

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes 🔀 No 🗌

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes 🗌 No 🔀

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 🖂 No 🗌

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes 🗌 No 🗌

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Accelerated filer Large accelerated filer X

Non-accelerated filer 🗌 (Do not check if a smaller reporting company)

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes 🗌 No 🖂

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) based on the last reported sale price of the common stock on June 30, 2009 (the last trading day of the registrant's second fiscal quarter of 2009) was \$6.4 billion. As of February 16, 2010, the registrant had 200,576,408 shares of common stock outstanding.

### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive Proxy Statement for the 2010 Annual Meeting of Stockholders to be held on May 13, 2010 are incorporated by reference into Part III of this Annual Report on Form 10-K.

# VERTEX PHARMACEUTICALS INCORPORATED

# **ANNUAL REPORT ON FORM 10-K**

# TABLE OF CONTENTS

Page

	PART I	
Item 1.	Business	1
		26
Item 1A.	NISK I dotors	31
Item 1B.		50
Item 2.		50
Item 3.	Legal Proceedings	51
Item 4.	Submission of Matters to a Vote of Security Holders	51
	PART II	
Item 5.	x dronabob or 24mil boroning to the transferred by	52
Item 6.	Scheeled I maneral Data	54
Item 7.	Operations	55
Item 7A.	Quantinuario and Quantum - 2 lottoper to the test set	75
Item 8.	Financial Statements and Supplementary Data	76
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial	76
Item 9A.	Controls and Procedures	76
Item 9B.		79
	PART III	
Item 10.	Directors, Executive Officers and Corporate Governance	80
Item 11.	Executive Compensation	80
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related	
	Stockholder Matters	80
Item 13.	Certain Relationships and Related Transactions, and Director Independence	80
Item 14.	Principal Accountant Fees and Services	8(
	PART IV	
Item 15.		81 86

"We," "us," "Vertex" and the "Company" as used in this Annual Report on Form 10-K, refer to Vertex Pharmaceuticals Incorporated, a Massachusetts corporation, and its subsidiaries.

"Vertex" is a registered trademark of Vertex. "Lexiva" and "Telzir" are registered trademarks of GlaxoSmithKline plc. Other brands, names and trademarks contained in this Annual Report on Form 10-K are the property of their respective owners.

#### **ITEM 1. BUSINESS**

#### OVERVIEW

We are in the business of discovering, developing and commercializing small molecule drugs for the treatment of serious diseases. Telaprevir, our lead drug candidate, is an oral hepatitis C protease inhibitor and one of the most advanced of a new class of antiviral treatments in clinical development that target hepatitis C virus, or HCV, infection. Telaprevir is being evaluated in a registration program focused on treatment-naïve and treatment-failure patients with genotype 1 HCV infection. We currently intend to submit a new drug application, or NDA, for telaprevir in the United States in the second half of 2010 and to initiate sales of telaprevir in the United States in 2011, assuming the successful completion of the registration program.

We are engaged in a number of other clinical development programs and intend to continue to invest in our research programs with the goal of adding promising new compounds to our drug development pipeline. VX-770, the lead drug candidate in our cystic fibrosis, or CF, program is being evaluated in a registration program that focuses on patients with CF who have the G551D mutation in the gene responsible for CF. We are conducting or are planning to begin in 2010 a number of Phase 2a clinical trials of our earlier-stage drug candidates. These clinical trials consist of a planned clinical trial that will evaluate telaprevir in combination with the HCV polymerase inhibitor VX-222, a planned clinical trial of VX-809 in combination with VX-770 in patients with the most common mutation in the gene responsible for CF, a clinical trial of VX-509 in patients with moderate-to-severe rheumatoid arthritis and a clinical trial of VX-765 in patients with treatment-resistant epilepsy.

#### **OUR PIPELINE**

Our pipeline is described in the following table. In addition to those listed below, we are engaging in preclinical activities with respect to a number of additional drug candidates.

Drug or Drug Candidate	Clinical Indication(s)	Mechanism/Target	Development Stage	Collaborator(s)
HCV Infection telaprevir (VX-950)	HCV Infection	HCV Protease Inhibitor	Phase 3	Janssen Pharmaceutica, N.V. Mitsubishi Tanabe Pharma Corporation
VX-222 VX-985 VX-759	HCV Infection HCV Infection HCV Infection	HCV Polymerase Inhibitor HCV Protease Inhibitor HCV Polymerase Inhibitor	Phase 2a Phase 1 Phase 1	•
Cystic Fibrosis VX-770	Cystic Fibrosis	CFTR Potentiator	Phase 3	Cystic Fibrosis Foundation Therapeutics Incorporated
VX-809	Cystic Fibrosis	CFTR Corrector	Phase 2a	Cystic Fibrosis Foundation Therapeutics Incorporated
Immune-mediated Inflamm	atory Diseases			· · · · · · · · · · · · · · · · · · ·
VX-509	Rheumatoid Arthritis	JAK3 Inhibitor	Phase 2a	
<i>Epilepsy</i> VX-765	Epilepsy	Caspase-1 Inhibitor	Phase 2a	•
HIV Infection Lexiva/Telzir	HIV Infection	HIV Protease Inhibitor	Marketed	GlaxoSmithKline plc*

\* We sold our rights to future royalties from sales of Lexiva/Telzir in May 2008.

#### **OUR STRATEGY**

Our goal is to become a fully-capable biopharmaceutical company with industry-leading capabilities in the research, development and commercialization of innovative drugs that provide substantial benefits to patients with serious diseases. The key elements of our strategy are:

Obtain FDA approval for and effectively commercialize telaprevir in the United States. We are focused on obtaining approval for and effectively commercializing telaprevir as a treatment for patients infected with genotype 1 HCV who have not received previous treatment for their infections, referred to as treatment-naïve patients, and patients infected with genotype 1 HCV who have failed to achieve a sustained viral response, or SVR, after prior treatment with pegylated-interferon, or peg-IFN, and ribavirin, or RBV, referred to as treatment-failure patients. Our registration program is designed to support 24-week response-guided telaprevir-based treatment regimens for treatment-naïve patients, and to support treatment of all categories of treatment-failure patients, including null responders to peg-IFN and RBV, who are the most difficult category of patients with HCV infection to treat successfully. We expect to receive final SVR data from the ongoing registration clinical trials for telaprevir during the second and third quarters of 2010 and expect to submit the NDA for telaprevir in the second half of 2010. If we obtain positive results from the ongoing registration program and are able to obtain approval of telaprevir on our current timeline, we plan to initiate sales of telaprevir in the United States in 2011.

Become a fully-capable biopharmaceutical company. In order to become a fully-capable biopharmaceutical company, we believe we need to build and establish an effective sales and marketing organization to augment our existing research capabilities along with the late-stage development organization and third-party manufacturing relationships that we have built over the last several years. Although we have been expanding our commercial infrastructure, we will need to further expand these capabilities in order to effectively launch telaprevir and to position our company for the future.

Invest in research and early and mid-stage development programs. We intend to continue to invest significant resources in research programs and early-stage and mid-stage clinical development programs as part of our strategy to develop drug candidates in therapeutic areas with significant unmet need. In 2010, we expect to conduct Phase 2a clinical trials involving drug candidates, which we have developed internally or acquired through business development activities, that are intended to address significant unmet needs in HCV, CF, rheumatoid arthritis and epilepsy. We expect to continue focusing our research activities toward therapies addressing serious diseases, because we believe these therapies have the potential to deliver the greatest value for patients, physicians and the health care system.

Capitalize on collaboration arrangements and business development opportunities. Collaborations have provided us with financial support and other valuable resources for our development and research programs, and business development opportunities have provided us with drug candidates and important research resources that have contributed to a number of the drug candidates in our current development pipeline. We plan to continue to rely on collaborators to support, develop and commercialize some of our drug candidates either worldwide or in markets in which we are not concentrating our resources. We also opportunistically seek to license and acquire drugs, drug candidates and other technologies that have the potential to strengthen our pipeline, drug discovery platform or commercial opportunities.

## DRUG CANDIDATES

#### **HCV** Infection

# Telaprevir (VX-950) (investigational oral HCV protease inhibitor for the treatment of HCV infection)

Telaprevir, our lead drug candidate, is an orally-administered hepatitis C protease inhibitor that is being evaluated in treatment-naïve and treatment-failure patients with genotype 1 HCV infection in combination with peg-IFN and RBV. Telaprevir is designed to inhibit the NS3-4A serine protease, an enzyme necessary for HCV replication. The United States Food and Drug Administration, or FDA, has granted "Fast Track" designation to telaprevir. We have completed dosing of all study drugs in the registration program for telaprevir. Assuming the successful completion this year of our registration program for telaprevir, we intend to submit an NDA for telaprevir in the United States in the second half of 2010 and to initiate commercial sales of telaprevir in the United States in 2011. In addition to the current registration program, we also are planning to initiate a Phase 2a clinical trial to evaluate telaprevir in combination with VX-222, a polymerase inhibitor, with and without peg-IFN and RBV.

We have collaboration agreements relating to telaprevir with Janssen Pharmaceutica, N.V., or Janssen, a Johnson & Johnson company, and Mitsubishi Tanabe Pharma Corporation, or Mitsubishi Tanabe. Pursuant to these agreements, Janssen will be responsible for the commercialization of telaprevir, including the manufacture of its own commercial supply of telaprevir, outside of North America and the Far East. Mitsubishi Tanabe will be responsible for the commercialization of telaprevir, including the manufacture of its own commercial supply of telaprevir, in Japan and specified other countries in the Far East. Telaprevir was discovered in our collaboration, now ended, with Eli Lilly and Company. We expect to pay Eli Lilly certain royalties on future sales of telaprevir, if approved.

#### Background: Prevalence and Treatment of Hepatitis C Virus Infection

HCV infection causes an inflammation of the liver called chronic hepatitis. This condition can progress to scarring of the liver, called fibrosis, or more advanced scarring, called cirrhosis. Patients with cirrhosis may go on to develop liver failure or other complications of cirrhosis, including liver cancer. The World Health Organization has reported that HCV infection is responsible for more than 50% of all liver cancer cases and two-thirds of all liver transplants in the developed world.

The World Health Organization has estimated that about 170 million people are chronically infected with HCV worldwide and that an additional 3 million to 4 million people are infected each year. The Centers for Disease Control and Prevention have estimated that approximately 3.2 million people in the United States are chronically infected with HCV.

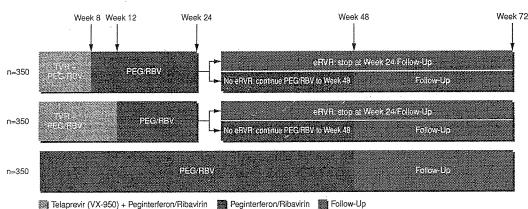
Our clinical development activities related to telaprevir are focused on genotype 1 HCV infection, which is the most prevalent form of HCV infection in the United States, the European Union and Japan. We believe that approximately 2.6 million patients in the United States have genotype 1 HCV infection. We believe that these patients include approximately 750,000 patients who already have been diagnosed with genotype 1 HCV infection and 1.8 million patients who remain undiagnosed.

In addition to being the most prevalent form of HCV infection, infection with genotype 1 HCV is the most difficult to treat of the primary HCV genotypes. The current standard treatment for infection with genotype 1 HCV, which was first approved in 2001, is a combination of peg-IFN and RBV, generally administered for 48 weeks. This treatment regimen is associated with significant side-effects, including fatigue, flu-like symptoms, rash, depression and anemia. Among patients who begin treatment, a significant percentage of patients infected with genotype 1 HCV fail to achieve a long-term sustained response to therapy. For example, on an intent-to-treat basis, 41% and 46%, respectively, of treatment-naïve patients in the standard therapy arms of our Phase 2b clinical trials known as PROVE 1 and PROVE 2 achieved an SVR. In another clinical trial conducted by another company, involving approximately 3,070 treatment-naïve patients in the United States infected with genotype 1 HCV, between 38% and 41% of patients receiving peg-IFN and RBV achieved an SVR. We believe that there are over 250,000 patients infected with genotype 1 HCV in the United States who have failed to achieve an SVR after therapy with peg-IFN and RBV.

