AMENDED COMPLAINT

1. Lead Plaintiff, the City of Fort Myers Police Officers’ Retirement System (“plaintiff”), on behalf of itself and all other persons similarly situated, allege the following based upon personal knowledge as to itself and its own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through its attorneys.

2. This is a class action for violations of the anti-fraud provisions of the federal securities laws on behalf of all purchasers of Vertex Pharmaceuticals Incorporated (“Vertex” or the “Company”) publicly traded securities between June 12, 2007 and November 2, 2007 (the “Class Period”), who were damaged thereby (the “Class”).

3. Vertex is a pharmaceutical company engaged in the discovery, development and commercialization of small molecule drugs for the treatment of serious diseases. The Company was founded in 1989 and is headquartered in Cambridge, Massachusetts.

4. During the Class Period, defendants made false and misleading statements about the development of Vertex’s drug telaprevir (also known as VX-950) for the treatment of Hepatitis C. Specifically, defendants made favorable statements regarding telaprevir and failed to disclose unfavorable data from a trial of the drug called PROVE 2.
5. When the truth was finally disclosed, Vertex’s stock price dropped from $31.64 to $24.08 in two trading days. This decrease in Vertex’s stock price was a result of the artificial inflation caused by defendants’ misleading statements coming out of the stock price.

Telaprevir and Hepatitis C

6. Telaprevir is being co-developed by Vertex with Tibotec, a division of Janssen-Cilag and member of the Johnson & Johnson family of companies, and Mitsubishi Tanabe Pharmaceuticals, though Vertex bears the majority of the development burden.

7. Hepatitis C Virus (“HCV”) is the blood-borne pathogen which causes the disease Hepatitis C. HCV is a single strand RNA virus which is transmitted by blood to blood contact, most often by shared needles and sexual contact. The virus replicates extremely rapidly, with approximately 1 trillion particles produced daily in an infected individual, and has a very high mutation rate; these factors make it very difficult for the immune system to neutralize the infection. The high mutation rate has led to the emergence of six genotypes of HCV (1-6) with several subtypes within each genotype.

8. Hepatitis C manifests most prominently as an inflammation of the liver, which, if left untreated, can lead to potentially fatal conditions such as cirrhosis (liver scarring), liver cancer, or liver failure. There are an estimated 3,400,000 Americans with chronic HCV infection and approximately 170,000,000 infected worldwide. Hepatitis C is a worldwide epidemic and is about five times as prevalent as HIV.

9. Effective treatments to eliminate HCV from the body have only developed in the last 25 years. Interferon, the first successful treatment, works by triggering the body’s own immune response to fight the infection. Unfortunately, the drug is very expensive, causes severe side-effects, and is barely effective, with early trials yielding only a 6% cure rate. The addition of ribavirin to the treatment regimen, as well as the isolation of more effective interferons (e.g., PEG-interferon alfa),
has led to the present standard of care treatment, which is still costly and causes severe side-effects, but has a cure rate of 54-56%. This is a remarkable improvement, but treatment still fails for almost half of the patients who endure the regimen.

10. Telaprevir is an attempt at a different approach to fighting the virus; it works by interrupting a vital step in the HCV replication process. Telaprevir is a first-in-class drug and has maintained its lead time in the FDA review process over competitors' drugs. As a first-in-class drug, it stands to be marketable without competition for some time if approved. Vertex is conducting clinical trials of telaprevir designed to provide data which would support an application for marketing approval for HCV as a treatment for patients who have never been treated and patients who have previously failed other treatment regimens.

Importance of Telaprevir to Vertex

11. Vertex is a research-driven company and its business model depends on the development and regulatory approval of new, patent-protected products. The series of drugs in development is referred to as the "drug pipeline." The drug pipeline is critical to pharmaceutical companies' financial successes and important to investors because new drug products are necessary to sustain growth and profitability.

12. Since Vertex was founded in 1989, it has only had two drug candidates approved for marketing by the FDA. Both are HIV protease inhibitors developed in collaboration with GlaxoSmithKline: amprenavir which is marketed as Agenerase, and fosamprenavir calcium which is marketed as Lexiva/Telzir. Lexiva/Telzir is a prodrug\(^1\) of Agenerase and has replaced Agenerase in the worldwide market. GlaxoSmithKline pays Vertex a royalty on the net sales of Lexiva/Telzir, but

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\(^1\) A prodrug is a drug which is taken in a relatively inactive form which is then metabolized into the active metabolite which causes the desired effect in the system.
this revenue falls well short of Vertex's operating expenses; Vertex operated at a net loss of $391.3 million, $206.9 million and $203.4 million during 2007, 2006 and 2005, respectively.

13. Developing a new drug is costly and time-consuming; on average, it takes 10-15 years and $800 million to conduct the research and development necessary to have a drug approved by the FDA. Although Vertex has been developing several other drug candidates over the years, none has been as important to Vertex as telaprevir. Telaprevir is the keystone of the Company, and is the drug upon which its future rests. Defendant and CEO Joshua S. Boger stated at the JPMorgan Annual Healthcare Conference in January 2007 that "we are building Vertex on Telaprevir." During the Class Period, analysts projected that telaprevir could generate over $2 billion in annual revenue in North America alone.²

The PROVE Studies

14. Clinical trials involving new drugs commonly proceed through four phases after the drugs have been screened in pre-clinical studies. 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. If Phase I studies do not reveal unacceptable toxicity, Phase II studies may be initiated. 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. Phase IIb trials are studies specifically designed to assess the efficacy of the drug, i.e., how well a drug works at a particular dosage and over a specific duration of treatment. 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. Phase IV clinical studies are undertaken after a drug has been approved, and may explore new uses for the drug, drug dosages, or long-term effects of the drug.

15. During the Class Period, defendants were conducting three Phase IIb trials of telaprevir's safety and efficacy in treating HCV to support a New Drug Application ("NDA") with the FDA. These studies were referred to as the PROVE studies. They looked at such outcomes as Rapid Viral Response ("RVR") which is when the virus becomes undetectable in a short period of time; Sustained Viral Response ("SVR"), which is when the virus becomes undetectable before the end of treatment and remains undetectable for some time after a treatment regimen ends; and relapse rate, which is how frequently patients who initially respond to treatment with a significant reduction in viral load, later return to their baseline viral load.

16. PROVE 1 was a trial of 250 genotype 1 HCV patients who had not been previously treated. The study observed patients who received telaprevir-based treatment regimens of 12, 24 and 48-week durations, compared to a 48-week control group taking PEG-interferon and ribavirin. PROVE 1 was conducted at 37 clinical centers in the U.S. The study began enrolling patients some time before June 2006 and closed enrollment in September 2006.

17. PROVE 2 was a four-arm clinical trial of 323 genotype 1 HCV patients who had not been previously treated. The study assessed patients who received telaprevir-based treatment regimens of 12 and 24-week durations and a 12-week arm of telaprevir and PEG-interferon, compared to a 48-week control group of PEG-interferon and ribavirin. PROVE 2 was conducted at 28 clinical centers in Europe. The study began enrolling patients in June 2006 and closed enrollment in January 2007.

18. PROVE 3 was a four-arm clinical trial of 453 genotype 1 HCV patients who did not achieve an SVR with a prior course of PEG-interferon and ribavirin treatment. The study was
conducted to assess patients who receive telaprevir-based treatment regimens of 24 and 48-week total duration, compared to a 48-week control group of PEG-interferon and ribavirin. PROVE 3 is being conducted at 50 clinical centers in the U.S. and the E.U.

19. Defendants first shared four and 12-week interim data from the PROVE 1 trial at the 42nd Annual Meeting of the European Association for the study of the Liver on April 14, 2007. This data signaled efficacy of the drug beyond the standard of care treatment, and was looked upon as positive and encouraging by analysts.3

20. On June 12, 2007, rather than waiting until an upcoming medical conference to discuss study data, Vertex issued a press release which stated: “Interim results from PROVE 2 consistent with findings from PROVE 1.” The press release went on to report some encouraging preliminary results for PROVE 2.

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3 See, e.g., April 16, 2007 Needham Analyst Report, “Encouraging 12 Week End of Treatment Data from Telaprevir PROVE 1 Study Announced at EASL Mtg.”; April 16, 2007 Bernstein Research Analyst Report, “The data from this study provides further confirmation of the potential of VX 950, and shows that the drug will offer substantial incremental activity, and benefit, with an acceptable increase in adverse events and the drug’s development is continuing as fast as feasible.”; April 16, 2007 Cowen Company Analyst Report, “Unquestionably the highlight of this weekend’s EASL meeting was the presentation of interim data from telaprevir’s (TVR) Phase II PROVE-1 trial. Notably the 12 week interim analysis of all 250 patients in the PROVE-1 trial continued to show a high proportion of patients undetectable at the end of 12 weeks of therapy (70% for TVR/PEG-IFN/RBV vs. 39% PEG-IFN/RBV by ITT analysis, n=250, p<0.001). . . . Telaprevir does not just look like an approvable drug, but it continues to seem to be among the most potent therapies in development for HCV, likely the first to market, and thus far the only one capable of both shortening the HCV treatment paradigm and increasing SVR rates. We continue to recommend Vertex.”; April 16, 2007 Canaccord Adams Analyst Report, “There is no change to our investment thesis, and we believe that it has been strengthened with this weekend’s data presentation. We believe that telaprevir will represent a change in the landscape in how hepatitis C is treated. The 12-week response data are unprecedented, in our belief. This is based on what we perceive to be the achievable goal of having a much shorter treatment duration and higher efficacy compared to the current interferon standard of care.”
21. On July 24, 2007, Vertex issued another press release which reiterated that for PROVE 2, “preliminary results for 12-week safety and antiviral activity were consistent with findings previously reported for PROVE 1.” On a conference call later that day, defendant and CMO John J. Alam again reported promising interim results for PROVE 2.

PROVE 2 Results Are Unfavorable and Vertex Stock Plummet When They Are Disclosed

22. On November 2, 2007, defendants finally announced the adverse results of PROVE 2. First, telaprevir failed to show significantly higher SVR rates than the control group. Indeed, telaprevir’s advantage in PROVE 2 over drugs already approved by the FDA to treat Hepatitis C was only 6%, less than half that seen in PROVE 1. Second, telaprevir’s relapse rate in PROVE 2 was extremely high compared to PROVE 1. Specifically, the PROVE 2 relapse rate was 14%, seven times greater than in PROVE 1, meaning that seven times as many telaprevir patients in PROVE 2 subsequently had their viral loads return to baseline or higher during follow-up because the treatment ultimately failed.

23. Defendants were aware of poor SVR and relapse results from PROVE 2 throughout the Class Period. As such, their dissemination of other, more promising data from PROVE 2 was misleading. Further, their assertions that the results of PROVE 2 were consistent with PROVE 1 were false when made.

24. Following the disclosure of the poor SVR and relapse results from PROVE 2, Vertex’s stock price dropped from $31.64 to $24.08 in two trading days as artificial inflation came out of the stock price.

