceuticals.... The great potential of this merger lies in the new gene families we will be able to access and in new classes of drug targets that we will be able to develop, which will greatly expand our ability to create novel drugs to treat large, unmet medical needs.”

*“During the first half of 2001, we made significant advances in drug discovery,” continued Dr. Boger. “We continued to make clear progress in our broad kinase research program where we are focusing on kinase involvement in multiple therapeutic areas.*

\* \* \*

*“Our chemogenomics approach to the kinase gene family and our acquisition of Aurora Biosciences provide an organizational and technological model for moving rapidly into additional gene families.* We have now targeted our chemogenomics efforts at an additional gene family – proteases. Proteases represent a target-rich gene family with application in a broad range of therapeutic areas including hypertension, diabetes, Alzheimer’s Disease and viral disease. We already have a strong track record with single protease targets and are confident we can build upon these efforts across the entire human protease gene family.”

\* \* \*

#### Selected Pipeline Update

Vertex has 12 drug candidates in development to treat viral diseases, inflammation, cancer, autoimmune diseases and neurological disorders.

#### Vertex-driven Programs

##### P38 MAP Kinase Program: VX-745

\*Vertex has begun a pilot Phase II clinical trial of VX-745 in patients with myelodysplastic syndrome (MDS). The trial will assess safety, tolerability and effect on blood cell counts of VX-745 administered for 12 weeks to approximately 30 patients with MDS.... The demonstrated ability of VX-745 to inhibit the cytokines IL-1 beta and TNF alpha ***points to a potential therapy role for VX-745 in MDS.***

\*Separately, VX-745 continues to be tested in a three-month dose-ranging multi-center, double-blinded, placebo-controlled Phase II clinical trial in patients with rheumatoid arthritis.

\* \* \*

Conference Call and Webcast: Second Quarter Financial Results: Vertex Pharmaceuticals will host a conference call on July 26, 2001 at 5:00 p.m. ET to review financial results and recent developments.

71. **Reasons the July 26, 2001 Statements Were False and Misleading:** Defendants specifically touted the progress of VX-745, despite knowledge that the drug crossed the blood-brain barrier and was toxic. Defendants also failed to acknowledge that their drug delivery system had failed in encouraging the selection of VX-745, and continued to count it as one of 12 viable drug candidates. Indeed, the company announced here that it was expanding the potential development of VX-745 into MDS, implying that the drug was doing well in testing.

#### **DEFENDANTS' FRAUD BEGINS TO UNRAVEL**

72. Just two months later, on September 24, 2001, the Company pulled the plug on VX-745. In finally telling the market the problems with VX-745, the Company stated in part:

The decision to suspend clinical development of VX-745 is based directly on adverse effect findings within nonclinical (animal) tests. In one of two animal species receiving high-dose VX-745 exposure, adverse effect findings within the central nervous system (CNS) were noted. The tests were conducted as part of standard nonclinical safety evaluations in support of long term human clinical studies. The blood levels of VX-745 that were associated with neurological effects in animals were approximately ten times higher than the blood levels obtained in human clinical trials to date. Nonclinical tests have indicated that VX-745 crosses from the blood into the CNS. No neurological side effects associated with the drug have been observed in clinical trials of VX-745 to date.

“Vertex’s strategy focuses on the discovery of multiple drug candidates, representing distinct chemical classes, for each novel protein target,” said Dr. Joshua Boger, Chairman and CEO of Vertex. “In our p38 MAP kinase program, we have two second generation drug candidates which do not cross from the bloodstream into the CNS, VX-702 and VX-850, one or both of which we can move into clinical development quite rapidly. Based on the clinical data we have gathered to date, Vertex remains committed to maintaining our leadership position in exploring the clinical and commercial opportunity of p38 MAP kinase inhibitors.”

Vertex intends to present the clinical data from the Phase II clinical study in rheumatoid arthritis in a peer-reviewed forum in 2002. In January 2001, Vertex began a 12-week, randomized, placebo-controlled clinical trial of VX-745 in rheumatoid arthritis patients. The objective of the study was to assess the safety, pharmacokinetics and clinical activity of VX-745 at two dose levels. Vertex has completed the treatment and preliminary evaluation of the first (lower dose) cohort of patients in the study. In this study, VX-745 was generally well-tolerated and no CNS adverse events were observed. Vertex also obtained confirmatory evidence that

inhibition of the p38 MAP kinase mechanism with an orally active drug can produce a significant clinical effect, based on the study's primary endpoint of ACR 20 response in patients dosed with VX-745 compared to placebo. ACR 20 is a standard measure of response to treatment in rheumatoid arthritis patients, and represents improvement in a variety of clinically relevant signs and symptoms of disease.

Based on the CNS effects observed in ongoing nonclinical (animal) toxicology testing, Vertex voluntarily made the decision to not proceed with enrollment of patients in the higher-dose cohort of the rheumatoid arthritis study and to suspend the trial. In addition, ***an ongoing trial of VX-745 in myelodysplastic syndrome has also been stopped.*** The Company does not anticipate any material financial effect in 2001 related to the change in focus for the p38 MAP kinase program. The potential for further clinical development of VX-745 will be evaluated following a full analysis of clinical and nonclinical data, as well as possible additional nonclinical tests.