#### Telaprevir Clinical Development

The three clinical trials in our registration program are ADVANCE and ILLUMINATE, Phase 3 clinical trials of telaprevir-based treatment regimens in treatment-naïve patients with genotype 1 HCV infection, and REALIZE, a Phase 3 clinical trial of telaprevir-based treatment regimens in treatment-failure patients with genotype 1 HCV infection. Dosing of all study groups in these three clinical trials has been completed. SVR data are expected from ADVANCE in the second quarter of 2010 and from ILLUMINATE and REALIZE in the third quarter of 2010.

The ADVANCE trial is a 3-arm double-blinded placebo-controlled clinical trial that enrolled approximately 1,050 patients with genotype 1 HCV infection. ADVANCE contains two telaprevir-based treatment arms, one in which patients receive 12 weeks of telaprevir-based triple combination therapy and one in which patients receive 8 weeks of telaprevir-based triple combination therapy, in each case taking peg-IFN and RBV for a period of time after completing telaprevir dosing. Patients in both of the telaprevir-based treatment arms who meet extended rapid viral response criteria, or eRVR, complete all treatment after 24 weeks, while patients who are responding to treatment but do not meet the eRVR criteria continue receiving peg-IFN and RBV for a total of 48 weeks of therapy. To achieve an eRVR a patient must have undetectable HCV RNA levels at the end of week 4 and week 12 after the start of treatment.

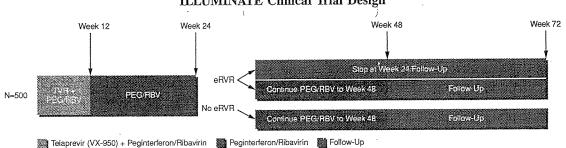


### **ADVANCE** Clinical Trial Design

eRVR = extended rapid viral response (undetectable HCV RNA at Week 4 AND Week 12)

4

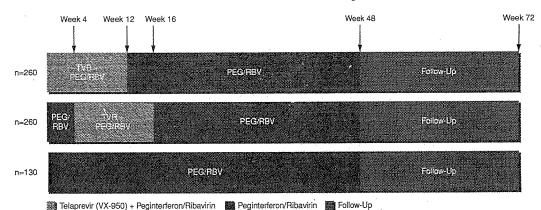
ILLUMINATE is a Phase 3 clinical trial, which includes evaluation of 24-week and 48-week total treatment durations in treatment-naïve patients infected with genotype 1 HCV who achieve an eRVR in response to telaprevir-based treatment regimens. This clinical trial is a randomized, open-label trial that enrolled approximately 500 patients. ILLUMINATE is designed to supplement SVR data obtained from the ADVANCE trial to evaluate the benefits and risks, for patients who achieve an eRVR, of extending total treatment duration from 24 to 48 weeks.



### **ILLUMINATE** Clinical Trial Design

The REALIZE trial is a 3-arm clinical trial of telaprevir-based treatment regimens in approximately 650 patients with genotype 1 HCV infection who failed to achieve an SVR after treatment with peg-IFN and RBV alone. One treatment arm is evaluating a lead-in strategy in which patients receive four weeks of pre-treatment with peg-IFN and RBV prior to starting telaprevir. REALIZE is being managed by our collaborator Tibotec Pharmaceuticals Ltd., which is a Johnson & Johnson company and an affiliate of Janssen. REALIZE includes the following patient groups:

- null responders-those patients who experienced less than a 2 log<sub>10</sub> reduction in HCV RNA levels at week 12 of prior therapy;
- partial responders-those patients who experienced at least a 2 log<sub>10</sub> reduction in HCV RNA levels at week 12 of prior therapy, but who failed to achieve undetectable HCV RNA levels by week 24: and
- relapsers-those patients who experienced undetectable HCV RNA levels at the completion of at least 42 weeks of prior treatment, but who relapsed after treatment ended.



#### **REALIZE Clinical Trial Design**

eRVR = extended rapid viral response (undetectable HCV RNA at Week 4 AND Week 12)

#### Telaprevir Clinical Data

#### PROVE Phase 2b Clinical Trials

We have completed three Phase 2b clinical trials of telaprevir-based combination therapy in patients infected with genotype 1 HCV, referred to as the PROVE trials. The PROVE trials enrolled an aggregate of approximately 580 treatment-naïve patients and 440 treatment-failure patients. The SVR rates on an intent-to-treat basis for patients in the 24-week telaprevir-based treatment arms and the control arms of PROVE 1 and PROVE 2, the two Phase 2b clinical trials that evaluated treatment-naïve patients, are set forth in the table below:

	PROVE 1	PROVE 2
24-week telaprevir-based treatment arm: telaprevir in combination with peg-IFN and RBV for 12 weeks, followed by peg-IFN and		
RBV alone for 12 weeks	61%	69%
48-week control arm: 48 weeks of therapy with peg-IFN and RBV	41%	46%

PROVE 3 was a Phase 2b clinical trial that evaluated telaprevir-based treatment of patients who had failed at least one course of treatment with peg-IFN and RBV, the current standard of care. The SVR rates on an intent-to-treat basis for patients in the 24-week telaprevir-based treatment arm, the 48-week telaprevir-based treatment arm and the control arm of PROVE 3 are set forth in the table below. Non-responders are patients who were not responsive to prior treatment and consist of a mixture of null and partial responders. Relapsers are patients who had viral rebound during the period following prior treatment. Breakthroughs are patients who experienced a viral rebound during prior treatment.

	Non-responders	Relapsers	Breakthroughs	Total
24-week telaprevir-based triple-therapy treatment arm: telaprevir in combination with peg-IFN and RBV for 12 weeks, followed by peg-IFN and RBV alone for 12 weeks	39% (n=66)	69% (n=42)	57% (n=7)	51% (n=115)
48-week telaprevir-based treatment arm: telaprevir in combination with peg-IFN and RBV				
for 24 weeks, followed by peg-IFN and RBV alone for 24 weeks	38% (n=64)	76% (n=41)	50% (n=8)	52% (n=113)
<b>48-week control arm:</b> 48 weeks of therapy with peg-IFN and RBV	9% (n=68)	20% (n=41)	40% (n=5)	14% (n=114)

The adverse event profile of telaprevir generally was consistent across our Phase 2 clinical trials, which have principally involved clinical trial sites in North America and Europe. Safety data from our Phase 2 clinical trials indicated that the most common adverse events, regardless of treatment assignment, were fatigue, rash, headache and nausea. The most common adverse events reported more frequently in patients receiving telaprevir than in the control arms were gastrointestinal events, skin events—rash and pruritus—and anemia. There have been reports of severe rashes in clinical trials involving telaprevir-based treatments, including several reports from the clinical trials being conducted by Mitsubishi Tanabe in Japan, where telaprevir is being evaluated in Phase 3 clinical trials in combination with peg-IFN and RBV. Rash resulted in treatment discontinuations in the telaprevir-based treatment arms in approximately 7% of patients in PROVE 1 and PROVE 2 and 5% of patients in PROVE 3. Other adverse events reported in our Phase 2 clinical trials generally were similar in type and frequency to those seen with peg-IFN and RBV treatment. Our ongoing registration program includes a rash management program that was developed based on the information from the PROVE 1 and PROVE 2 clinical trials and first implemented in our PROVE 3 clinical trial.

#### Additional Phase 2 Clinical Trials of Telaprevir

In October 2009, we announced data from the C208 trial, which was an exploratory open-label clinical trial that enrolled 161 treatment-naïve patients infected with genotype 1 HCV in Europe. The purpose of the C208 trial was to compare twice-daily dosing regimens of telaprevir—1,125 mg every 12 hours—in combination with peg-IFN and RBV, with three-times daily dosing regimens—750 mg every 8 hours—in combination with peg-IFN and RBV. A three-times daily dosing regimen is being used in the ongoing registration program for telaprevir and has also been used in the other clinical trials for telaprevir.

In the C208 trial, patients received telaprevir, peg-IFN and RBV for 12 weeks followed by an additional period of therapy of peg-IFN and RBV alone in a response-guided trial design. The design is response-guided because the time period during which a patient remains on therapy with peg-IFN and RBV alone after completion of therapy with a combination of telaprevir, peg-IFN and RBV is adjusted depending on the nature of the patient's early response to treatment. Patients who achieved at week 4 HCV RNA levels of less than 25 IU/mL, which is undetectable in the test used and is referred to as a rapid viral response or RVR, and also demonstrated undetectable HCV RNA through week 20, were able to stop all treatment after 24 weeks. Patients who did not meet the response-guided criteria were treated for a total of 48 weeks. 18% of patients across the treatment arms were required to continue treatment for 48 weeks.

The following table summarizes the RVR and SVR data on an intent-to-treat basis from the C208 trial.

Telaprevir Dosing	Combination Therapy	Total Number of Patients	RVR (undetectable at week 4 on treatment)	SVR (undetectable 24 weeks after end-of-treatment)
1,125 mg every 12 hours	alfa-2a (PEGASYS)/RBV	40	83% (n=33)	83% (n=33)
1,125 mg every 12 hours	alfa-2b (PEGINTRON)/RBV	39	67% (n=26)	82% (n=32)
750 mg every 8 hours	alfa-2a (PEGASYS)/RBV	40	80% (n=32)	85% (n=34)
750 mg every 8 hours	alfa-2b (PEGINTRON)/RBV	42	69% (n=29)	81% (n=34)

The frequency and severity of adverse events and the rate of treatment discontinuations were similar to those reported in prior telaprevir trials. The most common adverse events reported in patients in this clinical trial were pruritis, nausea, rash, anemia, flu-like illness, fatigue and headache, and the adverse events were similar overall across the patient groups receiving three-times daily dosing and those receiving twice-daily dosing. Serious adverse events leading to permanent treatment discontinuation of all drugs occurred in 5% of patients and were mainly related to rash, which resulted in discontinuation of 4 out of 161, or 3%, of patients, and anemia, which resulted in discontinuation of 3 out of 161, or 2%, of patients.

We also provided interim data in 2009 from an exploratory clinical trial, referred to as the 107 Trial, in patients from the control arms of the PROVE 1, PROVE 2 or PROVE 3 clinical trials who did not achieve an SVR. We expect to present final data from the 107 Trial during 2010.

#### Mitsubishi Tanabe Clinical Program

Mitsubishi Tanabe has three ongoing Phase 3 trials of telaprevir-based combination therapy in approximately 300 treatment-naïve and treatment-failure patients with HCV infection in Japan. Mitsubishi Tanabe has completed the telaprevir dosing portion of these Phase 3 clinical trials.

# VX-222 (investigational oral HCV polymerase inhibitor for the treatment of HCV infection)

HCV polymerase inhibitors, including our HCV polymerase inhibitor VX-222, are direct-acting antiviral agents that inhibit the replication of HCV, but through a mechanism distinct from HCV protease inhibitors such as telaprevir. VX-222 was evaluated by ViroChem Pharma Inc., or ViroChem, in Phase 1 clinical trials prior to our acquisition of ViroChem in March 2009. In this Phase 1 viral kinetics clinical trial, which involved five treatment-naïve patients with genotype 1 HCV infection, VX-222 dosed at 750 mg twice daily resulted in a median 3.7 log<sub>10</sub> decrease in HCV RNA—equivalent to a 5,000-fold reduction in virus in the blood—at the end of three days of dosing. The results were consistent from patient to patient, and across HCV genotype 1 subtypes. We recently reported interim data from a multiple-dose Phase 1b viral kinetic clinical trial of VX-222 that we are conducting to evaluate the antiviral activity, safety, tolerability and pharmacokinetics of VX-222 in patients with genotype 1 HCV infection. Interim results were consistent with the findings of the previously-conducted three-day viral kinetics clinical trial. No serious adverse events were reported in this trial.