JURISDICTION AND VENUE

25. The claims asserted arise under §§10(b) and 20(a) of the Securities Exchange Act of 1934 (“1934 Act”) and Rule 10b-5. Jurisdiction is conferred by §27 of the 1934 Act. Venue is proper pursuant to §27 of the 1934 Act. Vertex’s headquarters are located in Cambridge,
THE PARTIES

26. By Court Order dated May 29, 2008, The City of Fort Myers Police Officers’ Retirement System was appointed Lead Plaintiff in this action. As set forth in the certification filed in connection with its motion to be appointed Lead Plaintiff, The City of Fort Myers Police Officers’ Retirement System purchased Vertex securities during the Class Period and, as a result of defendants’ conduct detailed herein, suffered damages.

27. Defendant Vertex is a pharmaceutical company engaged in the discovery, development and commercialization of small molecule drugs for the treatment of serious diseases, with its headquarters located in Cambridge, Massachusetts. Vertex’s stock is traded under the symbol VRTX on the NASDAQ, which is an efficient market.

28. Defendant Joshua S. Boger (“Boger”) was, at all relevant times, President and Chief Executive Officer (“CEO”) of the Company.

29. Defendant Ian F. Smith (“Smith”) was, at all relevant times, Executive Vice President and Chief Financial Officer (“CFO”) of the Company. During the Class Period, Smith sold 90,925 shares of Vertex stock for gross proceeds of $3,637,000.

30. Defendant John J. Alam (“Alam”) was, at all relevant times, Executive Vice President, Medicines Development, and Chief Medical Officer (“CMO”) of the Company. During the Class Period, Alam sold 30,720 shares of Vertex stock for gross proceeds of $1,075,200.

31. Defendant Peter Mueller (“Mueller”) was, at all relevant times, Executive Vice President, Drug Innovation and Realization, and Chief Scientific Officer of the Company.
32. Defendant Johanna Messina Power ("Messina Power") was, at all relevant times, Vice President and Controller of the Company. During the Class Period, Messina Power sold 2,875 shares of Vertex stock for gross proceeds of $98,694.50.

33. The defendants named in ¶¶28-32 are referred to herein as the "Individual Defendants."

PRE-CLASS PERIOD EVENTS

34. On October 26, 2006, on the Company's Q3 2006 earnings conference call, defendants made the following statements:

[Alam:] Ian touched upon our plans for investment in the telaprevir development program broadly. The clinical trials I just mentioned, while large, are just one part of bringing a major drug to the marketplace.

We're also preparing for commercial success of telaprevir. We completed the technical development work for the commercial formulation of telaprevir and have established a dosing regimen of two 375-milligram tablets to be taken every eight hours.

This launch formulation is what will be used in our PROVE 3, the 6-month clinical trial in treatment-experienced patients. We have begun to manufacture drug substance registration batches and we expect to complete all registration batches of telaprevir in the first half of 2007.

* * *

[Boger:] I'll start my brief [re]marks by reiterating that telaprevir continues to be our highest priority. HCV is a major disease and there are more than 3 million people in the United States with chronic HCV.

There is a tremendous unmet medical need. We believe our lead investigational product has the potential to address the significant unmet need in the treatment of HCV.

The telaprevir development and commercialization program is running on all cylinders. The global Phase 2b development program is well underway.

Data from this program will begun [sic] to rollout in the fourth quarter of this year and will be followed by a steady stream of data during the first half of 2007. This data will inform us as we design future trials for telaprevir and determine its full medical and commercial potential.
We have a tremendous opportunity to truly make a difference in patient’s lives. At the same time we also face challenges that go along with this kind of opportunity.

As we look ahead to our strategic plan for telaprevir in 2007, we’re focused not only on the clinical development of this drug candidate but also on our commercial objectives. We have completed the commercial launch formulation and are on track to complete registration batches of the drug in the first half of next year.

We’re fully committed to realizing our vision of transforming HCV disease. We have the financial, operational and strategic resources to support our objectives and execute on a larger scale in 2007.

* * *

Geoffrey Porges – Sanford C. Bernstein & Company – Analyst

...[P]articularly interested in the potential implications of the FDA panel’s guidance about development. They sort of were pretty clear that you need to be adding a new drug to standard of care and, but you need to be looking at SVR 24 weeks after the end of that standard of care arm.

So what do you think the implications of this are for Phase III design and where you might need to go in terms of duration of dosing in the study and the duration of the study?

* * *

[Alam:] Actually, I think the outcome of the FDA discussion, the advisory committee discussion in general was very positive, in fact, consistently positive. The most important takeaway was that they clearly affirmed that the virologic endpoint, SVR at the end of 24 weeks of treatment, is and should be the primary end point for any strategy whose goal is to eradicate the virus, so any antiviral strategy. So any other end points, histologic, etcetera, all become secondary end points.

They also specifically to the FDA’s question of does SVR need to be defined at the same time point, which is 24 weeks after control across all treatment arms, there was actually the advisory committee was very specific that the timing should be 24 weeks after the duration of treatment regardless of what the duration is. So a very positive outcome there as well in our mind.

And I’ll say that the other positive development in the discussion was that they did talk, and that’s for Phase III for registration, but there was a discussion that the advisory committee supported that in moving from Phase II to Phase III that using a what they called an SVR 12, 12 weeks after the end of treatment that you can use that information for phase transition going from Phase II to Phase III.

[Porges:] So, John, what does all of that mean for Phase III design, then?
I think the Phase III design will be, for us will be based on the clinical results PROVE 1 and PROVE 2 as a rollout. If we, as we expect, if we are able to demonstrate robust SVR 12 and then full 24 weeks SVR data with the durations that we have in the trials, then that would support moving into Phase III with 12 to 24 weeks of duration.

And again, we would expect that SVR 12 data from both the 12-week and the 24-week, which otherwise we call the 12 plus 12 arm, to provide the data to support the design of the Phase III trials.

Sorry to hop on but, John, do you need to have a 72-week control arm in that Phase III study, then?

That’s a discussion we’re going to be having with the FDA. It’s at this point it’s a discussion that doesn’t – there’s no reason to have the discussion because we really need the data with PROVE 1 and PROVE 2 to have the discussion with the FDA.

As you know, our view is that whether we have a control arm in Phase III or not, by the time we get into 2008 we will have data – our plan is to have data and our expectation is to have data from three large trials, PROVE 1, PROVE 2, PROVE 3, each of which has a control arm, and has the ability to demonstrate superiority, is powered in that way to standard of care, that at that point we won’t need to have the data from – we won’t need to wait on the data from the control arm in Phase III to file an NDA. But again the specifics of that – all of that is going to be data driven and based on discussions with the FDA which we will engage in starting in the second quarter and middle half of next year.


- PROVE program to prepare for Phase 3 initiation of telaprevir (VX-950)
- Expanding clinical development into important HCV sub-populations
- Vertex building foundation for commercialization of telaprevir

Vertex Pharmaceuticals Incorporated today announced its key business objectives for 2007 and provided an overview of recent developments, including highlights from research and development programs. Joshua Boger, Ph.D., President and Chief Executive Officer of Vertex Pharmaceuticals, will provide a corporate update at the 25th Annual JPMorgan Healthcare Conference in San Francisco on Tuesday, January 9, 2007.
“2006 was a year characterized by significant clinical progress, including the first clinical data from the global Phase 2 development program, which established telaprevir as a leading investigational drug candidate for hepatitis C virus (HCV) infection,” stated Dr. Boger. “With these important advancements, we are uniquely positioned in 2007 to build Vertex on telaprevir.”

“The initiation of Phase 3 clinical development with telaprevir is our primary objective for 2007. We anticipate that information derived from the PROVE program and other studies will support the design and initiation of a Phase 3 program,” continued Dr. Boger. “More broadly, we are building our capabilities and adding expertise in key areas-clinical development, regulatory affairs, quality control, supply chain management, and commercial development-designed to support an NDA filing in 2008.”

2007 Clinical and Corporate Objectives

Broad clinical development program for telaprevir (VX-950)

- Vertex today announced it has completed patient recruitment in the PROVE 2 trial in Europe of treatment naive patients with HCV. Additionally, patient recruitment in the PROVE 3 trial is expected to commence in January.

- PROVE 3 is a Phase 2b study of telaprevir in more than 400 patients with genotype-1 HCV who have not achieved SVR with a previous interferon-based treatment.

- To date, more than 600 patients have been enrolled in telaprevir clinical trials. PROVE 3 will increase this number to more than 1,000 patients. Vertex expects that clinical results from the PROVE program will provide important information supporting the design and initiation of Phase 3 trials in 2007.

- Vertex expects that it will expand clinical development of telaprevir into important HCV sub-populations in 2007, including patients with genotype 2 and genotype 3 HCV infection. Vertex also anticipates that it will initiate in 2007 a clinical trial exploring twice-daily dosing of telaprevir.

- Vertex is conducting a variety of clinical, manufacturing, regulatory and market development activities in 2007 to support an NDA filing in 2008.

36. On January 9, 2007, at the JPMorgan 25th Annual Healthcare Conference, defendants made the following statements:

[Boger:] I think in 2006, a major theme for Vertex was does VX-950, Telaprevir, have the legs to be a major drug? We had substantial, consistent clinical and
nonclinical progress over the year. I think we can go into 2007 with a new theme – we are building Vertex on Telaprevir.

*   *   *

Transforming hepatitis C, actually capturing the opportunity that this interesting molecule has put in front of us, is frankly a massive undertaking.

So many parts have to come together. They have to come together on time. And they are coming together this year, 2007. We have a vision for transforming hepatitis C. In 2007, we are building Vertex [around] Telaprevir.

*   *   *

We are using three Phase IIb trials called PROVE 1, 2 and 3 to form a basis for building the Telaprevir profile. PROVE 1 is a 260-patient trial in the United States, which we announced – that will have response rates in treatment-naive patients. We will have a safety profile established through 12 weeks. We will have a regimen and duration that we can use to design Phase III. And we will have a comparison to the standard of care. And that trial you are all familiar with.

PROVE 2 is a very similar trial configured in Europe – 320-patient European trial. That one we announced yesterday, that the patient recruitment is now completed – has those same questions, plus it will test whether ribavirin is necessary in treatment at all – a heightened question, of heightened importance, given this modest increase in what looks like ribavirin side effects out of PROVE 1.

And then PROVE 3, a greater than 400-patient trial in U.S. and Europe that we expect to initiate this month, will address these same questions in treatment-failure patients. It will provide a look at the safety of Telaprevir through 24 weeks of Telaprevir in combination.

*   *   *

Now, building Telaprevir is a very exciting challenge. And I am energized every day by this challenge. But to me, it is even more exciting to build a Company on Telaprevir. What this means to me is that Telaprevir opportunity allows us now to build a company that can deliver the same kind of innovation over and over and over again in different therapeutic areas.

37. On February 1, 2007, the Company issued a press release entitled “Vertex Pharmaceuticals Reports 2006 Financial Results,” which stated in part:

Vertex Pharmaceuticals Incorporated today reported consolidated financial results for the quarter and year ended December 31, 2006.
“2006 was characterized by significant progress across our business, and in particular by advances in the clinical program for our lead investigational hepatitis C virus protease inhibitor telaprevir,” stated Joshua Boger, Ph.D., President and Chief Executive Officer of Vertex Pharmaceuticals. “The initiation of Phase 3 clinical development for telaprevir is our primary objective for 2007, and we are now positioned to build Vertex on telaprevir.”