“Based on the ‘proof of principle’ clinical and safety data we have generated to date, we remain highly confident that we can develop and commercialize p38 MAP kinase inhibitors that will provide a major clinical advance in inflammatory diseases such as rheumatoid arthritis,” said John Alam, M.D., Senior Vice President of Drug Evaluation and Approval at Vertex. “Although clinical data provided support for continued development of VX-745, at this time we believe the prudent action is to refocus our development efforts on second generation p38 inhibitors. We intend to initiate clinical studies with our second generation p38 inhibitors in the first half of 2002.”

“Vertex is well-positioned as a leader in small molecule drug discovery and development,” said Dr. Boger. “Vertex has one drug on the market, more than ten drug candidates in development addressing multiple areas of significant unmet medical need, a strong cash position and more than 25 collaborations with pharmaceutical and biotechnology companies. We look forward to continued advancement of our pipeline and the addition of new drug candidates into development in the months ahead.”

73. The market reacted sharply to this news. A September 24, 2001 *Reuters News* article entitled “UPDATE 1-Vertex suspends arthritis drug trial, shares plunge,” stated in part:

Shares of Vertex Pharmaceuticals Inc. plunged on Monday after the biotech firm suspended trials of a promising experimental arthritis drug, VX-745, citing neurological side effects in animals.

But the Cambridge, Massachusetts-based firm said that it plans by the first half of next year to begin human trials of one or two similar orally administered compounds, VX-702 and VX-850, that block inflammation by the same method. It said the newer compounds do not cross from the bloodstream into the central nervous system – and are therefore less likely than VX-745 to cause neurological side effects.

Vertex was off \$6.62 to \$16.85, or 28 percent, in heavy afternoon trading on the Nasdaq.

74. As a result of the defendants' revelations regarding the cancellation of the VX-745 development program, and the concealment of certain of its preclinical studies, the price of Vertex shares plummeted 24.4%, from a share price of \$23.47 to \$17.74, only two months after completion of the merger with Aurora. Of course, defendants have never revealed or admitted that early preclinical studies reflected that VX-745 would not survive clinical studies because it was not safe.

75. In fact, defendants had no choice but to disclose the cancellation of the VX-745 program, since (i) defendants had completed their merger with Aurora, obviating the need to conceal adverse material facts to preserve the deal; (ii) to continue the concealment would have put additional patients at risk of exposure to a potent and highly lipophilic p38 MAPK inhibitor that could be expected to cross the blood-brain barrier and thus cause neuronal effects; (iii) the VX-745 development program had reached a point where the cost of the resources necessary to continue the concealment was outweighed by the advantages of making a correcting disclosure, including the significantly reduced risks associated with development of the identified second-generation p38 MAPK inhibitors VX-702 and VX-850; (iv) ultimately, VX-745, for reasons related to its poor design, particularly its ability to cross the blood-brain barrier, would not stand a reasonable chance for drug approval; and (v) Vertex employees had become aware of the concealed issues with VX-745. Prior to the public revelation that VX-745 was not a viable drug candidate, defendant Marks insider traded and was charged with that by the Securities and Exchange Commission ("SEC").

### **The Indictment and Plea of Marks**

76. According to the complaint filed by the SEC, in September 2001, defendant Marks' title was Chief Patent Counsel at Vertex, and he had primary responsibility for overseeing the Company's patents. In addition to these responsibilities, Marks was the highest ranking lawyer on

Vertex's staff from June 2001 until September 24, 2001. As a result, defendant Marks was consulted frequently on matters other than just patent issues, including requests concerning Company stock. Marks was asked to review press releases and was also very involved with the Vertex-Aurora merger.

77. On December 3, 2002, the SEC released the following notice regarding charges against defendant Marks, former Counsel at Vertex:

SEC CHARGES HIGH-RANKING ATTORNEY AT CAMBRIDGE BIOTECH COMPANY WITH INSIDER TRADING

The Commission announced today that it has filed insider trading charges against Andrew S. Marks, of Wayland, Massachusetts, in connection with his September 2001 sale of stock in Vertex Pharmaceuticals, Inc., a Cambridge-based biotechnology company. The Commission's complaint alleges that Marks, who at the time was Vertex's highest-ranking attorney, learned on September 20, 2001 that Vertex planned to announce the suspension of clinical trials of one of its promising drugs on September 24. According to the Commission's complaint, on September 21, Marks liquidated all of his Vertex stock despite having previously acknowledged in writing that the impending release would not be viewed favorably by Wall Street and that he should not sell his Vertex shares. The Commission's complaint alleges that, by selling his holdings prior to the company's public announcement on September 24, Marks avoided a loss of \$105,999.