We are engaged in late-stage discussions with the FDA and other international regulatory authorities, regarding the initiation of a Phase 2a combination trial of telaprevir and VX-222. This clinical trial is expected to begin in the first quarter of 2010 and to evaluate SVR rates using multiple regimens of telaprevir/VX-222-based therapy in patients with HCV infection.

# Additional HCV Research Activities and Development Programs

In addition to our development activities focused on telaprevir and VX-222, we are conducting a number of earlier-stage research and development activities aimed at identifying compounds that have advantageous characteristics for potential use against HCV infection. As we obtain new data and scientific, business and commercial insights into our own drug candidates and the drug candidates being developed by other companies, we may periodically change our focus and priority with respect to the drug candidates we are developing and the research programs we are pursuing. We currently consider VX-759, a second polymerase inhibitor that we acquired in our ViroChem acquisition, to be a back-up drug candidate to VX-222. VX-759 has been evaluated in Phase 1 clinical trials, and there are no ongoing clinical trials for VX-759. VX-985, an investigational HCV protease inhibitor that we discovered, is currently in Phase 1 clinical development. VX-813, another investigational HCV protease inhibitor, is no longer in development. We have an ongoing research program directed at identifying NS5A inhibitors, a third class of specifically targeted anti-viral compounds that we believe may be useful in the treatment of HCV infection.

### **Cystic Fibrosis**

Cystic fibrosis is a genetic disorder that affects about 30,000 people in the United States and 70,000 worldwide. The drug candidates that we are developing for CF were selected because of their potential to address the underlying cause of CF by increasing the function of a defective protein in CF patients, known as the cystic fibrosis transmembrane conductance regulator, or CFTR. While CF is a systemic disease, progressive loss of lung function is the primary cause of increased mortality in patients with CF. Abnormally thick mucus in the lungs of patients with CF leads to chronic lung infections, lung inflammation and progressive decline in lung function. Some patients with CF also experience problems with digestion, due to a lack of CFTR function in the pancreas, resulting in the need for enzyme replacement therapy. According to the Cystic Fibrosis Foundation in 2008, the predicted median survival for patients with cystic fibrosis is 37 years. The underlying cause of CF is a genetically inherited deficiency in the production or activity of the CFTR protein. The CFTR protein is involved in controlling the movement of chloride ions into and out of cells in the lung, sweat glands, pancreas and other organs.

CF develops when neither of the two copies of the *CFTR* gene, referred to as alleles, produce sufficient functional CFTR protein. There are numerous mutations in the *CFTR* gene that result in CF, including the G551D mutation and the F508del mutation. The G551D mutation results in a defect known as a gating defect, in which the CFTR protein reaches the cell surface but does not efficiently transport chloride ions across the cell membrane. The F508del mutation results in a defect known as a trafficking defect, in which the CFTR protein does not reach the cell surface in sufficient quantities.

According to the 2007 Cystic Fibrosis Foundation Patient Registry Annual Data Report in the United States, approximately 4% of patients with CF have the G551D mutation on at least one allele, 49% of patients with CF have the F508del mutation on both alleles and an additional approximately 38% of patients with CF have the F508del mutation on one allele.

There is no available therapy that improves the function of defective CFTR proteins. Instead, available treatments for CF pulmonary disease focus on improving mucus clearance from the lungs as well as treating lung infections and inflammation. Improved mucus clearance is sought through physical therapy, inhalation of a mucus thinning drug such as Pulmozyme, or inhalation of hypertonic saline. Lung infections are treated with inhaled and systemic antibiotics while inflammation is treated with anti-inflammatory agents like ibuprofen. In addition, the majority of CF patients take pancreatic enzyme supplements to assist with food absorption in digestion.

 $FEV_1$ , a test of the amount of air that an individual can exhale in one second, is the lung function test most commonly used to monitor CF disease progression, which is characterized by progressive decreases in  $FEV_1$  values compared to  $FEV_1$  values observed in healthy individuals. The  $FEV_1$  test has been used as an efficacy end-point during testing of the currently approved pulmonary drugs for the treatment of CF. Since CF is a chronic disease, pivotal clinical trials of CF drug candidates have involved the measurement of  $FEV_1$  values over a number of months. Mean increases in percent predicted  $FEV_1$  of between 5% and 10% over 24-week periods have been observed in the pivotal clinical trials of the mucus thinning drugs and antibiotics most widely used for the management of CF.

We are conducting clinical trials of two drug candidates, VX-770 and VX-809, that were selected because of their potential to improve the function of defective CFTR proteins in patients with CF. We discovered VX-770 and VX-809 in our research collaboration with The Cystic Fibrosis Foundation Therapeutics Incorporated, or CFFT, and with the support and participation of the Cystic Fibrosis Foundation. We hold worldwide development and commercialization rights to VX-770 and VX-809, but we will pay royalties to CFFT on any future sales of VX-770 or VX-809.

#### VX-770 (investigational oral CFTR potentiator for the treatment of cystic fibrosis)

VX-770 is an investigational oral drug candidate that was selected because of its potential to increase chloride ion transport across cell membranes by partially restoring the activity of defective CFTR protein. In May 2009, we initiated a registration program, referred to as ENDEAVOR, for VX-770. The VX-770 registration program focuses on patients with the G551D mutation. The registration program consists of three clinical trials.

The primary clinical trial, which is referred to as STRIVE, is a Phase 3 clinical trial of VX-770 that enrolled approximately 170 patients 12 years and older with the G551D mutation on at least one of the patient's two *CFTR* genes, or alleles. In this randomized, placebo-controlled, double-blind, parallel-group clinical trial, patients will receive either VX-770 or placebo for 48 weeks. The second clinical trial, which is referred to as ENVISION, is a Phase 3 clinical trial of VX-770 in patients between 6 to 11 years of age with the G551D mutation on at least one allele. ENVISION is a two-part, randomized, placebo-controlled, double-blind, parallel-group clinical trial of ENVISION, which evaluated single-dose pharmacokinetics to determine the dose selection for children ages 6 to 11. We expect that Part 2 of the ENVISION trial will enroll approximately 30 patients who will receive either VX-770 or placebo for 48 weeks. The primary endpoint for the STRIVE and ENVISION clinical trials is absolute change from baseline in FEV<sub>1</sub>

through week 24. Additional  $\text{FEV}_1$  measurements will be taken through 48 weeks as a secondary endpoint. Secondary endpoints, including sweat chloride levels, will be measured to evaluate the effectiveness of VX-770 in improving the function of the defective CFTR protein.

The third clinical trial, which is referred to as DISCOVER, is a Phase 2 exploratory clinical trial of VX-770 that enrolled approximately 120 patients with CF who are 12 years and older and with the F508del mutation on both alleles. In this randomized, placebo-controlled, double-blind, parallel-group trial, patients will receive either VX-770 or placebo for 16 weeks. The primary endpoints of the DISCOVER clinical trial are safety and change from baseline in FEV<sub>1</sub> through week 16. Additional secondary endpoints, including sweat chloride levels, will be measured to evaluate the effectiveness of VX-770 in improving the function of the defective CFTR protein. We currently anticipate that further clinical trials in patients homozygous for the F508del mutation will involve a combination of VX-770 and VX-809.

STRIVE and DISCOVER are fully-enrolled and we expect to complete enrollment in ENVISION in the first half of 2010. If our registration program for VX-770 is successful and completed on the timeline that we currently anticipate, we could submit an NDA for VX-770 in the second half of 2011.

# Completed Phase 2a Clinical Trial of VX-770

We have completed a Phase 2a clinical trial of VX-770 that enrolled 39 patients with the G551D mutation on at least one allele, 20 of whom were enrolled in Part 1 of the clinical trial and 19 of whom were enrolled in Part 2 of the clinical trial. Patients in Part 1 of this clinical trial were dosed with VX-770 or placebo over 14 day periods. In Part 2 of this Phase 2a clinical trial, patients were dosed over 28 days in the following three arms: eight patients received 150 mg of VX-770 twice daily; seven patients received 250 mg of VX-770 twice daily; and four patients received a placebo twice daily.

#### Safety (primary endpoint)

The primary endpoint of this VX-770 Phase 2a clinical trial was safety. In Part 1, observed adverse events were similar between VX-770 and placebo treatment over the dosing period. Two serious adverse events were observed in one patient in Part 1, but were not attributed to VX-770. In Part 2 of this clinical trial, no serious adverse events were reported and no patients discontinued treatment over the 28-day dosing period. Also in Part 2, all reported adverse adverse were mild or moderate in severity.

### Lung Function and CFTR Protein Function (secondary endpoints)

In this VX-770 Phase 2a clinical trial, we measured secondary endpoints of lung function and CFTR protein function. We measured changes in lung function using FEV<sub>1</sub>. CFTR activity was evaluated through measurements of sweat chloride levels and nasal potential difference, or NPD. Elevated sweat chloride levels—high levels of salt in sweat—occur in CF patients and result directly from defective CFTR activity in epithelial cells in the sweat ducts. Patients with CF typically have elevated sweat chloride levels that are in excess of 60 mmol/L, compared to normal values of less than 40 mmol/L. NPD assesses several aspects of ion channel activity by measuring voltage changes across the nasal epithelia and is used as a direct measure of CFTR activity and chloride ion movement in upper airway epithelial cells. Typical assessments of patient NPD show very low CFTR-mediated chloride ion transport in the nasal passage of patients with CF.

In Part 1 of the Phase 2a clinical trial of VX-770, the eight patients who received 150 mg twicedaily over 14 days had a 10.1% improvement in lung function as measured by an increase in FEV<sub>1</sub>. In these patients, sweat chloride levels had a mean decrease of 42.3 mmol/L from a mean baseline of 95.5 mmol/L over the 14-day dosing period. The NPD component decreased by 5.4 mV, indicating increased CFTR function. There were no statistically significant changes in any of the efficacy measures in the placebo arms of Part 1. The four patients receiving placebo in Part 1 showed a slight decrease in FEV<sub>1</sub>, no notable change in sweat chloride levels and a -1.74 mV change in NPD.

A summary of data regarding lung function and biomarkers of the CFTR protein function, including "p-values" from Part 2 of this Phase 2a clinical trial, is set forth in the table below. The result of statistical testing is often defined in terms of a "p-value," with a p-value of 0.05 or less generally considered to represent a statistically significant difference.

Number of Patients	Treatment Arm	FEV <sub>1</sub> Mean Increase from Baseline at Day 28 (p-value)	Sweat Chloride Mean Decrease from Baseline at Day 28 (p-value)	Sweat Chloride Baseline	NPD Mean Decrease from Baseline at Day 28 (p-value)
8	150 mg	11.6% (p<0.01)	- 52.8 mmol/L(p<0.01)	102 mmol/L	-4.3 mV (p<0.05)
7	250 mg	7.4% (p<0.05)	-32.4 mmol/L (p<0.05)	94.9 mmol/L	-10.1 mV (p<0.05)
4	Placebo	7.0% (p=0.13)	+4.8 mmol/L (p=0.38)	98.3 mmol/L	+0.3 mV (p=0.88)

The pattern of FEV<sub>1</sub> response in the VX-770 arms was characterized by a rapid and sustained increase in  $FEV_1$  through 28 days. The increase in  $FEV_1$  in the placebo arm was not considered statistically significant.

# VX-809 (investigational oral CFTR corrector compound for the treatment of CF)

We are evaluating VX-809, an oral corrector compound that was selected because of its potential to increase the concentration of CFTR proteins on cell surfaces, in patients with the F508del mutation, a mutation that results in a trafficking defect. *In vitro*, studies of correctors have suggested that these compounds can restore function of defective F508del CFTR protein, with increased trafficking of F508del CFTR protein to the cell surface and enhanced gating activity of F508del CFTR protein on the cell surface.