*   *   *

Key 2006 Achievements and 2007 Objectives

- Broad clinical development program for the hepatitis C virus (HCV) protease inhibitor telaprevir (VX-950)

- Vertex today announced the initiation of the PROVE 3 clinical trial. PROVE 3 is a Phase 2b trial of telaprevir that is designed to enroll 440 patients infected with genotype-1 HCV who have not achieved a sustained viral response (SVR) with a previous interferon-based treatment. In the trial, patients will be randomized equally across four treatment arms. The trial is planned for more than 50 centers in the U.S., Canada and the E.U. The treatment arms include:

  • 12 weeks of therapy, with telaprevir dosed at 750 mg every eight hours (q8h) in combination with standard doses of pegylated interferon alfa-2a (peg-IFN) and ribavirin (RBV), then continuing for another 12 weeks with peg-IFN and RBV alone; or

  • 24 weeks of therapy, with telaprevir dosed at 750 mg q8h in combination with standard doses of peg-IFN. Patients in this arm will not receive RBV; or

  • 24 weeks of therapy, with telaprevir dosed at 750 mg q8h in combination with standard doses of peg-IFN and RBV, then continuing for another 24 weeks with peg-IFN and RBV alone; or

  • A control arm with peg-IFN and RBV dosed for 48 weeks. Patients in this arm who do not respond to therapy at week four or beyond will have the option to roll into treatment with telaprevir, peg-IFN and RBV under a separate protocol.

- Vertex expects to complete enrollment in PROVE 3 by the end of the second quarter. This will increase to more than 1,000 the number of patients that have enrolled in telaprevir clinical trials to date.
The Company expects that clinical data disclosures in 2007 from the Phase 2b PROVE program will occur principally at medical conferences, and that the disclosure of any interim information will be governed in part by the need to maintain the integrity of the PROVE data to support potential registration activities.

Vertex expects that it will expand clinical development of telaprevir into important HCV sub-populations. Vertex's collaborator Tibotec will undertake clinical development in patients with genotype 2 and genotype 3 HCV infection. Vertex also anticipates that it will initiate in 2007 a clinical trial exploring twice-daily dosing of telaprevir.

In 2007, Vertex will manufacture registration batches of telaprevir, and will begin building an inventory of commercial supply.

Vertex expects to initiate Phase 3 clinical development of telaprevir in the second half of 2007. Vertex expects that clinical results from the PROVE 1 and PROVE 2 clinical studies will provide important information supporting the design and initiation of the Phase 3 program. The timing of efficacy data availability from the Phase 3 program is dependent upon a number of factors, including the trial design, treatment durations, and the time required to enroll patients into the program.

The current PROVE clinical program (PROVE 1, 2, and 3) has the potential to generate sufficient safety and efficacy data in a broad range of genotype 1 HCV patients, along with safety data from the Phase 3 program, to support an NDA filing in late 2008. An NDA filing in that timeframe would also be dependent upon successful completion of all chemistry, manufacturing and controls (CMC) requirements for registration. The Company's current registration plan is based upon these assumptions. If efficacy data from the Phase 3 program is required for the NDA, the filing may be later than 2008. Discussions with regulatory authorities that are planned for mid-2007 will define the registration pathways and timelines for regulatory filings worldwide.

38. On February 1, 2007, on the Company’s Q4 2006 earnings conference call, defendants made the following statements:

In summary, 2007 is a year in which we are building the Company on telaprevir. Our strong financial profile entering 2007 and our funding from collaborations continues to be important enablers to managing our business investment profile.

* * *
In 2006 we made substantial clinical progress across our pipeline. Telaprevir led the way. In a little less than two years, we have advanced telaprevir from first in man to 1,000 patient Phase II program. We’re now in the lead position to improve HCV treatment options and potentially provide a new treatment for millions of patients.

In 2007 we expect to substantially define the product profile and initiate Phase III. I will start my prepared remarks with an update on PROVE 3, the start and design of which we announced today. PROVE 3 is a four arm placebo controlled trial designed to enroll 440 genotype 1 infected patient who have not achieved a sustained viral response with a previous a pegylated interferon and ribavirin treatment. It is planned for more than 50 centers in the U.S., Europe and Canada. PROVE 3 is the first trial of telaprevir combination therapy for patients who have failed prior treatment. It is also the first trial that would dose telaprevir through 24 weeks.

As I walk through the PROVE 3 trial design it may be helpful to refer to slide 14 on our webcast presentation. Patients in this trial will be randomized across four arms. In the three telaprevir containing arms, telaprevir will be dosed at two 375-milligram tablets every eight hours. In this trial there are two 24-week treatment arms and two 48-week treatment arms. Each arm varies from the others as follows. The first 24-week arm will be twelve weeks of telaprevir therapy dosed in combination with pegylated interferon and ribavirin followed by another 12 weeks of peg interferon and ribavirin. The second 24-week arm will be 24 weeks of telaprevir in combination with pegylated interferon. This arm will not contain ribavirin. The third arm will be a 48-week arm. This arm will be 24 weeks of telaprevir in combination with pegylated interferon and ribavirin followed by 24 weeks of pegylated interferon and ribavirin.

The fourth arm is 48 weeks of pegylated interferon and ribavirin and is a control arm. This arm is unique since patients who do not respond to the standard of care in week four and beyond based on protocol defined criteria, will have the option to roll over onto telaprevir-based combination therapy. This option provides additional incentives for patients who enroll in PROVE 3. Additional details about this trial can be found on clinical trials.gov. I would like now to talk about the Phase II program as a whole. PROVE 1 and PROVE 2 began last year together with PROVE 3 will build telaprevir’s profile. Each trial in this Phase II B program has been carefully designed to answer questions with regarding 12 or 24-week regiments of telaprevir in combination with pegylated interferon in both treatment naive and treatment failure patients.

PROVE 1 is a 250 patient trial in the U.S. in treatment naive patients. This trial will answer questions regarding the safety of telaprevir combination through 12 weeks of treatment in comparison to standard of care and also to cam pair the response rates after varying durations of combination therapy. All patients in PROVE 1 have completed the telaprevir doses out to twelve weeks. Data from those patients will be analyzed together with SVR 12 [data] from all patient[s] who [] stop
treatment at 12 weeks or earlier. This next analysis in PROVE 1 will occur towards the end of the first quarter of 2007.

PROVE 2 is a 320-patient trial taking place in Europe also in treatment naive patients. We initiated the trial in the third quarter and completed enrollment on schedule in the fourth quarter of 2006. This trial will address the same questions as PROVE 1 plus it will provide information about the role of ribavirin since one arm in this trial does not include that drug. We plan to initiate Phase III clinical development of telaprevir in the second half of 2007. We expect that clinical results from PROVE 1 and PROVE 2 on the PROVE 1 and PROVE 2 clinical studies will provide important information supporting the design and initiation of the Phase III trial. The timing of when efficacy data from the Phase III program will become available is dependent on a number of factors including the trial design which includes treatment duration and the time required to enroll patients into the program.

We believe that the current PROVE clinical program, PROVE 1, 2 and 3 along with safety data from Phase III has the potential to generate sufficient safety and efficacy data in a broad range of genotype 1 HCV-infected patients to support an NDA filing in the fourth quarter of 2008. An NDA filing in that time from would also be dependant upon successful completion of all required chemistry, manufacture, and controls or CMC requirements for registration. If efficacy data from the Phase III program is required in the NDA, the filing may be later than 2008. Discussions with regulatory authorities that are planned from mid 2007 will define the registration pathways and timelines of regulatory filings worldwide.

At this point I would like to review our communications strategy around telaprevir program. The principle objective of the PROVE program is to provide insight that will allow us to design and initiate Phase III and generate data that will support an NDA filing. Consistent with this objective and with a significant amount of antiviral and safety data we’ve already disclosed around telaprevir, our focus in 2007 will be to communicate data from the telaprevir program principally in medical forums when and as is appropriate. This strategy is consistent with the stage of development of telaprevir.

* * *

[Boger:] We’re very pleased with the progress we made in 2006. We began the year with the first results for telaprevir in combination therapy, and we initiated a large Phase II B program that would enroll more than 1,000 patients. 2007 is starting out with very strong developmental momentum. This year we expect to start Phase III and we’re focused on our goal of filing an NDA in 2008. More than that, in 2007 we’re truly building a company on telaprevir.

* * *

Steve Herr – Morgan Stanley – Analyst
Good afternoon, guys. Two questions. The first one is I guess if you point to the SVR twelve data as an important data point for a long time L we see that data he’s he will or are you going to wait to show that at a medical meeting this year?

[Alam:] I can’t comment today on such a specific a meeting as [European Association for the Study of the Liver ("EASL")] as with any scientific meeting there is a process of abstract submission, acceptance, et cetera, that we’re not at the point and the meeting is not at the point that we could actually discuss any specific meetings. In terms of SVR 12 data, the data we’re going to be really focused on is relapse rates, and the first set of data which internally we expect analysis occurred near the end of the first quarter will really be we’re viewing it as, you know, where our focus is. It is dialing up or down in terms of the dure reconciliation of twelve and 24 weeks, and it really will be most helpful in the extremes of either a very low or very high relapse rate. It is obviously the numbers of patients involved won’t give under the circumstances a precise number in terms of either SVR rate or relapse rates, but it will give us that guidance in terms of how to go forward.

Steve Herr – Morgan Stanley – Analyst

Given how important you stress these data to be, in you unblind them internally, isn’t that a material event that you need to disclose to us or do you think you can wait for a medical meeting?

[Smith:] We’ve always been very clear on where what we want to do. We want to protect the integrity of the study we’re running. I think that’s important given the importance of the studies. We’re going it use medical forms to provide the data. In terms of asking us whether it is material, that’s a completely separate question. We’ll provide the data in a forum appropriate for the data, and that’s a later conference in towards the first quarter, and end of the first quarter to begin the second quarter of this year.

39. On April 14, 2007, the Company issued a press release entitled “Interim Results Presented at EASL from PROVE 1 Clinical Trial of Investigational Drug Telaprevir in Patients with Genotype 1 Hepatitis C,” which stated in part:

- PROVE 1 data support potential to shorten treatment duration in treatment-naive, genotype 1 HCV patients –

In a late-breaker presentation at the 42nd Annual Meeting of the European Association for the Study of the Liver (EASL), researchers today presented data from a planned interim analysis of the PROVE 1 clinical trial, which is the first trial to evaluate short-duration therapy with the investigational hepatitis C protease inhibitor telaprevir (TVR, VX-950) in combination with pegylated interferon (peg-IFN) and ribavirin (RBV) in treatment-naive, genotype 1-infected hepatitis C patients. The data from PROVE 1 demonstrated a high rate of rapid viral response (RVR) in the
telaprevir groups and a low rate of on-treatment viral breakthrough, and suggested that 12 weeks of telaprevir-based therapy enabled some patients to clear the virus. Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) is developing telaprevir in collaboration with Tibotec.