According to the Commission's complaint, at the time he traded, Marks was the designated attorney for employees to consult regarding compliance with Vertex's employee securities trading policy. In that capacity, the complaint alleges, Marks wrote Vertex's CEO an email on September 20, advising him to make sure that an employee who had requested permission to trade had no knowledge of the impending press release. According to the Commission's complaint, Marks' email went on to say:

I guess that I am troubled about any employee trading prior to that release because it is likely to have an effect on the stock (looks like I can't sell any shares) and, depending on the degree of that effect, could create the perception of insider trading.

The Commission's complaint alleges that, on Sept. 21, less than 24 hours after writing this email to the CEO, Marks sold 20,900 shares of Vertex at an average price of \$22.81 per share, receiving \$476,765. According to the Commission's complaint, Vertex announced its decision to terminate clinical trials at approximately

7:10 a.m. on September 24. Vertex's shares closed that day at \$17.74, down \$5.33 from the previous close on volume of 9.8 million shares ....

The Complaint alleges that Marks traded in breach of a fiduciary duty to Vertex and its shareholders not to trade in the Company's stock while in possession of material, nonpublic information about the Company. As a result of the conduct described in the Complaint, the Commission has charged Marks with violations of the antifraud provisions of federal securities laws. The Commission's Complaint seeks injunctive relief, disgorgement, plus prejudgment interest, and civil penalties and seeks an order barring Marks from acting as an officer or director of any publicly-traded company.

The Commission staff acknowledges the assistance of the NASD Regulation, Inc., in connection with this investigation.

78. The SEC's complaint pointed to the unlawful selling of Vertex shares by Marks, based on insider information regarding the termination of the VX-745 program. Additionally, the SEC's complaint points to the concealed preclinical testing activities, as well as the interests of one or more Vertex employees interested in selling the stock, following the internal decision to suspend the VX-745 program, but preceding the public announcement of September 24, 2001.

79. Defendant Marks has now pled guilty to these charges of insider trading.

### **FIRST CLAIM FOR RELIEF**

#### **For Violation of §10(b) of the Exchange Act and Rule 10b-5 Against All Defendants**

80. Plaintiffs incorporate ¶¶1-79 by reference.

81. During the Class Period, defendants disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

82. Defendants violated §10(b) of the Exchange Act and Rule 10b-5 in that they:

- (a) Employed devices, schemes, and artifices to defraud;

(b) Made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

(c) Engaged in acts, practices, and a course of business that operated as a fraud or deceit upon plaintiffs and others similarly situated in connection with their purchases of Vertex publicly traded securities during the Class Period.

83. Plaintiffs and the class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Vertex publicly traded securities. Plaintiffs and the class would not have purchased Vertex publicly traded securities at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by defendants' misleading statements.

84. As a direct and proximate result of these defendants' wrongful conduct, plaintiffs and the other members of the class suffered damages in connection with their purchases of Vertex publicly traded securities during the Class Period.

## **SECOND CLAIM FOR RELIEF**

### **For Violation of §20(a) of the Exchange Act Against All Defendants**

85. Plaintiffs incorporate ¶¶1-84 by reference.

86. The Individual Defendants acted as controlling persons of Vertex within the meaning of §20(a) of the Exchange Act. By reason of their positions as officers and/or directors of Vertex, and their ownership of Vertex stock, the Individual Defendants had the power and authority to cause Vertex to engage in the wrongful conduct complained of herein. Vertex controlled each of the Individual Defendants and all of its employees. By reason of such conduct, the Individual Defendants and Vertex are liable pursuant to §20(a) of the Exchange Act.

## CLASS ACTION ALLEGATIONS

87. Plaintiffs bring this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased or otherwise acquired Vertex publicly traded securities (the “Class”) during the Class Period. Excluded from the Class are defendants.

88. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. During the Class Period, Vertex had more than 59 million shares of stock outstanding, owned by hundreds if not thousands of persons.

89. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

- (a) Whether the Exchange Act was violated by defendants;
- (b) Whether defendants omitted and/or misrepresented material facts;
- (c) Whether defendants’ statements omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;
- (d) Whether defendants knew or deliberately disregarded that their statements were false and misleading;
- (e) Whether the prices of Vertex publicly traded securities were artificially inflated; and
- (f) The extent of damage sustained by Class members and the appropriate measure of damages.

90. Plaintiffs’ claims are typical of those of the Class because plaintiffs and the Class sustained damages from defendants’ wrongful conduct.

91. Plaintiffs will adequately protect the interests of the Class and have retained counsel who are experienced in class action securities litigation. Plaintiffs have no interests which conflict with those of the Class.

92. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

### **PRAYER FOR RELIEF**

WHEREFORE, plaintiffs pray for judgment as follows:

- A. Declaring this action to be a proper class action pursuant to Fed. R. Civ. P. 23;
- B. Awarding plaintiffs and the members of the Class damages, interest and costs; and
- C. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

### **JURY DEMAND**

Plaintiffs demand a trial by jury.

DATED: July 26, 2004

Respectfully submitted,

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\* Denotes service via U.S. mail on July 26, 2004.