We recently completed a Phase 2a, 28-day clinical trial of VX-809 as a single agent in 89 patients 18 years or older with the F508del mutation on both alleles. This Phase 2a clinical trial was a randomized, double-blind, placebo-controlled, multiple dose clinical trial. Patients received one of four doses of VX-809, or placebo, in addition to standard therapies for 28 days. The trial was designed primarily to evaluate the safety and tolerability of VX-809. Multiple secondary endpoints were utilized to determine any effect of VX-809 on CFTR protein function and lung function.

Based on a preliminary analysis of the data from the trial, VX-809 was well-tolerated through 28 days of 25 mg, 50 mg, 100 mg and 200 mg once-daily dosing. In the trial, one patient discontinued treatment in each of the VX-809 treatment arms due to adverse events. Respiratory-related adverse events were the most commonly reported adverse event in the trial. Safety and tolerability were the primary endpoints of the trial, and a detailed safety analysis is ongoing.

We also evaluated several secondary endpoints in the Phase 2a clinical trial. In the trial, there was a statistically significant decline in sweat chloride at both the 100 mg and 200 mg once-daily doses, suggesting that the activity of the CFTR protein was increased in patients during dosing. Additionally, we observed a dose response in change in sweat chloride across the four dose groups. A summary of the preliminary data regarding sweat chloride levels from this Phase 2a clinical trial is set forth in the table below. The patients' mean baseline sweat chloride levels were approximately 100 mmol/L, which is consistent with sweat chloride measurements of patients with severe CF.

Treatment Arm	Mean Change in Sweat Chloride Levels from Baseline at Day 28	p-value
25 mg (once-daily)	0.10 mmol/L	.9753
50 mg (once-daily)		.1323
100 mg (once-daily)	-6.13 mmol/L	.0498
200 mg (once-daily)	-8.21 mmol/L	.0092

The trial also included additional secondary endpoints to evaluate CFTR protein function, including CFTR protein trafficking, and lung function. Additional sub-analyses are ongoing to determine any potential trends in other measures of CFTR-dependent chloride ion transport, such as nasal potential difference; or CFTR maturation, as measured by an exploratory Western blot assay, however no statistically significant changes in these measures were observed in the preliminary analysis of data from this trial. The results from this Phase 2a clinical trial did not show any change in lung function, as measured by FEV<sub>1</sub>. Based on the results of this clinical trial, we expect to initiate a combination trial of VX-770 and VX-809 in the second half of 2010 in patients with the F508del mutation on both alleles.

Prior to the above mentioned Phase 2a clinical trial, we completed two Phase 1 clinical trials of VX-809 in healthy volunteers and a Phase 1 clinical trial of VX-809 in CF patients who carry the F508del mutation on at least one of the two alleles. The first clinical trial in healthy volunteers was a single and multiple-dose trial. The second was a single-dose clinical trial examining the pharmacokinetics and safety of a solid dosage form of VX-809. The Phase 1 clinical trial in patients with CF was an escalating dose pharmacokinetics and safety clinical trial.

#### Immune-mediated Inflammatory Diseases

# VX-509 (investigational oral JAK3 inhibitor for the treatment of immune-mediated inflammatory diseases)

VX-509 is designed to inhibit Janus kinase 3, or JAK3, which is involved in signaling pathways that control the survival and proliferation of a type of white blood cells referred to as lymphocytes. Because of JAK3's role in lymphocyte biology, we believe it is a promising target for the design of immunosuppressant drugs for treatment of a variety of immune-based diseases. Based on *in vitro* data, VX-509 appears to be a potent and selective inhibitor of JAK3. We have completed Phase 1 clinical trials of VX-509, including a Phase 1 single dose and a multiple dose-ranging 14-day clinical trial of VX-509 in healthy volunteers.

In January 2010, we initiated a Phase 2a clinical trial of VX-509 in patients with moderate-tosevere rheumatoid arthritis, or RA, expected to enroll approximately 200 patients. This double-blind, randomized, placebo-controlled trial will evaluate the safety, tolerability and clinical activity of four doses of VX-509. Patients will receive 12 weeks of treatment with VX-509 dosed twice daily compared to placebo. The primary endpoints of the clinical trial are to evaluate safety and to measure clinical signs and symptoms of RA in patients after 12 weeks of treatment. Efficacy assessments will include the American College of Rheumatology criteria—ACR20, ACR50 and ACR70—for defining clinical improvement in patients with RA. ACR20, ACR50 and ACR70 are standardized measures of the number of patients who achieve at least a 20, 50 or 70 percent improvement, respectively, in ACR-specified measures of RA activity. The trial will also utilize disease activity score, or DAS, and European League Against Rheumatism, or EULAR, response criteria as additional efficacy assessments. We expect to obtain interim clinical data from this clinical trial, including measurements of safety, tolerability and clinical activity, as early as the second half of 2010.

We plan to pursue collaborative opportunities for VX-509 with major pharmaceutical companies, but expect that we would not enter into a collaboration until after the receipt of clinical data from the Phase 2a trial.

#### Epilepsy

### VX-765 (investigational oral Caspase-1 inhibition for the treatment of epilepsy)

VX-765 is designed to inhibit the interleukin-1 converting enzyme, which is an enzyme that controls the generation of cytokines, IL-1 $\beta$  and IL-18, that are believed to mediate a wide range of immune and inflammatory responses in many cell types. Epilepsy is a chronic neurological disorder that

is defined by recurrent seizures that are the result of overactive neurons in the brain. Recent studies suggest that inflammation and overproduction of IL-1 $\beta$  may be associated with the initiation and maintenance of epileptic seizures. While there are a number of currently approved anticonvulsant medications used to treat patients with epilepsy, a substantial portion of patients are considered to be treatment-resistant because they continue to have seizures while taking approved anti-epileptic drugs.

VX-765 has been shown to inhibit acute seizures in preclinical models. In addition, VX-765 has shown activity in preclinical models of chronic epilepsy that do not respond to approved anti-epileptic drugs. VX-765 previously has been dosed in over 100 patients in Phase 1 and Phase 2a clinical trials relating to other indications, including a 28-day Phase 2a clinical trial in patients with psoriasis. We terminated development for psoriasis in 2006 because patients did not show an adequate response to therapy with VX-765. We believe that the data we have from the nonclinical studies together with safety information from previous clinical trials in humans for VX-765 provide a rationale to explore the clinical potential of this drug candidate as a treatment for epilepsy. We expect that VX-765 will be the first clinical drug candidate to target epilepsy through the inflammation pathway.

The Phase 2a trial for VX-765 we initiated in the first quarter of 2010 is expected to enroll approximately 75 patients with treatment-resistant epilepsy. The double-blind, randomized, placebocontrolled clinical trial is expected to evaluate the safety, tolerability and clinical activity of VX-765. Patients will be monitored for seizure frequency during an initial six week baseline period and then for six weeks while they are receiving treatment with VX-765. The primary endpoints of the trial are safety and tolerability. The secondary endpoints will evaluate clinical efficacy relative to baseline measured by reduction in seizure frequency and number of patients with a 50 percent or greater reduction in seizure frequency.

#### COMMERCIAL ORGANIZATION

We plan to market telaprevir in North America, and we hold worldwide commercial rights to the other drug candidates in our pipeline. Over the past several years, we have expanded our commercial organization with a focus on building our understanding of the HCV market, developing our commercial strategy for the potential launch of telaprevir, and planning the infrastructure necessary to support future commercial activities. In addition, our commercial organization has continued to provide market insight to our research and development organization regarding VX-770 and our earlier-stage drug candidates.

We believe that we have developed a deep understanding of the HCV market in the United States. Our understanding incorporates information regarding the current standard of care as well as both patient and health care providers' attitudes toward current and potential, future therapies. Based on this information and the data obtained from our Phase 2 clinical trials of telaprevir, we have begun developing our marketing strategy for telaprevir, which we intend to update and refine as we obtain additional information regarding the potential commercial profile for telaprevir. In particular, we plan to incorporate the information we obtain regarding the efficacy and safety of telaprevir from our registration program into our marketing strategy.

In the period prior to the anticipated launch of telaprevir, we will expand our commercial organization to an even more significant extent. This expansion will include implementation of internal systems and infrastructure in order to support commercial sales, incorporation of appropriate compliance policies and procedures, establishment of patient-focused programs and hiring a sales force to promote telaprevir, if approved, to health care providers. We are assembling a group of executives with broad experience in marketing, sales, distribution, and reimbursement of drugs. We will continue to expand our commercial infrastructure by hiring a sales management team followed by a commercial sales force in the United States.

In addition, our government affairs and public policy group has begun the process of advocating with state and federal legislatures, government agencies, public health officials and other policy-makers.

We are advocating policies that promote life sciences innovation and greater awareness regarding HCV infection.

Under our collaboration agreement with Janssen we will be reliant on Janssen to effectively market telaprevir in the European Union and the rest of its territory. Mitsubishi Tanabe will market telaprevir in Japan and specified other countries in the Far East. If we obtain approval, we may further develop our own capabilities to market and sell one or more of our other drug candidates in markets outside North America. We are assessing various scenarios to support VX-770, both within and beyond the United States. CF markets tend to be highly concentrated and are therefore accessible through a variety of promotional approaches.

#### **RESEARCH PROGRAMS**

We believe that our integrated drug design approach has significantly enhanced our ability to discover and develop small molecule drug candidates directed at biologically complex targets associated with serious diseases. Our drug design platform integrates biology, pharmacology, drug metabolism and pharmacokinetics, toxicology, material sciences, biophysics, medicinal chemistry and process chemistry, automation and information technologies in a coordinated and simultaneous fashion throughout the discovery process. We believe that our approach has been validated through our success in moving drug candidates into clinical trials. We have decided to focus on several core therapeutic areas, in order to expand and develop our expertise in specific therapeutic areas and to permit a framework for portfolio planning and execution. Currently, the four therapeutic areas of highest priority to us are: infectious diseases, including viral and bacterial infections; IMIDs; cancer; and neurological diseases and disorders, including pain. Driven by the complexity of the therapeutic areas selected, we are attempting to identify multiple targets within each indication that, either as a stand-alone therapy or combination therapy, could provide treatment options that are transformational in nature. The objective of this approach is to enable us to eventually provide multiple drugs in each of these therapeutic areas. We selected these therapeutic areas by mapping our research strengths, including expertise in kinases, proteases and membrane proteins, onto therapeutic areas with high unmet need, with an emphasis on indications where we believe we, independently or in collaboration with other pharmaceutical companies, will be able to discover, develop, and commercialize important medicines for serious diseases. Within each therapeutic area, we intend to focus initially on specific indications.

Our past drug discovery efforts have produced a variety of drug candidates that have been commercialized or are currently in preclinical or clinical development. We believe our ongoing research programs continue to create value for us by generating new drug candidates in areas of significant unmet medical need. We have commenced preclinical activities for a number of additional investigational compounds, one or more of which may enter clinical development in 2010.

To augment our internal research programs, we seek to collaborate with leading academic research institutions, government laboratories, foundations and other organizations in order to advance research in our areas of therapeutic interest as well as in areas of basic technological enablement. We have established relationships with organizations and organized consortia of organizations from around the world with expertise in areas of interest to us, and intend to leverage that experience to further our research efforts. For example, we have entered into a collaboration with CHDI Foundation, Inc., a non-profit foundation committed to accelerating the discovery and development of new drugs that delay the onset or slow the progression of Huntington's disease. This collaboration is aimed at developing assays for use in discovering novel compounds for the treatment of Huntington's disease.

#### CORPORATE COLLABORATIONS

We have entered into corporate collaborations with pharmaceutical and other companies and organizations that provide financial and other resources, including capabilities in research, development, manufacturing, and sales and marketing, to support our research and development programs.