“The high rates of RVR observed in the telaprevir groups in PROVE 1, and the fact that some patients have remained persistently viral negative 20 weeks after stopping the 12 weeks of telaprevir-based therapy, suggest that we may be able to shorten the treatment duration in genotype 1 HCV patients,” said John McHutchison, M.D., Principal Investigator for the PROVE 1 study and Director of Gastroenterology and Hepatology Research at Duke Clinical Research Institute. “These interim results are encouraging and suggest that high sustained viral response (SVR) rates may be achieved with regimens that are 24 weeks in total duration. We look forward to 24 week follow-up data from the initial group of patients who stopped treatment at 12 weeks, and follow-up data from patients in the study who received 24 weeks of treatment.”

PROVE 1 Summary

- 88% and 79% of patients receiving telaprevir achieved a rapid viral response (RVR) as measured by plasma HCV RNA (less than)30 IU/mL and (less than)10 IU/mL, respectively, at 4 weeks.

- Six of 9 patients in one treatment arm who completed 12 weeks of treatment, and who had achieved an RVR as defined by the study protocol ((less than)10 IU/mL), continued to have undetectable HCV RNA 20 weeks after stopping all treatment (“SVR20”).

- The treatment discontinuation rate due to adverse events through 12 weeks was 11% in telaprevir arms and 3% in the control arm. Rash, gastrointestinal events and anemia were the most common events leading to discontinuation in the telaprevir arms.

“These interim results support our approach to evaluating telaprevir-based regimens of differing durations in our Phase 2 program. The results of the 12-week duration regimen provide a level of confidence in the shorter duration approach, and we look forward to safety and antiviral data, including SVR data, from the 24-week telaprevir-based regimens,” said John Alam, M.D., Executive Vice President, Medicines Development, and Chief Medical Officer of Vertex. “The information from PROVE 1 and PROVE 2 should allow us to design optimized durations and regimens for Phase 3 development.”

PROVE 1 and PROVE 2 represent two of three large, ongoing clinical studies of telaprevir. In aggregate, the three studies are designed in part to evaluate the safety and antiviral activity of different durations of telaprevir-based therapy in genotype-1 infected HCV treatment-naive and treatment-failure patients, both with and without
ribavirin. Taken together, the PROVE studies are expected to provide information to
optimize the treatment duration and treatment regimen for telaprevir-based therapy.

PROVE 1: Implications for Clinical Development and Registration Path

Vertex today discussed the potential implications that the new information from PROVE 1 has for future clinical development of telaprevir. Vertex stated its intention to consider evaluation of treatment regimens that would include telaprevir in combination with peg-IFN and RBV, and depending on PROVE 2 data, regimens that may exclude RBV. Vertex expects to focus on treatment durations of no more than 24 weeks. Vertex and Tibotec are planning to meet with regulatory authorities to discuss the Phase 3 design in mid-2007 and are planning to initiate Phase 3 clinical development in the fourth quarter of 2007. The registration strategy and timing of an NDA filing will be dependent on discussions with regulatory authorities.

40. On April 30, 2007, the Company issued a press release entitled “Vertex Pharmaceuticals Reports First Quarter 2007 Financial Results,” which stated in part:

“In 2007, a major goal for Vertex is to build the product profile of the investigational hepatitis C protease inhibitor telaprevir,” stated Joshua Boger, Ph.D., President and Chief Executive Officer of Vertex Pharmaceuticals. “The presentation of the interim data from the PROVE 1 clinical trial, and the start of the PROVE 3 clinical trial evaluating telaprevir in HCV patients who failed prior treatment with an interferon, represent key progress toward this goal this year. We expect that additional data gathered from the PROVE clinical program in the coming months will inform the design of our Phase 3 program.”

*       *       *

Recent Achievements and 2007 Objectives

– Broad clinical development program for the hepatitis C virus (HCV) protease inhibitor telaprevir (VX-950)

– Vertex today announced that it received in the first quarter a $15 million milestone payment from Janssen Pharmaceutica in connection with patient enrollment in the PROVE 3 clinical trial. PROVE 3 is a Phase 2b trial of telaprevir that is designed to enroll 440 patients infected with genotype-1 HCV who did not achieve a sustained viral response (SVR) with prior interferon-based treatment. In the trial, patients will be randomized equally across four treatment arms.

– Vertex expects to complete enrollment in PROVE 3 by the end of the second quarter. This will increase to more than 1,000 the number of patients that have been enrolled in telaprevir clinical trials.

– Earlier this month, clinical investigators presented data from an interim analysis of the Phase 2b PROVE 1 clinical trial at the 42nd Annual Meeting of the European
Association for the Study of the Liver (EASL). The data indicated a high rate of rapid viral response (RVR) in the telaprevir groups as compared with the control arm, and a low rate of on-treatment viral breakthrough. In addition, some patients appeared to clear the virus with 12 weeks of telaprevir-based therapy. The types of adverse events that have been commonly observed with interferon and ribavirin were seen across all treatment arms. Gastrointestinal disorders, rash and anemia were more common in the telaprevir arms.

- Vertex expects that the interim PROVE 1 data, together with additional data from PROVE 1 and PROVE 2, will inform the Phase 3 trial design for telaprevir. Vertex expects to meet with the FDA in mid-2007, and expects to initiate Phase 3 development of telaprevir in the fourth quarter of 2007.

- Vertex expects to complete registration batches of telaprevir in the first half of 2007. The Company also has begun the process of building commercial supply, investing approximately $32 million in the first quarter of 2007.

41. On April 30, 2007, on the Company’s Q1 2007 earnings conference call, defendants made the following statements:

Lynne Brum – Vertex Pharmaceutical Incorporated – VP, Strategic Communications

* * *

2007 is an important year for Vertex. It’s a year where we’re building Vertex on telaprevir. In the first quarter we advanced the telaprevir global clinical development program. In particular we made progress towards realizing our vision for telaprevir of eradicating the agency of most patients with shorter treatment duration.

* * *

[Alam:] I’d like to begin today by reviewing some of the key telaprevir results presented at EASL earlier this month. In light of the fact that we have discussed these data at several recent events I will be brief in my remarks and will focus my discussion on how these data will inform the future development of telaprevir. On April 14, we presented interim data from the PROVE 1 clinical trial in a late breaker presentation at EASL. These data had significant implications in guiding our understanding of the opportunity for and the development strategy for telaprevir. A total of 250 patients were enrolled in PROVE 1 with 175 patients enrolled in telaprevir arms and 75 in the control arm. At the time of the interim analysis, all patients had reached at least a 12 week time point on the study. The interim anti-viral data from PROVE 1 indicated a high rate of rapid viral response in the telaprevir group, a low rate of on treatment viral breakthrough, and suggests that that 12 weeks of telaprevir based therapy enabled some patients to clear the virus completely.
The key conclusions from the interim analysis and [our] take-away toward planning and executing late stage development are as follow—One, it is possible to treat some treatment naive genotype one HCV patients successfully with 12 weeks of telaprevir based combination therapy. Two, clinically meaningful improved SVR rates may be achieved with a 24 week treatment regimen and three, we will focus on improved management of side effects to increase the number of patients who successfully complete therapy. We’re looking forward to safety and anti-viral data including additional SVR data on the 12 and 24 week telaprevir based regimens in PROVE 1 and PROVE 2 to allow us to design optimized treatment regimens and durations for a Phase III development of telaprevir. We expect to meet with regulatory authorities in mid 2007 and plan to initiate Phase III clinical development in the fourth quarter of 2007. We expect to report further data at upcoming major medical meetings.

In summary, we are on track to initiate Phase III development in the fourth quarter and have increased confidence in our strategy to evaluate telaprevir with short treatment duration of 24 weeks or less. In addition to the data presentation at EASL we have continued to advance the global Phase II redevelopment program for telaprevir in the first quarter. In January, we initiated PROVE 3, a four arm placebo controlled trial designed to enroll 440 genotype one HCV infected patients who have not achieved a sustained viral response with the previous pegylated interferon and ribavirin treatment. This was an important advancement in that PROVE 3 is the first trial of telaprevir combination therapy for patients who have failed to clear virus with prior treatments with an interferon. It is also the first trial that will dose telaprevir through 24 weeks.

More than half the patients are currently enrolled in PROVE 3 and we are on track to complete enrollment within the second quarter. In summary, the development of the product profile for telaprevir continues on track and at a rapid pace.

* * *

[Boger:] Already this year, we have moved decisively closer to defining the product profile for telaprevir. The global Phase II B proved program is doing what it was designed to do. Specifically we are collecting data that allows us to evaluate telaprevir’s potential to enhance SVR rates with a short treatment duration, whether dosing combination with pegylated interferon and ribavirin or with pegylated interferon alone.

This program is data driven. What we are learning from this comprehensive development program is helping us design a Phase III plan for telaprevir that will maximize its potential to change the HCV treatment landscape. Bringing a major drug to the market is no easy task. It takes time, money, and an eye for developing innovative processes and the most important part, the human talent to move our [sic] forward. We are readying the Company for this progression and in some ways, it involves every person at Vertex. We hope that at the end of the day, telaprevir could
have a major positive impact on the lives of HCV patients and on Vertex as well. That's the reason we're in this business. I look forward to keeping you updated on Vertex and telaprevir as we move forward.

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Geoff Porges—Sanford Bernstein—Analyst

First, on the telaprevir program, Josh or John, could you give us a sense of how many patients are actually on telaprevir today in the Phase II program and when the treatment you estimate is likely to end meaning when the patients will have rotated off telaprevir and maybe just say how many have already been treated and exposed to the drug in that program so we’re all clear.

[Alam:] On the Phase II B program, as you know, in PROVE 1, there were 175 patients who were on telaprevir who received telaprevir, at least one dose of telaprevir, and all of those patients have completed their telaprevir dosing. In PROVE 2, there were 240 patients who were to be enrolled into that study to receive telaprevir. 320 all together, 80 in control, 240 in telaprevir constraining arms. At this point, all patients have completed their telaprevir dosing in that study, and are either on pegylated interferon and ribavirin or on further follow-up, and then as I provided an update in PROVE 3, more than half the patients are now enrolled into that study and the randomization, there are four treatment arms, one control and three study arms with telaprevir in it.

So all told by the time PROVE 3 is enrolled, more than a thousand patients will have been enrolled into those studies, of which approximately 750 will have received telaprevir.

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Brian Abrahams—CIBC—Analyst

Hi, guys, thanks for taking my question. Congratulations on the progress this quarter. Based on what you’re seeing from the ongoing Phase II B program, I was just wondering if you had any changes to your thoughts about filing an NDA at the end of next year based on efficacy data from the Phase II B program or if you thought there might be any efficacy data from certain arms of the pivotal program that might be necessary for filing.

[Alam:] Brian, this is John. We are, as I stated in my comments, we are on track and expect to begin Phase III development of telaprevir in the fourth quarter. The current focus of the Phase III program is the use of what we have called the 12 plus 12 regimen which is 12 weeks of telaprevir pegylated interferon and ribavirin followed by 12 weeks of peg interferon and ribavirin. Now this is to be confirmed additional data from PROVE 1 and PROVE 2, but that data along with discussions we expect to initiate with the FDA in the middle part of this year will determine the specifics of the regulatory path and the timeline for a telaprevir NDA. Otherwise in
today’s call, we’re not going to comment more specifically on the NDA strategy and timing.

DEFENDANTS’ STATEMENTS DURING THE CLASS PERIOD

42. On June 12, 2007, the Company issued a press release entitled “Vertex Pharmaceuticals Reports 2007 Pipeline Progress,” which stated that interim results of PROVE 2 were consistent with the positive results of PROVE 1 that defendants had already reported. It also reported positive RVR results for PROVE 2. Specifically, the release stated:

- More than 1000 patients have now been enrolled in Phase 2b PROVE trials
- More than 350 patients have completed 12 weeks of telaprevir dosing in PROVE trials
- Interim results from PROVE 2 consistent with findings from PROVE 1.

* * *

“In the first half of 2007, we have made significant progress in advancing our business and in the development of our pipeline,” said Joshua Boger, Ph.D., Vertex’s President and Chief Executive Officer. “Specifically, we have enrolled more than 1,000 patients in the PROVE studies evaluating telaprevir, our investigational hepatitis C protease inhibitor, and more than 350 patients have now completed 12 weeks of telaprevir-based dosing. Today, we announced the completion of enrollment in PROVE 3. We are now focused on discussions with regulatory agencies in the U.S. and Europe to enable transitioning to the start of Phase 3 development of telaprevir planned for the fourth quarter of this year.”

Mid-2007 Pipeline Update

Broad clinical development program for telaprevir (VX-950)

- The PROVE clinical program, consisting of three major Phase 2b trials, is designed to evaluate: 1) the optimal SVR (sustained viral response) rate that can be achieved with telaprevir-based therapy; 2) the optimal treatment duration for telaprevir; 3) the safety profile of telaprevir; and 4) the role of ribavirin in telaprevir-based therapy. In its program for treatment-naive patients, Vertex is focused on evaluating regimens of 24 weeks total duration, with the inclusion of ribavirin in the treatment combination.

- The PROVE 1 clinical trial is continuing on track in the U.S. PROVE 1 is a randomized, placebo-controlled trial that enrolled 250 treatment-naive genotype 1 patients with hepatitis C. Vertex anticipates completing a planned interim analysis in July 2007 for patients in the 24-week treatment arm of this trial. The interim analysis will focus on 12-week post-treatment antiviral results, and Vertex expects that these data will be presented at a medical meeting later in 2007.
The PROVE 2 clinical trial is also continuing on track in Europe. PROVE 2 is a randomized, placebo-controlled trial that enrolled approximately 240 genotype 1 treatment-naive HCV patients on telaprevir-based regimens and 80 patients who were randomized to receive pegylated interferon alfa 2a (peg-IFN) and ribavirin (RBV). Vertex recently received preliminary data from the first planned interim analysis of PROVE 2, and expects that these data will be presented at a medical meeting later in 2007. At this time, Vertex is reporting that the preliminary results are consistent with findings reported for PROVE 1. Patients in the treatment arms that included telaprevir, peg-IFN and RBV had rates of undetectable HCV RNA (10 IU/mL) at 4 and 12 weeks similar to those observed in PROVE 1. The adverse events observed in the PROVE 2 trial, and the rate of treatment discontinuations for 240 patients through 12 weeks of telaprevir-based dosing, appear consistent with the PROVE 1 results reported by Vertex in April. At 12 weeks, the treatment arm in PROVE 2 that did not include ribavirin was associated with antiviral activity that was lower compared to treatment arms that included ribavirin, telaprevir, and peg-IFN, but still substantially higher than that observed in the control arm. As reported for PROVE 1, rash, gastrointestinal events and anemia were the most common events leading to discontinuation in the telaprevir arms. Fewer discontinuations due to adverse events were observed in patients receiving telaprevir and peg-IFN without ribavirin.

Vertex today announced that it has completed patient enrollment in the PROVE 3 clinical trial with more than 440 patients. PROVE 3 is a Phase 2b clinical trial of telaprevir in patients with genotype-1 HCV who have not achieved SVR with a previous interferon-based treatment.

With the completion of enrollment in PROVE 3, there are more than 1,000 patients enrolled in the PROVE clinical program for telaprevir and, to date, more than 350 patients who have completed 12 weeks of telaprevir-based dosing.

In May, Vertex successfully completed drug substance registration batches of telaprevir. The Company has also started the manufacturing validation process for telaprevir drug substance and expects to complete the validation by the end of the year. Vertex continues to make a significant investment to prepare for the commercial supply and marketing of telaprevir, subject to its continued progress.

43. The above statements were materially false and misleading because defendants failed to disclose adverse results of the PROVE 2 study. Specifically, in PROVE 2 telaprevir failed to generate significantly better SVR than drugs already approved by the FDA for the treatment of HCV. Further, patients taking telaprevir in PROVE 2 suffered a high relapse rate after they stopped taking the drug. Because of these adverse findings, the results of PROVE 2 were not consistent with
those of PROVE 1, as defendants represented. Further, it was misleading for defendants to report
positive data about telaprevir from PROVE 1, even if accurate, while concealing other materially
adverse data generated by PROVE 2.

44. On July 24, 2007, the Company issued a press release entitled “Vertex
Pharmaceuticals Reports Second Quarter 2007 Financial Results and Provides Development Pipeline
Update,” which again stated that the results of PROVE 2 were consistent with the positive results of
PROVE 1 that defendants had already reported. Specifically, the release stated:

– Vertex announced today that it received preliminary data from a planned
interim analysis of arm C of the PROVE 1 trial, which evaluated treatment-naive
genotype 1 HCV patients treated with telaprevir plus pegylated interferon alfa-2a
(peg-IFN) and ribavirin (RBV) for 12 weeks, followed by 12 weeks of treatment with
peg-IFN and RBV alone. The interim analysis included end-of-treatment data as well
as 12-week post-treatment data from all patients who completed the 24-week course
of therapy. Among the patients who completed 24 weeks of therapy and had
undetectable HCV RNA (less than 10 IU/mL) at the end of treatment, fewer than 10
percent had relapsed by the end of 12 weeks post-treatment follow-up. Results
obtained to date in PROVE 1 suggest that 12 weeks of telaprevir-based treatment
followed by 12 weeks of peg-IFN and RBV could be a promising treatment regimen
and duration. Preliminary safety data from the PROVE 1 and PROVE 2 trials are
summarized below.

– Summary of recent PROVE 1 and PROVE 2 data and PROVE 3 update

– In April at the 42nd Annual Meeting of the European Association for the
Study of the Liver (EASL), clinical investigators presented the first clinical data from
PROVE 1, a randomized, placebo-controlled trial involving approximately 250
patients. The PROVE 1 data reflected a high rate of rapid viral response (RVR) in the
telaprevir groups and a low rate of on-treatment viral breakthrough, and suggested
that 12 weeks of telaprevir-based therapy enabled some patients to clear the virus. A
Vertex press release dated April 14, 2007 provides additional information on the data
that were presented, including end-of-treatment data, post-treatment data and adverse
events.

– In June, Vertex reported that it had received preliminary data from the
first planned interim analysis of PROVE 2, a randomized, placebo-controlled trial
involving approximately 320 patients in Europe. Vertex indicated that the
preliminary results for 12-week safety and antiviral activity were consistent with
findings previously reported for PROVE 1. A Vertex press release dated June 12,
2007 provides additional conclusions from this analysis.
45. The above statements were materially false and misleading because they failed to disclose adverse results of the PROVE 2 study. Specifically, in PROVE 2 telaprevir failed to generate significantly better SVR than drugs already approved by the FDA for treatment of HCV. Further, patients taking telaprevir in PROVE 2 suffered a high relapse rate after they stopped taking the drug. Because of these adverse findings, the results of PROVE 2 were not consistent with those of PROVE 1, as defendants represented. Further, it was misleading for defendants to incorporate by reference positive data about telaprevir, even if accurate, while concealing other materially adverse data generated by PROVE 2.

46. On July 24, 2007, on the Company’s Q2 2007 earnings conference call, defendants discussed positive RVR data for PROVE 1 and 2 and stated that the relapse rate for both was under 10%. Specifically, defendants made the following statements:

[Brum:] We made significant progress in the first half of 2007 and met major milestones across our product pipeline. In particular we generated significant data on telaprevir from our global Phase II development program including safety and efficacy data from PROVE 1 and PROVE 2. These data are enabling us to identify regimens and durations suitable for late-stage development.

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[Smith:] Firstly to the second quarter 2007 financial results. The second quarter non-GAAP loss before certain charges was $95.4 million compared to a 2006 non-GAAP loss of $66 million.

The increased loss was due primarily to an increase in development investment for telaprevir including investment into our commercial supply chain.

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Now to R&D. Our total R&D expense was $136 million compared to $91 million in the second quarter of 2006.

This increase reflects advancements across our pipeline including the investment into the global Phase IIb clinical program of telaprevir, a $19 million investment into the commercial supply chain for telaprevir . . . .
Our second quarter SG&A expense was $23 million compared to $14 million in the second quarter of 2006. This increase reflects costs associated with building infrastructure that we have undertaken to support the clinical advancement and the commercialization of telaprevir.

* * * *

[Alam:] I'll begin today with telaprevir. I'll briefly summarize our recent progress and provide perspective on our goals for the remainder of the year. The start of Phase III is our top corporate priority and I know it's of high interest to many of you.

Year-to-date important pieces of data have emerged that have guided our thinking on the Phase III trial design. Specifically supporting 24 weeks as a viable total treatment duration for study in Phase III.

The most important of these supportive data is the post-treatment analysis we reported today for the 12 plus 12 arm in PROVE 1. This analysis showed a 12-week post-treatment relapse rate of less than 10% from the patients who completed the 12 weeks of telaprevir-based treatment followed by 12 weeks of pegylated interferon and ribavirin and were undetectable at completion of this dosing regimen.

With the current therapy of pegylated interferon and ribavirin administered for 48 weeks, relapse rates of 20 to 30% are typical and have been cited often in the medical literature. So as you might expect with a relapse rate of less than 10% we're very pleased with these data and this level of relapse rate, this low relapse rate, suggests to us that 24 weeks of total therapy with a telaprevir regimen is appropriate for further study.

Support for continued evaluation of a 24-week treatment duration also comes from the PROVE 1 interim data we reported at EASL in April. These data suggested that it may be possible to clear the HCV virus in some treatment naive patients successfully with only 12 weeks of telaprevir-based combination therapy, and represented the first evidence that short-term duration therapy could potentially be achieved in patients with genotype 1 HCV.

Within the PROVE data an additional important finding with respect to what was with respect to the slope of viral decline. In PROVE 1 80 to the 90% of patients receiving telaprevir had a rapid viral response, or RVR.

Several published studies of pegylated interferon and ribavirin have demonstrated a strong correlation between rapid viral response and the ability to shorten treatment duration in genotype 1 patients. Taken together these data, and in particular, the recent analysis that demonstrated low relapse rate in the, after the 12 plus 12 arm in PROVE 1 point to overall to an evaluation of 24 weeks total treatment durations with telaprevir treatment regimen in late-stage development.
We expect the further data from PROVE 1 and PROVE 2 will be presented at the [AASLD] (sic) meeting this year. In addition, certain data from PROVE 1 will be presented at ICAAC in September.