#### Janssen Pharmaceutica, N.V.

In June 2006, we entered into a license, development, manufacturing and commercialization agreement with Janssen. Under the collaboration agreement, we collaborate with Janssen to develop and commercialize telaprevir. Under the terms of the collaboration agreement, we retain exclusive commercial rights to telaprevir in North America and lead the development plan for telaprevir in North America and the Janssen territories. Janssen has exclusive rights to commercialize telaprevir outside of North America and the Far East. In connection with the execution of the collaboration agreement, we received an up-front payment of \$165.0 million in July 2006. As of December 31, 2009, we had received \$100.0 million of contingent milestone payments related to the development of telaprevir under the collaboration agreement. In addition, the agreement provides for additional contingent milestone payments to us of up to \$250.0 million related to the regulatory filing with and approval of telaprevir by the European Medicines Evaluation Agency, and the launch of telaprevir in the European Union. In the third quarter of 2009, we entered into two financial transactions related to these \$250.0 million in potential future milestone payments, which are discussed in detail in the consolidated financial statements and management's discussion and analysis contained in this Annual Report on Form 10-K. In the first transaction, we issued a note in the amount of \$155.0 million secured by the first \$155.0 million of these milestone payments, and in the second transaction we sold our rights to the remaining \$95.0 million in future milestone payments. Our collaboration agreement with Janssen was unchanged by these transactions.

Janssen is responsible for 50% of drug development costs under the development program for North America and the Janssen territories. Each of the parties to the collaboration agreement will be responsible for drug supply in their respective territories. The collaboration agreement also includes a tiered royalty payable to us averaging in the mid-20% range, as a percentage of net sales in the Janssen territories, depending upon successful commercialization. In addition, Janssen will be responsible for certain third-party royalties in its territories. Janssen may terminate the collaboration agreement upon six months' notice to us. In such an event, all manufacturing, commercialization and intellectual property rights to telaprevir in the Janssen territories under the collaboration agreement will revert to us.

As part of the collaboration agreement, following regulatory approval and commercialization of telaprevir in both North America and Janssen's territories, we have agreed to establish a global health initiative with Tibotec, with the goals of advancing the prevention, diagnosis, treatment and cure of HCV infection, which will be principally directed toward developing countries.

#### Mitsubishi Tanabe Pharma Corporation

In June 2004, we entered into a collaboration agreement with Mitsubishi Tanabe pursuant to which Mitsubishi Tanabe agreed to provide financial and other support for the development and commercialization of telaprevir. Under the terms of the agreement, Mitsubishi Tanabe has the right to develop and commercialize telaprevir in Japan and specified other Far East countries. The original agreement provided for payments by Mitsubishi Tanabe to us through Phase 2 clinical development, including an up-front license fee, development stage milestone payments and reimbursement of certain drug development costs for telaprevir.

In July 2009, we amended the collaboration agreement with Mitsubishi Tanabe. Under the amended agreement, we received \$105.0 million in the third quarter of 2009, and will be eligible to receive a further contingent milestone payment, which if realized would range between \$15.0 million and \$65.0 million. The amended agreement provides Mitsubishi Tanabe with a fully-paid license to commercialize telaprevir to treat HCV infection in Japan and specified other countries in the Far East, as well as the right to manufacture telaprevir for sale in its territory. Mitsubishi Tanabe is responsible for its own development and manufacturing costs in its territory. Mitsubishi Tanabe may terminate the agreement at any time without cause upon 60 days' prior written notice to us.

#### Cystic Fibrosis Foundation Therapeutics Incorporated

In May 2004, we entered into a collaboration agreement with CFFT, the non-profit drug discovery and development affiliate of the Cystic Fibrosis Foundation, pursuant to which CFFT provided us with funding for our CF research and development programs, which funding was completed in 2008. Two drug candidates currently in clinical development for CF, VX-770 and VX-809, were discovered by us under this research collaboration. We retain the right to develop and commercialize any compounds discovered in the course of the research collaboration, including VX-770 and VX-809, and we will pay a royalty to CFFT on the net sales of any approved drugs discovered in the collaboration.

#### Merck & Co., Inc.

In June 2004, we entered into a collaboration with Merck to discover, develop and commercialize Aurora kinase inhibitors. Under the agreement, Merck was responsible for developing and commercializing the drug candidates that resulted from the collaboration worldwide and would have paid us royalties on any product sales. Merck may terminate the agreement at any time without cause upon 90 days' advance written notice, except that a longer notice period is required in certain circumstances. Merck is conducting a Phase 1 clinical trial of MK-5108 (VX-689) involving patients with advanced and/or refractory tumors, but has indicated to us, based on its analysis of its broader portfolio of drug development programs, that it does not anticipate continuing further development activities with respect to MK-5108 after the completion of dosing of patients currently enrolled in this Phase 1 clinical trial. Merck is not conducting any other clinical trials of drug candidates that resulted from the collaboration.

### GlaxoSmithKline plc

In 1993, we entered into a collaboration with GlaxoSmithKline plc covering the research, development and commercialization of HIV protease inhibitors. The agreement provides that GlaxoSmithKline will pay us a royalty on all net sales of the HIV protease inhibitors covered by the agreement. In May 2008, we sold our right to receive future royalties from GlaxoSmithKline with respect to these HIV protease inhibitors, excluding the amount necessary to pay a third party a subroyalty on these net sales, for a one-time cash payment to us of \$160.0 million.

#### INTELLECTUAL PROPERTY

We actively seek protection for our products and proprietary information by means of United States and foreign patents, trademarks and copyrights, as appropriate. In addition, we rely upon trade secret protection and contractual arrangements to protect certain of our proprietary information and products. We have patents and pending patent applications that relate to potential drug targets, compounds we are developing to modulate those targets, methods of making or using those compounds and proprietary elements of our drug discovery platform.

Much of our technology and many of our processes depend upon the knowledge, experience and skills of key scientific and technical personnel. To protect our rights to our proprietary know-how and

technology, we require all employees, as well as our consultants and advisors when feasible, to enter into confidentiality agreements that require disclosure and assignment to us of ideas, developments, discoveries and inventions made by these employees, consultants and advisors in the course of their service to us.

While we have numerous issued patents and pending patent applications in our patent portfolio, we believe that the patents and patent applications in the United States and the European Union that are the most important to our business are those that claim the composition-of-matter of drug candidates that have progressed at least into Phase 2 clinical trials. The following table sets forth the status of the primary patents and patent applications in the United States and the European Union covering the composition-of-matter of these drug candidates:

Drug Candidate	Status of United States Patent (Anticipated Expiration, Subject to Potential Extensions)	Status of European Union Patent (Anticipated Expiration, Subject to Potential Extensions)
telaprevir (VX-950)         VX-770         VX-222         VX-809         VX-509         VX-765	Granted (2025) Application Pending (2027) Application Pending (2026) Application Pending (2025)	Granted (2021) Application Pending (2025) Application Pending (2027) Application Pending (2026) Application Pending (2025) Application Pending (2021)

We hold issued patents and pending patent applications in the United States, and in foreign countries we deem appropriate, claiming intellectual property developed as part of each of our significant research and development programs. In addition to the composition-of-matter patents and patent applications listed above, our intellectual property holdings include but are not limited to:

- United States and foreign patents and patent applications covering telaprevir, VX-222, VX-759, VX-985 and other HCV protease and polymerase inhibitors and the use of these compounds to treat HCV infection.
- United States and foreign patent applications covering potentiators and correctors of the CFTR
  protein, including VX-770 and VX-809 and many other related compounds, and the use of those
  potentiators and correctors to treat CF.
- United States and foreign patents and patent applications covering inhibitors of a variety of kinase proteins, including VX-509, a JAK3 inhibitor.
- United States and foreign patents and patent applications covering caspase-1 inhibitors, including VX-765.
- United States and foreign patent applications covering the manufacture, pharmaceutical compositions, related solid forms, formulations, dosing regimens and methods of use of these compounds, including telaprevir and VX-770.

We cannot be certain, however, that issued patents will be enforceable or provide adequate protection or that pending patent applications will result in issued patents

From time to time we enter into non-exclusive license agreements for proprietary third-party technology used in connection with our research activities. These license agreements typically provide for the payment by us of a license fee, but may also include terms providing for milestone payments or royalties for the development and/or commercialization of our drug products arising from the related research.

### MANUFACTURING

#### Manufacturing Approach and Philosophy

As we advance our proprietary drug candidates through clinical development toward commercialization, we will continue to build and maintain our supply chain and quality assurance resources. We rely on an international network of third parties to manufacture and distribute our drug candidates for clinical trials, and we expect that we will continue to rely on third parties for the foreseeable future to meet our commercial supply needs for any of our drug candidates that are approved for sale.

Our supply chain for sourcing raw materials and manufacturing drug product ready for distribution is a multi-step international endeavor. Third-party contract manufacturers, including some in Asia, supply us with raw materials, and contract manufacturers in the European Union and the United States convert these raw materials into drug substance, and convert the drug substance into final dosage form. Establishing and managing this global supply chain requires a significant financial commitment and the creation and maintenance of numerous third-party contractual relationships.

We are focusing resources on the development of systems and processes to track, monitor and oversee our third-party manufacturers' activities. We regularly evaluate the performance of our third-party manufacturers with the objective of confirming their continuing capabilities to meet our needs efficiently and economically. Manufacturing facilities, both foreign and domestic, are subject to inspections by or under the authority of the FDA and by or under the authority of other federal, state, local or foreign authorities. A failure by any of our third-party manufacturers to pass an inspection could adversely affect our ability to launch telaprevir or VX-770 in a timely manner, if we obtain marketing approval, or adversely affect our ability to continue to distribute telaprevir or VX-770 after launch.

We have established a quality assurance program intended to ensure that our third-party manufacturers and service providers produce materials and provide services, when applicable, in accordance with the FDA's current Good Manufacturing Practices, or cGMP, and other applicable regulations.

#### Manufacture of Telaprevir Clinical and Commercial Supplies

We require a supply of telaprevir for our clinical trials and have agreed to exercise our contractual rights from our third-party manufacturers to provide a supply of telaprevir to Janssen and Mitsubishi Tanabe for their clinical trials. We will require a supply of telaprevir for sale in North America if we obtain marketing approval and have agreed to exercise our contractual rights from our third-party manufacturers to provide, until April 2012, a supply of telaprevir drug substance to Mitsubishi Tanabe for their use in manufacturing final dosage telaprevir for sale, if approved, in its territory.

We have completed the technical development work for our commercial formulation of telaprevir, established relationships with multiple third-party manufacturers for the manufacture of clinical and commercial supply of telaprevir, and completed contracts for our primary supply of drug substance, drug product and key raw materials. We are manufacturing telaprevir, through our third-party manufacturer network, to meet our, Janssen's and Mitsubishi Tanabe's clinical supply needs. We believe our past and continuing efforts to expand our relationships with third-party manufacturers and oversee their activities will be important to support a timely and effective commercial launch of telaprevir and its consistent supply in subsequent years.

We have completed the transfer of technical information regarding the manufacture of telaprevir to Janssen so that Janssen will be able to manufacture telaprevir, if approved, for sale in Janssen's territories and as a secondary supply source of drug substance for us. While we believe there are multiple third parties capable of providing most of the materials and services we need in order to manufacture and distribute telaprevir, and that supply of materials that cannot be second-sourced can be managed with inventory planning, there is always a risk that we may underestimate demand, and that our manufacturing capacity through third-party manufacturers may not be sufficient. In addition, because of the significant lead times involved in our supply chain for telaprevir, we may have less flexibility to adjust our supply in response to changes in demand than if we had shorter lead times.

#### Manufacture of VX-770 Clinical and Commercial Supplies

We require VX-770 for clinical trials in North America and Europe, and will require a supply of VX-770 for sale in North America and Europe if we obtain marketing approval. We obtain VX-770 to meet our clinical supply needs through a third-party manufacturer network and are focused on completing the technical development work required to produce VX-770 at a commercial scale. We are in the process of expanding our existing relationships with our third-party manufacturers and establishing new relationships with third-party manufacturers, in order to establish a supply chain for VX-770 to support the potential commercial launch of VX-770.