Next let me tell you where we are focused in the third quarter. We told you that we should begin discussions with the FDA in mid 2007.

All available data to date was recently submitted to the FDA including post-treatment SVR data from the 24-week telaprevir-based regimens in PROVE 1 and available 12-week data from PROVE 2. A meeting has been scheduled with the FDA to review these data. In summary, transition to Phase III is our top priority and we look forward to updating you further on this exciting program.

* * *

Kurt Graves – Vertex Pharmaceuticals Incorporated – EVP, Chief Commercial Officer, Head Strategic Development

The biggest near-term draw for me, obviously, is telaprevir. Telaprevir is the kind of opportunity that is truly rare in this industry and I look forward to working with John and the rest of the team to progress telaprevir to Phase III with the FDA’s input and doing everything necessary to prepare the Company, prepare the market and prepare telaprevir for a successful launch.

* * *

[Boger:] We are building the company on Telaprevir. . . .

The rest of our pipeline is progressing as we further reduce risk in the telaprevir development program.

* * *

Geoff Porges – Sanford C. Bernstein & Company - Analyst

Thanks very much for taking my question and appreciate the data here. So I guess I'll ask the obvious question which is what’s the denominator. You’ve told us that less than 10% of patients have relapse patients who reach end of treatment are detectable of relapsing, can you help us go from the 79 patients who were actually enrolled through the 11% of patients who drop out in the first 12 weeks, give us a sense of how many drop out in a second 12 weeks, how much withdraw from protocols, then what sort of break through rates you’re seeing so we can start trying to understand what we can work toward as real SVR rates, thanks.

[Alam:] Thanks Jeff for the question. So I can’t give you the specific numbers because we’re, as we’ve said from the beginning of the year in terms of specific data from the proof trials, because of the stage of development, because of the where we are and the scope of the studies, the specific data and the numbers we

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are going to be presenting in, at various scientific conferences. In particular, we pointed to with PROVE 1 and PROVE 2 that the majority of the data would be presented at AASLD.

The objective of this release was really to bring you up-to-date in terms of where we are from PROVE 1 and PROVE 2 and where we have come to in terms of the overall, our assessment of the duration and where we’re headed in terms of the product, in terms of the product profile.

I think the low relapse rate here, which, you know, we have, we have sufficient numbers to be confident that we are in, in that less than 10% range, provides a lot of assurance from our perspective in terms of an appropriate duration is 24 weeks of treatment.

The second part of the discussion is in which is the first major conclusion from the very low relapse rate. Again, keep in mind that the relapse rate after 48 weeks interferon and ribavirin is 20 to 30%. So as we kind of set up the expectations internally for these data we felt that if we were under 20%, then 24 weeks would be an appropriate.

Obviously getting to less than 10% is that much more supportive of that concept. So that’s the first part, that it does support the duration.

I think the second part is you have to look the sum total of the data at PROVE 1 and PROVE 2, which is where we’re headed in terms of the product profile from an SVR standpoint. And the basis there comes from what we’ve already reported which is a very high rate of on treatment response, an 80 to 90% rapid viral response, getting to undetectable within the first month of treatment, an overall discontinuation rate or an discontinuation rate for adverse events of around 11%, a low break through rate of, you know, it’s 7% overall, but most of that actually happened with before, in the patients who never got to undetectable.

The breakthrough rate after patients become undetectable is in fact very low, it’s well under 5% and it’s in the range of around 2%. If you take all of that and then come to then, when you complete treatment and you are undetectable and you haven’t broken through, that the relapse rate in those patients is very low, it’s under 10%, you can come to why it supports the overall notion of being able to increase SVR rates with a treatment duration of 24 weeks.

Now, what I’m not going to do is actually calculate the specific number for you, because it is. We have put all the information out there to be able to do that. And, you know, if people want to walk through the specific calculation we’re happy to do that after the call.

Geoff Porges – Sanford C. Bernstein & Company – Analyst

John, I just walked through it now, so if I add up what you talked about, 11% distinction rates due to AEs, a couple percent due to breakthroughs after RVR, 7% of
patients don’t get to RVR, and then 5% for everything else, protocol violators, treatment withdrawals, I get to about 25% who drop out prior to getting to end of treatment. And then I start thinking about the 10% of that number as being the patient who relapse, is that the right way to think about it?

[Alam:] I think in very rough terms you’re absolutely headed in the right direction. The real conclusion from this is that, as I think you’ve come to, that the base case of SVR with a low relapse rate is, we are, well, first of all, we are, again, 24 weeks of treatment duration is an appropriate duration. We don’t necessarily need to go longer than that because we’re already, you know, the patients who aren’t going to -- who aren’t relapsing giving more interferon and ribavirin doesn’t necessarily do anything for them. So that’s the first conclusion.

Again, 24 weeks of treatment duration. And then beyond that in terms of how, where we end up with the ultimate SVR rate, it clearly is going to be about in Phase III of optimizing management of side effects and managing discontinuations and getting treatment, getting patients to a full duration of treatment.

But from a purely antiviral standpoint, we have a high response rate, low breakthrough rate, low relapse rates, all of which are very consistent with that we can achieve and increase in the SVR rates from where we are today.

47. The above statements were materially false and misleading because they failed to disclose adverse results of the PROVE 2 study. Specifically, in PROVE 2 telaprevir failed to generate significantly better SVR than drugs already approved by the FDA for the treatment of HCV. Further, patients taking telaprevir in PROVE 2 suffered a high relapse rate after they stopped taking the drug. Because of these adverse findings, it was misleading for defendants to report positive data about telaprevir while concealing other materially adverse data generated by PROVE 2.

48. On September 28, 2007, the Company issued a press release entitled “Vertex Announces Publication of Abstracts for Presentation at 58th AASLD Meeting,” which stated in part:

- Conference Presentations to Include Data from Two Randomized, Controlled Phase 2 Clinical Studies of Investigational HCV Protease Inhibitor Telaprevir

* * *

Vertex Pharmaceuticals Incorporated today announced that 6 abstracts related to its investigational hepatitis C protease inhibitor telaprevir have been accepted for presentation at the 58th Annual Meeting of the American Association for the Study of Liver Diseases (AASLD), November 2-6, 2007, and are being published online by
the AASLD. Included in these abstracts are planned presentations of interim data from PROVE 1 and PROVE 2, two randomized, controlled Phase 2 studies of telaprevir. Vertex is developing telaprevir in collaboration with Tibotec.

At the AASLD conference, Vertex expects that researchers will present the most recent antiviral and safety data that are available from PROVE 1 and PROVE 2. Data from PROVE 1 and PROVE 2 being presented at AASLD represent interim analyses, and Vertex continues to gather information on the safety and antiviral effect of telaprevir-based therapy to determine the appropriate regimens and durations for evaluation in further studies. An overview of PROVE 1 and PROVE 2 clinical studies, expected data available, and abstract title and presentation time information are provided below.

PROVE 1 (Study 104)

PROVE 1 is an ongoing, four-arm, 250-patient Phase 2 study whose primary objective is to assess the proportion of patients who achieve sustained viral response (SVR), defined as undetectable (less than 10 IU/mL, as measured by the Roche TaqMan(R) assay) HCV RNA 24 weeks after the completion of dosing. The study is assessing patients who receive telaprevir-based treatment durations of 12, 24 and 48 weeks, compared to a 48-week control arm of Peg-IFN+RBV. PROVE 1 is being conducted at more than 30 clinical centers in the U.S.

Key interim data expected to be available at AASLD include:

- 24-week post-treatment (SVR24) data from patients from the “12+12” arm, who received telaprevir dosed in combination with pegylated interferon (peg-IFN) and ribavirin (RBV) for 12 weeks, followed by 12 weeks with peg-IFN and RBV alone (arm C of PROVE 1)

- 24-week post-treatment (SVR24) data from patients who received telaprevir dosed in combination with peg-IFN and RBV for 12 weeks only (arm D of PROVE 1)

- End of treatment data from patients from the “12+36” arm, who received telaprevir dosed in combination with peg-IFN and RBV for 12 weeks, followed by 36 weeks with peg-IFN and RBV alone (arm B of PROVE 1)

- End of treatment data from patients from the control arm, who received 48 weeks of therapy with peg-IFN and RBV only (arm A of PROVE 1)

- Available data on safety and tolerability across all arms of the study, including characterization of the most commonly observed adverse events, and identification of the adverse events that led to treatment discontinuation.

PROVE 1 data will be presented on Tuesday, November 6, 2007. The abstract is titled “Interim Analysis Results from a Phase II Study of Telaprevir with Peg-interferon alfa-2a and Ribavirin in Treatment-naive Subjects with Hepatitis C,”
and the authors are I. M. Jacobson, G. T. Everson, S. C. Gordon, R. Kauffman, L. McNair, A. Muir, and J. G. McHutchison.

PROVE 2 (Study 104EU)

PROVE 2 is a four-arm Phase 2 study of approximately 320 patients whose primary objective is to assess the proportion of patients who achieve SVR. The study assesses patients who receive telaprevir-based treatment durations of 12, 24 and 48 weeks, compared to a 48-week control arm. PROVE 2 is being conducted at more than 40 clinical centers in Europe.

Key interim data expected to be presented at AASLD include:

- 12 week post-treatment (SVR12) data from patients in the “12+12” arm (arm B of PROVE 2)
- 24-week post-treatment (SVR24) data from patients who received telaprevir dosed in combination with peg-IFN and RBV for 12 weeks only (arm C of PROVE 2)
- 24-week post-treatment (SVR24) data from patients who received telaprevir dosed in combination with peg-IFN for 12 weeks only, without RBV (arm D of PROVE 2)
- Available on-treatment data for patients in the control arm, who received 48 weeks of therapy with peg-IFN and RBV (arm A of PROVE 2).
- Available data on safety and tolerability across all arms of the study, including characterization of the most commonly observed adverse events, and identification of the adverse events that led to treatment discontinuation.

PROVE 2 data will be presented on Monday, November 5, 2007. The abstract is titled “PROVE 2: Phase II Study of VX-950 (Telaprevir) in Combination with Peginterferon alfa-2a with or without Ribavirin in Subjects with Chronic Hepatitis C, First Interim Analysis,” and the authors are C. Hezode, P. Ferenci, G. M. Dusheiko, S. Pol, T. Goeser, J. Bronowicki, S. Gharakhanian, D. Devonish, R. Kauffman, J. Alam, J. Pawlotsky, and S. Zeuzem.

49. On October 29, 2007, on the Company’s Q3 2007 earnings conference call, defendants made the following statements:

[Graves:] As you all know, progressing Telaprevir is our top priority. I have now been at Vertex for a few months and as we analyze the unmet needs and the treatment of HCV, I like what I see about our position in HCV, our interactions with the FDA and thought leaders and the significant market opportunity ahead of us. Our emerging data that will be released at ASLD reinforces our confidence in the direction of our overall HCV development program, while Telaprevir is setting new standards in the development of HCV, we aim to be a top innovator and leader in the
field long term. Because of this, it's the right time for us to be making investments into a second generation HCV protease inhibitor program.

Today, we announced that we have selected our second protease inhibitor, VX 500 for development and expect to enter the clinic by the end of the year. We recognize that the HCV landscape is competitive with many product candidates in development. Telaprevir is leading the field. To strengthen our position as a leader in the STAT-C therapies, we will continue to move Telaprevir ahead as a cornerstone to establishing a broad presence in the treatment of HCV.

* * *

[Alam:] Today, I will talk broadly about where we are in development with Telaprevir and upcoming milestones of the program. I would also provide a brief update on our pipeline. Since ASLD begins at the end of this week we are reserving our detailed Telaprevir discussion for the data presentations and the Investor Relations event that is scheduled in conjunction with the medical conference. We have high confidence in Telaprevir. It is our top priority. At ASLD, which starts this Friday, we will be presenting important data from two comprehensive trials involving more than 500 patients.

From a Novel drug development perspective, we believe it's the most extensive data to be presented in the HCV arena in several years. First and foremost, it will be the first time that extensive SVR 24 and SVR 12 data will be presented for our HCV protease inhibitor. Along with the top line data we have also began [sic] to characterize the effect of an initial rapid decline in maximizing on treatment response, minimizing viral breakthrough, and achieving SVR. This is truly a meaningful time for Vertex in advancement of our therapy through HCV, and we look forward to speaking with you about Telaprevir data at ASLD.

We told you in our last call that we would begin discussions with the FDA in the third quarter. These interactions began in August and at that time, we presented the data we had in hand. The discussions are progressing and are to date constructive. We continue to submit new data to the FDA as it becomes available to Vertex. More specifically, we have recently provided to the FDA the SVR data that will be disclosed at ASLD. We look forward to continuing our interactions based on the new data. In addition to providing data we plan to discuss a protocol for the next stage of development of Telaprevir. We expect to provide an update on our discussions with the FDA as soon as they are complete. Together, with Tibotec, we're planning additional trials to evaluate Telaprevir in certain important HCV subpopulations. In the coming months we're focused on initiation of a first clinical trial in patients with genotype two or three, and initiation of a clinical trial with Telaprevir dosed twice daily in combination with pegylated interferon and ribarivin. The details of this latter trial can now be found on clinical trials.gov.

In summary, we believe Telaprevir has the potential to significantly advance how we may treat HCV in the future.
Steve Harr – Morgan Stanley – Analyst

Okay, and then second, you guys have previously discussed beginning a Phase III trial for Telaprevir prior to year-end. Is that something that’s still on the table or just given the timeliness with the FDA, should we think about that as an early 2008 event now?

[Alam:] The results that we’re going to be presenting in terms of SVR and overall safety and efficacy results that we will be presenting at ASLD, we believe do support moving Telaprevir in particular with the 12 plus 12 regimen into Phase III.

[Alam:] [I]n terms of the specific issues we’re discussing with the FDA, I’m not going to, again, I’m not going to go into detail, but just say that in the data we presented to them earlier in the third quarter, and that we reviewed, all of the available safety data with Telaprevir or all of the data, the full set of safety data from PROVE 1 and PROVE 2 were provided to them because that was through to the full duration of Telaprevir dosing in those studies was through to 12 weeks, so all of that information was already available to them in the prior discussion.

THE TRUTH BEGINS TO COME TO LIGHT

50. On November 2, 2007, the Company issued a press release entitled “First Studies Demonstrating Greater than Sixty Percent Sustained Viral Response Rates with Half the Standard Treatment Duration in Genotype 1 Chronic Hepatitis C Patients,” which stated in part:

Two Large Phase 2 Trials of Telaprevir, an Investigational Hepatitis C Protease Inhibitor, Dosed in Combination with Pegylated Interferon and Ribavirin Show SVR Rates of 61% and 65% Initial Rapid Viral Decline Appears Important to Achieve SVR Safety Profile Consistent with Prior Interim Analyses

... Vertex Pharmaceuticals Incorporated today announced results from interim analyses of PROVE 1 and PROVE 2, two large Phase 2b clinical trials evaluating the investigational hepatitis C protease inhibitor telaprevir (VX-950), dosed in combination with pegylated interferon and ribavirin. In 24-week telaprevir-based treatment regimens, genotype 1 treatment-naive HCV patients achieved sustained viral response rates of 61% and 65% in PROVE 1 (SVR 12 and SVR 24) and PROVE 2 (SVR 12), respectively. In addition, clinical researchers reported a correlation between achieving rapid viral response (RVR) and achieving SVR in a 24-week telaprevir-based regimen.

Interim analyses of telaprevir safety from PROVE 1 and PROVE 2 appear consistent with prior analyses, with the most common adverse events, regardless of
treatment assignment, being fatigue, rash, headache and nausea. Gastrointestinal disorders, skin adverse events (rash, pruritus) and anemia were higher in the telaprevir arms compared to the control arm over the dosing period. Data from PROVE 1 and PROVE 2 being presented at the 58th Annual Meeting of the American Association of the Study of Liver Diseases (AASLD) in Boston November 2-6, 2007 represent interim analyses. Vertex is developing telaprevir, an investigational hepatitis C protease inhibitor, in collaboration with Tibotec.

“The SVR data from the PROVE studies are promising as the expectation today is that approximately 40% to 50% of people with genotype 1 hepatitis C who undergo 48-week treatment regimens with currently available therapies achieve sustained viral response (SVR). In this Phase 2 study, we saw 24-week telaprevir-based regimens result in SVR of greater than 60% in patients with genotype 1 hepatitis C,” said John McHutchison, M.D., Principal Investigator for the PROVE 1 study and Director of Gastroenterology and Hepatology Research at Duke Clinical Research Institute. “If these efficacy results are confirmed in larger studies, and there are no new safety or tolerability concerns, this 24-week regimen could be an important medical advance.”

* * *

In the 48-week telaprevir treatment arm (12+36; n=79) of PROVE 1, 65% had undetectable HCV RNA (<10 IU/mL) at end of treatment.

Sustained viral response results from the control arms of PROVE 1 and PROVE 2 are not available. At the time of the interim analysis, in the PROVE 1 control arm (n=75), 45% of patients receiving 48-weeks of pegylated interferon (peg-IFN) and ribavirin (RBV) had undetectable HCV RNA (<10 IU/mL) at end of treatment. At the time of the interim analysis, in the control arm of PROVE 2 (n=82), 59% of patients receiving 48 weeks of peg-IFN and RBV had undetectable HCV RNA (<10 IU/mL) at week 36 on-treatment. Typically, following the completion of 48 weeks of treatment with peg-IFN+RBV, a certain proportion of patients with undetectable HCV RNA relapse.

SVR rates given for the telaprevir arms include patients who completed dosing in their study arm as well as patients who discontinued treatment prior to completion of dosing, but who met the criteria for SVR 24 (defined as undetectable HCV RNA <10 IU/mL 24 weeks after completing treatment).

SVR results for the telaprevir 12+36-week treatment arm in PROVE 1 and the control arms for PROVE 1 and PROVE 2, including viral relapse observed post-treatment, will be presented at a future medical meeting. A detailed overview of the PROVE 1 and PROVE 2 clinical trial designs can be found in a Vertex press release dated May 23, 2006.

Rapid Viral Response (RVR)
In PROVE 1 and PROVE 2 combined, on an ITT basis, 77% of patients receiving telaprevir in combination with peg-IFN and RBV achieved a rapid viral response at 4 weeks (79% in PROVE 1, 75% in PROVE 2), defined as undetectable HCV RNA <10 IU/mL as measured by the Roche TaqMan(R) assay, compared to an average of 12% of patients across the control arms of PROVE 1 and PROVE 2 (11% in PROVE 1, 13% in PROVE 2; p<0.001 for the comparison in each study).

For those patients that achieved RVR, completed 24 weeks of telaprevir-based therapy, and had data available for SVR analysis, 91% achieved an SVR 24 or SVR 12. This finding demonstrates a correlation between RVR and SVR in a 24-week telaprevir-based treatment regimen.

Viral Breakthrough

In PROVE 1 and PROVE 2 combined, 5% of patients receiving telaprevir in combination with peg-IFN and RBV experienced viral breakthrough in the first 12 weeks of treatment (7% in PROVE 1, 2% in PROVE 2). Most viral breakthroughs occurred in the first month of treatment, and were generally associated with low interferon blood levels. After patients had undetectable HCV RNA (<10 IU/mL), less than 2% of patients receiving telaprevir in combination with peg-IFN and RBV experienced viral breakthrough on treatment.

Viral Relapse

In PROVE 1 and PROVE 2 combined, the relapse rate for patients who completed 24 weeks of treatment was 9% (2% in PROVE 1, 14% in PROVE 2). In PROVE 1 and PROVE 2 combined, for those patients that achieved an RVR and completed 24 weeks of therapy, 7% experienced viral relapse in the post-treatment period (2% in PROVE 1, 11% in PROVE 2). Per protocol in PROVE 1, only patients who achieved an RVR were to stop treatment at 24 weeks of therapy; no such criteria were utilized in PROVE 2. Following completion of treatment, no patient in PROVE 1 that received telaprevir in combination with peg-IFN and RBV relapsed after week 12 of the 24-week post-treatment period.

PROVE 1 and PROVE 2 Safety

The types of adverse events that have been commonly observed with Peg-IFN and RBV were seen across all treatment arms of PROVE 1 and PROVE 2. The most common adverse events, regardless of treatment assignment, were fatigue, rash, headache and nausea. Gastrointestinal disorders, skin adverse events (rash, pruritus) and anemia were higher in the telaprevir arms compared to the control arm over the dosing period.

In PROVE 1, the overall discontinuation rate through 12 weeks was 18% across all telaprevir treatment arms and 3% in the control arm. This includes discontinuations due to adverse events, withdrawal of consent and patients lost to follow-up. The incidence of treatment discontinuations through week 12 due to adverse events was 13% and 2% in the telaprevir and control arms, respectively. The
most common reason for discontinuation was rash, with 7% of patients discontinued for this reason in the telaprevir arms during the first 12 weeks of treatment. After week 12, discontinuations due to adverse events were 8% each in the telaprevir and control arms. Over the full course of the treatment period, the incidence of severe adverse events was 27% in the telaprevir arms and 24% in the control arm.

In PROVE 2, the overall discontinuation rate through 12 weeks was 14% across all telaprevir treatment arms and 6% in the control arm. This includes discontinuations due to adverse events, withdrawal of consent and patients lost to follow-up. The incidence of treatment discontinuations through week 12 due to adverse events were 10% and 3% in the telaprevir and control arms, respectively. As with PROVE 1, the most common reason for discontinuation was rash, with 7% of patients discontinued due to rash in the telaprevir arms, compared to less than one percent in the control arm during the first 12 weeks of treatment. Through to week 12, the time of the interim safety analysis being reported, the incidence of severe adverse events was 17% in the telaprevir arms and 10% in the control arm.

51. This press release disclosed for the first time the poor SVR and relapse results from PROVE 2. Specifically, telaprevir outperformed other drugs already approved by the FDA for the treatment of Hepatitis C by only 6%, compared to 16% in PROVE 1. Also, PROVE 2 reported a relapse rate of 14%, seven times that seen in PROVE 1.