#### **COMPETITION**

The pharmaceutical industry is characterized by extensive research efforts, rapid technological progress and intense competition. There are many public and private companies, including pharmaceutical companies, chemical companies and biotechnology companies, engaged in developing products for the same human therapeutic areas that we are targeting. Many of our competitors have substantially greater financial, technical and human resources than we do and are more experienced in the development of new drugs than we are. In order for us to compete successfully, we may need to demonstrate improved safety, efficacy, ease of manufacturing and market acceptance of our products relative to our competitors' products that have received or will receive regulatory approval for marketing.

We face competition based on the safety and efficacy of our drug candidates, the timing and scope of regulatory approvals, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, price, patent protection and other factors. Our competitors may develop or commercialize more effective, safer or more affordable products than we are able to develop or commercialize or obtain more effective patent protection. As a result, our competitors may commercialize products more rapidly or effectively than we do, which would adversely affect our competitive position, the likelihood that our drug candidates, if approved, would achieve initial market acceptance and our ability to generate meaningful revenues from those drugs. Even if our drug candidates are approved and achieve initial market acceptance, competitive products may render our drugs obsolete or noncompetitive. If any such drug is rendered obsolete, we may not be able to recover the expenses of developing, stockpiling and commercializing that drug. With respect to all of our drugs and drug candidates, we are aware of existing treatments and numerous drug candidates in development by our competitors.

#### **HCV** Infection

#### Current HCV Market

A 48 week course of both peg-IFN, which requires weekly injections, and RBV, which is an oral drug, is the current standard treatment for genotype 1 HCV infection. This treatment regimen is associated with significant side-effects, including fatigue, flu-like symptoms, rash, depression and anemia. A significant portion of patients who begin treatment do not achieve an SVR. Based on discussions with physicians who treat patients infected with HCV, we believe that there are a significant number of patients with HCV who have been diagnosed but not yet achieved an SVR that may consider treatment with new therapies that are more effective.

# Initial Anticipated Competitive Landscape

While we are aware of numerous companies that are developing potentially competitive drug candidates, Merck's (previously Schering-Plough's) protease inhibitor, boceprevir, is the only protease inhibitor that is being developed on a timeline comparable to telaprevir. Merck is conducting Phase 3 clinical trials of boceprevir and has indicated that it expects to submit an NDA for boceprevir in 2010, which would put it on a timeline to potentially launch boceprevir in 2011. Merck's Phase 3 clinical trials include a clinical trial that enrolled approximately 404 treatment-failure patients but excluded null responders to prior treatment and a Phase 3 clinical trial involving approximately 1,100 treatment-naïve patients with genotype 1 HCV infection. In November 2009, Merck initiated another Phase 3 clinical trial for boceprevir that it estimates will enroll approximately 660 patients infected with genotype 1 HCV to compare the effect on efficacy of erythropoietin use versus reducing the dose of RBV for the management of anemia.

If telaprevir and boceprevir are both approved on a comparable timeline, we believe that the drugs would compete in the marketplace based on, among other things, safety and efficacy data from their respective clinical trials, breadth of approved use, dosing regimen, cost, cost of co-therapies and side-effect profiles.

# Long-term Competitive Landscape

We are aware of numerous other compounds in clinical trials that target HCV infection through a number of different mechanisms of action, and we believe that there are many additional potential HCV treatments in research or early development. There are a number of earlier-stage protease inhibitors, HCV polymerase inhibitors and HCV NS5A inhibitors, each of which is a specifically targeted anti-viral compound. We believe that these earlier-stage drug candidates, if approved, would be launched several years after telaprevir. If any of these drug candidates is approved as a treatment for HCV infection, we expect that such drug candidates would compete with telaprevir on the basis of the factors described above.

Future competition in the HCV treatment market may result from the administration of combinations of new oral therapies, and we are aware of a number of companies focusing on developing combinations of specifically-targeted antiviral compounds. We are planning a Phase 2a clinical trial to evaluate a combination of VX-222, our lead polymerase inhibitor, and telaprevir with and without peg-IFN and RBV. We also are aware that Bristol-Myers Squibb Company is conducting Phase 2 clinical trials of an NS5A inhibitor it is developing in combination with a protease inhibitor it is developing, and Intermune, Inc. and Pharmasset, Inc., in collaboration with Roche, are evaluating a combination of a protease inhibitor being developed by Intermune and a polymerase inhibitor being developed by Pharmasset.

#### CF

Several companies are engaged in the process of developing treatments for CF, including a limited number of drug candidates that are designed to improve the function of CFTR proteins, and a number of antibiotics and anti-inflammatory drug candidates. PTC Therapeutics, Inc. is evaluating ataluren, which was formerly known as PTC124, in a Phase 3 clinical trial in patients with CF. Ataluren is a drug candidate designed to improve the production of CFTR proteins in patients with nonsense genetic mutations that halt the production of CFTR proteins before the protein is fully formed. Inspire Pharmaceuticals Inc. is conducting Phase 3 clinical trials of denufosol tetrasodium, an inhaled molecule designed to stimulate chloride and liquid secretions in the airways of patients with CF.

#### **GOVERNMENT REGULATION**

The research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record keeping, promotion, advertising, distribution and marketing of the drug candidates that we are developing are subject to extensive regulation by United States and foreign governmental authorities. In particular, pharmaceutical products are subject to rigorous preclinical, nonclinical and clinical testing and other approval requirements by the FDA in the United States under the Federal Food, Drug and Cosmetic Act, and by comparable agencies in most foreign countries. In addition to prohibiting the sale and distribution of pharmaceutical products prior to regulatory approval, the FDA and comparable agencies in most foreign countries prohibit the pre-approval promotion of investigational drugs. We have summarized the FDA process below, but other countries may have different approval processes with which we or our collaborators will need to comply if we seek to conduct clinical trials or obtain marketing approval in those countries. In addition, even if we ultimately intend to seek initial marketing approval in the United States, we may conduct early clinical trials in other countries, for a variety of reasons, and therefore the submission of our initial investigational new drug, or IND, application in the United States might not occur until after one or more foreign-sited clinical trials have been initiated.

#### **FDA Approval Process**

As an initial step in the FDA regulatory review process, toxicity studies in animals and other nonclinical studies typically are conducted to help identify potential safety problems that might be associated with administration of the drug candidate being tested. For certain diseases, animal models exist that are believed to be predictive of efficacy in humans. For such diseases, a drug candidate typically is tested for efficacy in that animal model. The results of these initial animal safety and disease model studies are submitted to the FDA as a part of the IND submission, prior to commencement of human clinical trials in the United States. For several of our drug candidates, no appropriately predictive animal model exists. As a result, no *in vivo* evidence of efficacy will be available until those drug candidates progress to human clinical trials. A variety of nonclinical studies in a number of animal species, and other nonclinical studies, ordinarily are conducted while human clinical trials are underway, to provide supplemental toxicology and other information. This information as well as the results from the early clinical trials provide a foundation for the design of broader and more lengthy human clinical trials.

Clinical trials typically are conducted in three sequential phases, although the phases may overlap. Phase 1 frequently begins with the initial introduction of the drug candidate into healthy human subjects prior to introduction into patients. The drug candidate may then be tested in a relatively small number of patients for preliminary information, dosage tolerance, absorption, metabolism, excretion, clinical pharmacology and, if possible, for early information on efficacy. Phase 2 typically involves trials in a small sample of the intended patient population to assess the efficacy of the drug for a specific indication, to determine dose tolerance and the optimal dose range and to gather additional information relating to safety and potential adverse effects. Phase 3 trials are undertaken to further evaluate clinical safety and efficacy in an expanded patient population at geographically dispersed trial sites, to obtain information on the overall risk-benefit ratio of the drug candidate and to provide an adequate basis for proposed labeling. Each trial is conducted in accordance with standards set forth in a protocol that details the design and objectives of the trial, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. For clinical trials in the United States, each protocol must be submitted to the FDA to supplement the original IND submission. Further, each clinical trial must be evaluated by an independent Institutional Review Board, or IRB, which evaluates clinical research at or for each institution at which the trial will be conducted. The IRBs will consider, among other things, ethical factors and the safety of human subjects in the proposed trials.

Data from nonclinical testing and all clinical trials, along with descriptions of the manufacturing process, analytical tests, proposed labeling and the proposed risk evaluation and mitigation strategies and other relevant information, are submitted to the FDA as part of requesting approval to market the drug in the NDA. The process of completing nonclinical and clinical testing, submitting the NDA and obtaining FDA approval for a new drug is likely to take a number of years and require the expenditure of substantial resources. Preparing an NDA involves extensive data collection, verification, analysis and expense, and there can be no assurance that approval of the drug candidate that is the subject of a particular NDA will be granted on a timely basis, if at all. The FDA reviews all NDAs to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The approval process is affected by a number of factors, including the severity of the targeted disease, the availability of alternative treatments and the risks and benefits demonstrated in clinical trials. The FDA may deny an NDA if applicable regulatory criteria are not satisfied or may require additional testing or information. Among the conditions for marketing approval is the requirement that the prospective manufacturer's quality control and manufacturing procedures conform to the FDA's cGMP regulations, which must be followed at all times. In complying with standards set forth in these regulations, manufacturers must continue to expend time, money and effort in the area of production and quality control to ensure full compliance. Manufacturing facilities, both foreign and domestic, also are subject to inspections by the FDA and by other federal, state, local agencies or foreign authorities. In addition, the company developing a drug candidate typically must submit a plan setting forth its risk evaluation and mitigation strategies.

Under the FDA Modernization Act of 1997, the FDA may grant "Fast Track" designation to facilitate the development of a drug intended for the treatment of a serious or life-threatening condition if the drug demonstrates, among other things, the potential to address an unmet medical need. The benefits of Fast Track designation include scheduled meetings with the FDA to receive input on development plans, the option of submitting an NDA in sections rather than submitting all sections simultaneously, and the option of requesting evaluation of trials using surrogate endpoints. Fast Track designation does not necessarily lead to a priority review or accelerated approval of a drug candidate by the FDA. Telaprevir and VX-770 have received Fast Track designation by the FDA.

#### **Timing to Approval**

We estimate that it generally takes 10 to 15 years, or possibly longer, to discover, develop and bring to market a new pharmaceutical product in the United States as outlined below:

Phase:	Objective:	Estimated Duration:
Discovery	Lead identification and target validation	2 to 4 years
Preclinical	Initial toxicology for preliminary identification of risks for humans; gather early pharmacokinetic data	1 to 2 years
Phase 1	Initial evaluation of safety in humans; study how the drug candidate works and is metabolized	1 to 2 years
Phase 2	Gather data on the effectiveness of the drug candidate and its optimal dosage; continue safety evaluation	2 to 4 years
Phase 3	Confirm efficacy, dosage regimen and safety profile of the drug candidate; submit NDA	2 to 4 years
FDA approval	Approval by the FDA to sell and market the drug for the approved indication	6 months to 2 years

A drug candidate may fail to progress at any point during this process. Animal and other nonclinical studies typically are conducted during each phase of human clinical trials.

#### **Patent Term Restoration**

Pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, some of our patents, under certain conditions, may be eligible for limited patent term extension for a period of up to five years as compensation for patent term lost during drug development and the FDA regulatory review process. However, this extension period cannot be extended beyond 14 years from the drug's approval date. The patent term restoration period is generally one-half the period of time elapsed between the effective date of an IND application and the submission date of an NDA, plus the period of time between the submission date of the NDA and FDA approval. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves applications for any patent term extension or restoration. We intend to seek the benefits of this statute, but there can be no assurance that we will be able to obtain any such benefits.

# **Orphan Drug Designation**

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a "rare disease or condition" that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting an NDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a drug that has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Nevertheless, competitors may receive approval of different drugs or biologics for the indications for which the orphan product has exclusivity. VX-770 has been granted orphan drug designation.