52. On November 2, 2007, the Maxim Group issued a “Sell” rating in its research report on Vertex, which stated in part:

- PROVE II: SFR 12 of 65% (ITT, n=81) for the “12+12” arm came in lower than our base case expectation (66-68%) and the Street expectation of 70%+, likely contributed by the much higher relapse rate in E.U. patients (14% vs. our expectation of 8%) – neutral to negative.

  * * *

- Discontinuation with first 12 weeks: 18% vs. 3% in the U.S. (13% vs. 2% due to AE); 14% vs. 6% (10% vs. 3% due to AE) in the E.U. The discontinuation rate overall was higher than what we expected and continues to be the Achilles’ heel for phase III as a much larger group of patients will likely be studied – negative.

Mixed SVR Data Reported. Last Friday, Vertex disclosed sustained viral response rate (SVR) data in treatment-naive patients treated with 12 weeks of telaprevir (TVR) plus standard of care (SOC, PEG-IFN + Ribavirin) followed by 12 weeks of SOC (the 12 + 12 arms) in its PROVE 1&2 trials. The PROVE-1 12+12 arm SVR (61%) came at the low end of our estimated range (60-65%) but it comfortably beats what may be expected from the control arm given that only 45% patients had undetectable HCV RNA (<10 IU/mL) at the end of 48 week treatment with SOC. PROVE-2 data on the other hand was not that impressive with the TVR arm having a SVR12 of 65% but 59% of patients treated for 36 weeks (still continuing treatment till 48 weeks) of SOC had undetectable HCV RNA. While some patients will relapse, additional patients may respond in the next 12 weeks of SOC treatment. Hence it is difficult to ascertain whether PROVE-2 12+12 arm SVR24 will be substantially higher than that of control arm. Since 65% [of] patients treated with 12+36 regimen had undetectable HCV RNA at the end of treatment, it appears 24 weeks of additional SOC treatment does not add additional benefit to the 12+12 regimen. Thus, Vertex is very likely to move forward with this 12+12 treatment regimen.

* * *

Downgrade To Market Perform. We believe last Friday’s data, while mixed, will be sufficient to support moving the 12+12 regimen into Phase III program. With the SVR data from 12+12 arm out of the way, we do not see many near term positive drivers for VRTX while risks remain. We are concerned that the FDA may take a more stringent stand and ask Vertex to complete 48 weeks of SOC treatment for the control arm before TVR NDA filing, given that the SVR data is not unequivocally strong. We believe the PROVE-3 trial of TVR in relapsers and non-responders carries a high hurdle. The promising data from Schering Plough (SGP, Not Rated)’s Phase II trial of boceprevir (better dosing regimen of tid vs. TVR’s q8h) points to the strengthening of competition for TVR. With a lack of key milestones in the next 12-months and a greater headline risk from competitors aggressively moving forward with their respective anti-viral products, we expect VRTX shares to be range-bound in the next 12-months and to not outperform the biotech indices. We therefore downgrade VRTX shares to Market Perform from Market Outperform.

54. As a result of the disclosure of the PROVE 2 SVR and relapse data, Vertex’s stock price dropped from $31.64 to $24.08 in two trading days. This decrease in Vertex’s stock price was a result of the artificial inflation caused by defendants’ misleading statements coming out of the stock price.
55. During the Class Period, the defendants had both the motive and opportunity to conduct fraud. They also had actual knowledge of the misleading nature of the statements they made or acted in reckless disregard of the true information known to them at the time. In so doing, the defendants participated in a scheme to defraud and committed acts, practices and participated in a course of business that operated as a fraud or deceit on purchasers of Vertex securities during the Class Period. Defendants were motivated to conceal the unfavourable PROVE 2 data during the Class Period in part by the insider sales detailed herein, but also by the hope that additional, more favorable data would turn up and cushion the blow from the PROVE 2 results.

56. A strong inference exists that defendants were aware of the PROVE 2 results because telaprevir was Vertex’s most important product. Defendants repeatedly stated that they were building the Company on telaprevir.

57. Indeed, the Company was intimately involved with the conduct of PROVE 2. An abstract regarding PROVE 2’s interim results was submitted to the American Association for the Study of Liver Diseases on June 4, 2007. Four of the authors of that abstract, defendant John Alam, Shahin Gharakhanian, Desirée Devonish, and Robert Kauffman, were Vertex employees.

58. Defendants performed an interim analysis of the PROVE 2 study after 24 weeks. Given that the study began in June of 2006 and was fully enrolled by January of 2007, that analysis was performed at least by June of 2007. That interim analysis showed that patients in one 12-week treatment arm showed SVR of 59%, roughly the same as the control group, meaning that telaprevir performed no better than other drugs already approved to treat HCV by the FDA. The 24-week interim analysis also showed relapse rates in PROVE 2 far higher than had been observed in PROVE 1. Indeed, defendants eventually revealed the relapse rate in PROVE 2 to be seven times greater than that observed in PROVE 1.
59. Defendants were aware of telaprevir's poor showing in the 12-week arms of PROVE 2 even before the interim analysis. The patient treatment and collection of data from the PROVE 2 study was managed by a clinical research organization (CRO). After each patient stopped taking medication, his or her results were unblinded, meaning that the patient and clinician learned what drug combination the patient had been taking and the results that the patient had experienced. After that, a CRO employee entered the results into a database called the Electronic Data Capture system (EDC). All members of the telaprevir study team at Vertex had full access to this database, including defendant Alam. Thus, by the spring of 2007, defendants knew how the vast majority of the patients in the 12-week arms had fared.

60. The first patients enrolled in PROVE 2 beginning in June of 2006 and were randomly assigned to one of the arms of the study. Starting then, anyone assigned to one of the 12-week arms of the trial took medication for 12 weeks, then stopped and went medication-free for another 12 weeks of follow-up. Patients who were assigned to the 12-week arms and who began treatment in June of 2006 were completed within 24 weeks, i.e., by December 2006 or January 2007. Given that the study began in June of 2006, the vast majority of patients in the 12-week arms had completely finished their participation in the study by the spring of 2007. Because defendants knew which patients were in the 12-week arms and had the results of the vast majority of those patients by the spring of 2007, defendants knew at that time that PROVE 2 was a disappointment. Specifically, they knew that PROVE 2 showed poor SVR results and relapse rates as set forth above.

4 In a double-blind, placebo-controlled clinical trial, like PROVE 2, neither the patients nor the researchers know who is getting a placebo and who is getting the treatment. Because patients don’t know what they’re getting, their belief about what will happen doesn’t taint the results. Because the researchers don’t know either, they can’t hint to patients about what they’re getting, and they also won’t taint results through their own biased expectations about what the results will be.
61. These facts are confirmed by the blog of Nick Mercer, a participant in PROVE 2. Mr. Mercer was in one of the 12-week arms of the trial, receiving 12 weeks of telaprevir and interferon. He received his first dose on January 2, 2007, and continued taking it for 84 days (12 weeks). On day 85, March 29, 2007, his results were unblinded. Telaprevir and interferon together had succeeded in reducing his viral load to undetectable levels. Unfortunately, after discontinuing treatment, Mr. Mercer learned on April 28, 2007 that he had relapsed. In fact, Mr. Mercer was then told “It’s little comfort, but you’re not the only one,” showing that the poor relapse results were already known.5

LOSS CAUSATION/ECONOMIC LOSS

62. During the Class Period, as detailed herein, defendants made false and misleading statements by means of concealment and obfuscation of critical clinical trial data and engaged in a scheme to deceive the market. This artificially inflated Vertex’s stock price and operated as a fraud or deceit on the Class. Later, when defendants’ prior misrepresentations and fraudulent conduct became apparent to the market, Vertex’s stock price fell precipitously, as the prior artificial inflation came out of the stock price over time. As a result of their purchases of Vertex securities during the Class Period, plaintiff and other members of the Class suffered economic loss, i.e., damages, under the federal securities laws.

5 Another patient in the PROVE 2 study, identified only as “Steve,” related his experience on www.medhelp.org. These postings confirm that each patient’s results were unblinded and reported to them immediately after they stopped taking the medication.
NO SAFE HARBOR

63. Vertex’s verbal “Safe Harbor” warnings accompanying its oral forward-looking statements ("FLS") issued during the Class Period were ineffective to shield those statements from liability.

64. The defendants are also liable for any false or misleading FLS pleaded because, at the time each FLS was made, the speaker knew the FLS was false or misleading and the FLS was authorized and/or approved by an executive officer of Vertex who knew that the FLS was false. None of the historic or present tense statements made by defendants were assumptions underlying or relating to any plan, projection or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by defendants expressly related to or stated to be dependent on those historic or present tense statements when made. On the contrary, such statements concealed critical data about the prospects of an important drug candidate.

APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET

65. Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:

(a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

(b) The omissions and misrepresentations were material;

(c) The Company’s stock traded in an efficient market;

(d) The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company’s stock; and
(e) Plaintiff and other members of the Class purchased Vertex securities between the time defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

66. At all relevant times, the market for Vertex securities was efficient for the following reasons, among others:

(a) As a regulated issuer, Vertex filed periodic public reports with the SEC; and

(b) Vertex regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts and other similar reporting services.

COUNT I

For Violation of §10(b) of the 1934 Act and Rule 10b-5 Against All Defendants


68. During the Class Period, defendants disseminated or approved the false statements specified above, which they knew or recklessly 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.

69. Defendants violated §10(b) of the 1934 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
Engaged in acts, practices, and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of Vertex publicly traded securities during the Class Period.

70. Plaintiff 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. Plaintiff 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.

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

COUNT II

For Violation of §20(a) of the 1934 Act Against All Defendants

72. Plaintiff incorporates ¶¶1-71 by reference.

73. The Individual Defendants acted as controlling persons of Vertex within the meaning of §20 of the 1934 Act. By virtue of their positions and their power to control public statements about Vertex, the Individual Defendants had the power and ability to control the actions of Vertex and its employees. Vertex controlled the Individual Defendants and its other officers and employees. By reason of such conduct, defendants are liable pursuant to §20(a) of the 1934 Act.

CLASS ACTION ALLEGATIONS

74. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased Vertex publicly traded securities during the Class Period (the “Class”). Excluded from the Class are defendants, directors and officers of Vertex and their families and affiliates.
75. 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. Vertex had more than 132 million shares of stock outstanding, owned by thousands of persons.

76. 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 1934 Act was violated by defendants;
(b) Whether defendants omitted and/or misrepresented material facts;
(c) Whether defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;
(d) Whether defendants knew or recklessly 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.

77. Plaintiff's claims are typical of those of the Class because plaintiff and the Class sustained damages from defendants' wrongful conduct.

78. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.
79. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

PRAYER FOR RELIEF

WHEREFORE, plaintiff prays for judgment as follows:

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

JURY DEMAND

Plaintiff demands a trial by jury.

DATED: July 21, 2008

SHAPIRO HABER & URMY LLP

/s/ Adam M. Stewart

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Certificate of Service

I hereby certify that this document(s) filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants on July 21, 2008.

/s/ Adam M. Stewart
Adam M. Stewart