#### **Post-approval Studies**

Even after FDA approval has been obtained, further studies, including post-approval trials, may be required to provide additional data on safety and will be required to gain approval for the sale of a drug as a treatment for clinical indications other than those for which the drug initially was approved. Also, the FDA will require post-approval reporting to monitor the side-effects of the drug. Results of post-approval programs may limit or expand the indications for which the drug may be marketed. Further, if there are any requests for modifications to the initial FDA approval for the drug, including changes in indication, manufacturing process, labeling or manufacturing facilities, submission of a supplemental NDA to the FDA may be required.

#### Reimbursement

Sales of drugs depend in significant part on the availability of third-party reimbursement. Thirdparty payors include government health administrative authorities, managed care providers, private health insurers and other organizations. We anticipate third-party payors will provide reimbursement for our drugs if we are successful in obtaining marketing approval. However, third-party payors are increasingly challenging pricing, and in some cases, examining the cost-effectiveness of drugs. In the future, we may need to conduct expensive pharmacoeconomic studies for some of our drug candidates in order to demonstrate their cost-effectiveness, if we successfully obtain marketing approval. The process of seeking reimbursement from third-party payors in the future may be time-consuming and expensive.

The Medicare Prescription Drug Improvement and Modernization Act of 2003, or the MMA, extended a prescription drug benefit to Medicare beneficiaries and imposed requirements for the distribution and pricing of prescription drugs under Medicare Part D. Unlike other Medicare benefits,

the drug benefit available under Part D is not standardized and there is no guarantee that any drug for which we obtain approval will be covered under Part D.

We expect that there may continue to be a number of federal and state proposals to implement governmental pricing controls and limit the growth of health care costs, including the cost of prescription drugs. At the present time, Medicare is prohibited from negotiating directly with pharmaceutical companies for drugs. However, Congress is considering passing legislation that would lift the ban on federal negotiations.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be marketed lawfully. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market.

#### **Foreign Regulation**

In addition to regulations in the United States, we and our collaborators are and will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of drugs. Whether or not we obtain FDA approval for a drug, approval of a drug candidate by the comparable regulatory authorities of foreign countries must be obtained before we or our collaborators can commence clinical trials or marketing of the drug in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Under European Union regulatory systems, marketing authorization applications may be submitted either under a centralized or decentralized procedure. The centralized procedure, which is compulsory for medicines produced by certain biotechnological processes and optional for those that are highly innovative, provides for the grant of a single marketing authorization that is valid for all European Union member states. For drugs without approval in any European Union member state, the decentralized procedure provides for assessment of a marketing application by one member state, known as the reference member state, and review and possible approval of that assessment by one or more other, or concerned, member states. Under this procedure, an applicant submits an application, or dossier, and related materials-draft summary of product characteristics, draft labeling and package leaflet-to the reference member state and concerned member states. The reference member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report, each concerned member state must decide whether to approve the assessment report and related materials. If a member state cannot approve the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points may eventually be referred to the European Commission, whose decision is binding on all member states of the European Union.

# **Other Regulations**

Pharmaceutical companies also are subject to various federal and state laws pertaining to health care "fraud and abuse," including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for any entity or person to solicit, offer, receive or pay any remuneration in exchange for or to induce the referral of business, including the purchase or prescription of a particular drug. False claims laws prohibit anyone from knowingly and willingly presenting to third-party payors including Medicare and Medicaid, or causing to be presented, for payment claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed or claims for medically unnecessary items or services.

In addition to the statutes and regulations described above, we also are subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other federal, state, local and foreign statutes and regulations, now or hereafter in effect.

#### EMPLOYEES

As of December 31, 2009, we had 1,432 employees (1,422 full-time, 10 part-time). The number of our full-time employees increased by 6% during 2009, from 1,339 on December 31, 2008. We are likely to further increase our headcount in 2010 as we invest in expanding our commercialization capabilities. Of our employees, 1,119 were based in Massachusetts, 177 were based in California, 103 were based in Europe and 33 were based in Canada. Our scientific staff members have diversified experience and expertise in molecular and cell biology, biochemistry, synthetic organic chemistry, protein X-ray crystallography, protein nuclear magnetic resonance spectroscopy, microbiology, computational chemistry, biophysical chemistry, medicinal chemistry, clinical pharmacology and clinical medicine. Our clinical development personnel have extensive expertise in designing and executing clinical trials, and we are building our commercialization organization. Our employees are not covered by a collective bargaining agreement, and we consider our relations with our employees to be good.

#### **OTHER MATTERS**

# Information Available on the Internet

Our internet address is *www.vrtx.com*. Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports, are available to you free of charge through the "Finances/Investor Info-SEC Filings" section of our website as soon as reasonably practicable after those materials have been electronically filed with, or furnished to, the Securities and Exchange Commission.

#### **Corporate Information**

Vertex was incorporated in Massachusetts in 1989, and our principal executive offices are located at 130 Waverly Street, Cambridge, Massachusetts 02139. We have research sites located in San Diego, California; Coralville, Iowa; Montreal, Canada and Milton Park, U.K. We also have an office in Washington, D.C.

# EXECUTIVE OFFICERS AND DIRECTORS

The names, ages and positions held by our executive officers and directors are as follows:

Name	Age	Position
Matthew W. Emmens	58	Chief Executive Officer, Chairman of the Board and President
Peter Mueller, Ph.D.	53	Executive Vice President, Global Research and Development, and Chief Scientific Officer
Ian F. Smith, C.P.A., A.C.A.	44	Executive Vice President and Chief Financial Officer
Nancy J. Wysenski	52	Executive Vice President and Chief Commercial Officer
Kenneth S. Boger, M.B.A., J.D	63	Senior Vice President and General Counsel
Lisa Kelly-Croswell	43	Senior Vice President, Human Resources
Amit K. Sachdev, J.D.	42	Senior Vice President, Corporate Affairs and Public Policy
Paul M. Silva	44	Vice President and Corporate Controller
Charles A. Sanders, M.D.	78	Lead Independent Director
Joshua S. Boger, Ph.D.	58	Director
Roger W. Brimblecombe, Ph.D., D.Sc.	80	Director
Stuart J.M. Collinson, Ph.D	50	Director
Eugene H. Cordes, Ph.D	73	Director
Jeffrey M. Leiden, M.D., Ph.D.	54	Director
Bruce I. Sachs	50	Director
Elaine S. Ullian	62	Director
Dennis L. Winger	62	Director

Mr. Emmens has been our Chairman, Chief Executive Officer and President since May 2009. He has been a member of our Board of Directors since 2004 and became our President in February 2009. Mr. Emmens is the Chairman of the Board of Directors of Shire plc, a specialty biopharmaceutical company, and has been a member of Shire's board since March 2003. From March 2003 to June 2008, Mr. Emmens was also the Chief Executive Officer of Shire plc, which had more than 2,500 employees and revenues of \$1.8 billion in 2006. Before joining Shire in 2003, Mr. Emmens served as President of Merck KGaA's global prescription pharmaceuticals business in Darmstadt, Germany. In 1999, he joined Merck KGaA and established EMD Pharmaceuticals, Inc., its United States prescription pharmaceuticals from 1999 to 2001. Prior to this, Mr. Emmens held various positions, including Chief Executive Officer, at Astra Merck, Inc. as well as several positions at Merck & Co., Inc. Mr. Emmens was a member of the Board of Directors of Incyte Corporation from 2006 through February 2009. Mr. Emmens received a B.S. degree in business management from Farleigh Dickinson University.

Dr. Mueller is our Executive Vice President, Global Research and Development, a position he has held since May 2009, and has been our Chief Scientific Officer since July 2003. Dr. Mueller was our Executive Vice President, Drug Innovation and Realization, from February 2006 to May 2009, and our Senior Vice President, Drug Discovery and Innovation, from July 2003 to February 2006. Prior to joining us, Dr. Mueller was the Senior Vice President, Research and Development, of Boehringer Ingelheim Pharmaceuticals, Inc., with responsibility for the development of all drug candidates in the company's worldwide portfolio in North America. He led research programs in the areas of immunology, inflammatory cardiovascular disease and gene therapy on a global basis. During his time with Boehringer Ingelheim, Dr. Mueller oversaw the discovery of numerous development candidates and held several positions in basic research, medicinal chemistry and management. Dr. Mueller received both an undergraduate degree and a Ph.D. in chemistry at the Albert Einstein University of Ulm, Germany, where he also holds a Professorship in Theoretic Organic Chemistry. He completed fellowships in quantum pharmacology at Oxford University and in biophysics at Rochester University.

Mr. Smith is our Executive Vice President and Chief Financial Officer, a position he has held since February 2006. From November 2003 to February 2006, he was our Senior Vice President and Chief Financial Officer, and from October 2001 to November 2003, he served as our Vice President and Chief Financial Officer. Prior to joining us, Mr. Smith served as a partner in the Life Science and Technology Practice Group of Ernst & Young LLP, an accounting firm, from 1999 to 2001. Mr. Smith initially joined Ernst & Young's U.K. firm in 1987, and then joined its Boston office in 1995. Mr. Smith currently is a member of the Boards of Directors of Acorda Therapeutics, Inc., Infinity Pharmaceuticals, Inc. and TolerRx Inc. Mr. Smith holds a B.A. in accounting and finance from Manchester Metropolitan University, U.K., is a member of the American Institute of Certified Public Accountants and is a Chartered Accountant of England and Wales.

Ms. Wysenski is our Executive Vice President and Chief Commercial Officer, a position she has held since December 2009. Prior to joining us, Ms. Wysenski held the position of Chief Operating Officer of Endo Pharmaceuticals, a 1,200-person specialty pharmaceutical company, where she led sales, marketing, commercial operations, supply chain management, human resources and various business development initiatives. Prior to her role at Endo, Ms. Wysenski participated in the establishment of EMD Pharmaceuticals, Inc., where she held various leadership positions, including the role of President and Chief Executive Officer from 2001 to 2006 and Vice President of Commercial from 1999 to 2001. From 1984 to 1998, Ms. Wysenski held several sales-focused roles at major pharmaceutical companies, including Vice President of Field Sales for Astra Merck, Inc. Ms. Wysenski serves on the North Carolina Central University Board of Trustees and is a founder of the Research Triangle Park chapter of the Healthcare Business Women's Association. Ms. Wysenski holds a B.S. from Kent State University and an Executive Masters in Business Administration from Baldwin Wallace College.

Mr. Kenneth Boger is our Senior Vice President and General Counsel, a position he has held since joining us in 2001. He came to us from the law firm of Kirkpatrick & Lockhart LLP, now known as K&L Gates, where he was a partner specializing in business and corporate law and was a member of the firm's Management Committee. Prior to the merger of Kirkpatrick & Lockhart with the Boston law firm of Warner & Stackpole LLP in 1999, Mr. Boger was a partner at Warner & Stackpole, where he served on its Executive Committee from 1988 to 1997. Mr. Boger holds an A.B. in history from Duke University, an M.B.A. from the Graduate School of Business at the University of Chicago, and a J.D. from Boston College Law School. Mr. Boger is the brother of Dr. Joshua Boger, one of our directors.

Ms. Kelly-Croswell is our Senior Vice President, Human Resources, a position she has held since July 2007. Ms. Kelly-Croswell served as our Vice President, Human Resources from July 2006 through June 2007. From November 2005 through June 2006, Ms. Kelly-Croswell served as Vice President of Human Resources of NitroMed, Inc., a pharmaceutical company. From February 2004 to November 2005, Ms. Kelly-Croswell served as Senior Vice President, Human Resources, for the Health Care Division and Service Operations, of CIGNA, an employee benefits company. From September 2001 to February 2004, Ms. Kelly-Croswell served as Vice President of Human Resources for Global Research and Development for the Monsanto Company, an agricultural products and solutions company that she joined in 1998. Ms. Kelly-Croswell holds a B.S. in Finance and an M.A. in Labor and Industrial Relations from the University of Illinois at Urbana-Champaign. Mr. Sachdev is our Senior Vice President, Corporate Affairs and Public Policy, a position he has held since he joined us in July 2007. Mr. Sachdev served as Executive Vice President, Health of the Biotechnology Industry Organization (BIO) from April 2005 through June 2007. At BIO, he was the senior executive responsible for managing BIO's Health Section and its Governing Board, and for directing all health care policy and execution. Mr. Sachdev was the Deputy Commissioner for Policy at the FDA from April 2004 through April 2005, and held several other senior positions within the FDA from September 2002 through April 2004. From 1998 to 2002, Mr. Sachdev served as Majority Counsel to the Committee on Energy and Commerce in the U.S. House of Representatives, where he was responsible for bioterrorism, food safety and environmental issues. From 1993 to 1997, Mr. Sachdev practiced law, first at the Chemical Manufacturers Association, and then with the law firm of Ropes & Gray. Mr. Sachdev holds a B.S from Carnegie Mellon University, and a J.D. from Emory University School of Law.

Mr. Silva is our Vice President and Corporate Controller, a position he has held since September 2008. Mr. Silva joined us in August 2007 as Senior Director, Accounting Operations. Prior to joining us, he was the Vice President, Internal Reporting at Iron Mountain Incorporated from July 2006 until August 2007 and a consultant to Iron Mountain's financing department from April 2005 until July 2006. He was the Finance Director of the Bioscience Technologies Division of Thermo Electron Corporation from 2002 to April 2005. Mr. Silva holds a B.S. in accounting from Assumption College.

Dr. Sanders has been a member of our Board of Directors since 1996 and has been our lead outside director since May 2009. Dr. Sanders served as our Chairman from May 2006 through May 2009 and was our lead outside director from 2003 through May 2006. He retired in 1994 as Chief Executive Officer and in 1995 as Chairman of Glaxo Inc. From 1990 to 1995, he served as a member of the board of Glaxo plc. From 1981 to 1989, Dr. Sanders held a number of positions at Squibb Corporation, including that of Vice Chairman. He is currently a director of Biodel Inc., Biocryst Pharmaceuticals Inc., Cephalon, Inc., and Icagen, Inc. Dr. Sanders was a member of the Board of Directors of Genentech, Inc. from 1999 through its acquisition by Roche in March 2009, Fisher Scientific International from 2004 through its merger in November 2006, BioPure Corporation from 1997 through 2007 and Trimeris, Inc. from 1996 through 2006. Dr. Sanders also has served in the past on the boards of Merrill Lynch, Reynolds Metals Co. and Morton International Inc. Dr. Sanders had his undergraduate education at the University of Texas, and earned an M.D. from the University of Texas Southwestern Medical School.

Dr. Joshua Boger is the founder of Vertex and has been a director since our inception in 1989. He was our Chief Executive Officer from 1992 through May 2009. He was our Chairman of the Board from 1997 until May 2006 and our President from our inception until December 2000, and from 2005 through February 2009. He was our Chief Scientific Officer from 1989 until May 1992. Prior to founding Vertex in 1989, Dr. Boger held the position of Senior Director of Basic Chemistry at Merck Sharp & Dohme Research Laboratories in Rahway, New Jersey, where he headed both the Department of Medicinal Chemistry of Immunology & Inflammation and the Department of Biophysical Chemistry. Dr. Boger holds a B.A. in chemistry and philosophy from Wesleyan University and M.S. and Ph.D. degrees in chemistry from Harvard University. Dr. Boger is the brother of Mr. Kenneth Boger, our Senior Vice President and General Counsel.

Dr. Brimblecombe has been a member of our Board of Directors since 1993 and a member of the Board of Vertex Pharmaceuticals (Europe) Ltd. since 2005. He served as Chairman of Vanguard Medica plc from 1991 to 2000, of Core Group plc from 1997 to 1999, of Oxford Asymmetry International plc from 1997 to 2000 and pSivida Ltd. from 2002 to 2007. From 1979 to 1990, he held various Vice Presidential posts in SmithKline & French Laboratories' research and development organization, including Vice President R&D for Europe and Japan. He is currently an advisor to MVM Life Science Partners LLP, a venture capital firm. He holds Ph.D. and D.Sc. degrees in pharmacology from the University of Bristol, England. Dr. Collinson has been a member of our Board of Directors since July 2001. He currently serves as a Partner at Forward Ventures, a venture capital firm. Prior to our acquisition of Aurora Biosciences Corporation in 2001, Dr. Collinson served as the President, Chief Executive Officer and Chairman of the Board of Aurora. Dr. Collinson held senior management positions with Glaxo Wellcome from December 1994 to June 1998, most recently serving as Co-Chairman, Hospital and Critical Care Therapy Management Team and Director of Hospital and Critical Care. Dr. Collinson received his Ph.D. in physical chemistry from the University of Oxford, England and his M.B.A. from Harvard University.

Dr. Cordes has been a member of our Board of Directors since 2005, and a scientific advisor to us since 1996. Dr. Cordes was the Chairman of Vitae Pharmaceuticals, Inc., a position he held from January 2002 to March 2006. Prior to joining Vitae Pharmaceuticals, Dr. Cordes was a professor of pharmacy at the University of Michigan. Dr. Cordes received a B.S. degree in chemistry from the California Institute of Technology and a Ph.D. in biochemistry from Brandeis University.

Dr. Leiden has been a member of our Board of Directors since July 2009. He has more than 20 years of experience in the biomedical and pharmaceutical sectors. Dr. Leiden was President and Chief Operating Officer of Abbott Laboratories, Pharmaceuticals Products Group, and a member of the Board of Directors of Abbott Laboratories from 2001 to 2006. From 1987 to 2000, Dr. Leiden held several academic appointments, including the Rawson Professor of Medicine and Pathology and Chief of Cardiology and Director of the Cardiovascular Research Institute at the University of Chicago, the Elkan R. Blout Professor of Biological Sciences at the Harvard School of Public Health, and Professor of Medicine at Harvard Medical School. He is an elected member of both the American Academy of Arts and Sciences, and the Institute of Medicine of the National Academy of Sciences. Dr. Leiden is currently a Managing Director at Clarus Ventures, a life sciences venture capital firm he joined in 2006. Dr. Leiden is also currently a director and the non-executive Vice Chairman of the board of Shire plc, and a director of several private biotechnology companies. Dr. Leiden was a member of the Board of Directors of Millennium Pharmaceuticals, Inc. from October 2007 until it was acquired in June 2008. Dr. Leiden received both his M.D. and Ph.D. degrees from the University of Chicago.

Mr. Sachs has been a member of our Board of Directors since 1998. He is a General Partner at Charles River Ventures, a venture capital firm he joined in 1999. From 1998 to 1999, he served as Executive Vice President and General Manager of Ascend Communications, Inc. From 1997 until 1998, Mr. Sachs served as President and Chief Executive Officer of Stratus Computer, Inc. From 1995 to 1997, he served as Executive Vice President and General Manager of the Internet Telecom Business Group at Bay Networks, Inc. From 1993 to 1995, he served as President and Chief Executive Officer at Xylogics, Inc. Mr. Sachs was a director of BigBand Networks, Inc. from 2005 through June 2009. Mr. Sachs holds a B.S.E.E. in electrical engineering from Bucknell University, an M.E.E. in electrical engineering from Northeastern University.

Ms. Ullian has been a member of our Board of Directors since 1997. From 1996 through January 2010, she served as President and Chief Executive Officer of Boston Medical Center, a private, not-for-profit, 626-bed, academic medical center with a community-based focus. From 1994 to 1996, she served as President and Chief Executive Officer of Boston University Medical Center Hospital. From 1987 to 1994, Ms. Ullian served as President and Chief Executive Officer of Faulkner Hospital. She also serves as a director of Thermo Fisher Scientific Inc. and Hologic, Inc. In addition, Ms. Ullian was a member of the Board of Directors of Valeant Pharmaceuticals, Inc. during 2005 through 2007. Ms. Ullian holds a B.A. in political science from Tufts University and an M.P.H. from the University of Michigan.

Mr. Winger has been a member of our Board of Directors since July 2009. Mr. Winger has over 30 years of experience as a financial executive, the majority of which has focused on the life sciences industry. He retired in 2008 from Applera Corporation, a life sciences company, where he had been

Senior Vice President and Chief Financial Officer since 1997. He was previously Senior Vice President of Finance and Administration, and Chief Financial Officer at Chiron Corporation. Before joining Chiron, Mr. Winger held various financial executive positions, including Chief Financial Officer of The Cooper Companies, Inc. Mr. Winger is currently a director of the following public companies: Accuray Incorporated; Cephalon Inc.; and Nektar Therapeutics. In addition, Mr. Winger was a member of the Board of Directors of A.P. Pharma, Inc. during 2005 and 2006 and a member of the Board of Directors of Cell Genesys, Inc. until its merger with BioSante Pharmaceuticals in October 2009. He holds an M.B.A. from Columbia University Graduate School of Business and he earned his undergraduate degree from Siena College.

## ITEM 1A. RISK FACTORS

#### **RISK FACTORS**

Investing in our common stock involves a high degree of risk, and you should carefully consider the risks and uncertainties described below in addition to the other information included or incorporated by reference in this Annual Report on Form 10-K. If any of the following risks or uncertainties actually occurs, our business, financial condition or results of operations would likely suffer, possibly materially. In that case, the trading price of our common stock could decline.

### **Risks Related to Our Business**

# We expect to incur future losses, and we may never become profitable.

We have incurred significant operating losses each year since our inception, including net losses of \$642.2 million, \$459.9 million and \$391.3 million during the years ended December 31, 2009, 2008 and 2007, respectively, and expect to incur significant operating losses in 2010. We expect to continue to incur operating losses at least until we are able to obtain approval for and successfully commercialize telaprevir, because we are continuing to invest significant amounts in the late-stage development of telaprevir and VX-770, and in clinical development of our earlier-stage drug candidates and research activities. As a result, we believe that it is likely that our expenses will exceed our revenues at least until we begin receiving substantial product revenues. There can be no assurance that any of our drug candidates will be approved or, if approved, will be commercially successful. Our net losses have had and will continue to have an adverse effect on, among other things, our stockholders' equity, total assets and working capital. We expect that losses will fluctuate from quarter to quarter and year to year, and that such fluctuations may be substantial. We cannot provide assurance that we will ever become profitable.

# We depend heavily on the success of our lead drug candidate, telaprevir, which is still being evaluated in a registration program. If we are unable to commercialize telaprevir, or experience delays in doing so, our business will be materially harmed.

We are investing a substantial portion of our personnel and financial resources in the development of telaprevir, and we believe that a significant portion of the value attributed to our company by investors relates to the commercial potential of telaprevir. We expect that we will be making significant additional investments in telaprevir in order to be prepared for the potential commercial launch of telaprevir in the United States in 2011, including the establishment of a sales force and marketing capabilities and additional investment in commercial inventory. The clinical development and commercial success of telaprevir will depend on many factors, including the following:

- successful completion of clinical trials with favorable outcomes relative to current standards of care and future competitive therapies;
- receipt and timing of marketing approvals for telaprevir from the FDA and comparable foreign regulatory authorities;
- receipt and timing of marketing approvals from the FDA and comparable foreign regulatory authorities for products being developed for the treatment of HCV infection by our competitors, including Merck's boceprevir;
- additional discussions with the FDA and similar foreign authorities regarding the quality of our manufacturing process for telaprevir and our clinical trial results, including the results we expect to obtain in the second and third quarters of 2010 from our Phase 3 clinical trials of telaprevir;

- interactions with regulatory authorities regarding the contents of any NDA submission, including the data from our clinical trials and nonclinical studies, any plan setting forth risk evaluation and mitigation strategies and our manufacturing processes;
- maintaining commercial manufacturing arrangements for telaprevir with third-party manufacturers that are subject to extensive regulation by the FDA, and successfully monitoring those manufacturing operations to ensure they meet our standards and those of regulatory authorities, including the FDA, that extensively monitor pharmaceutical manufacturing facilities;
- our ability to establish telaprevir, if approved, as a significant component of any oral combination therapies that may be approved as a treatment for HCV infection;
- the efficacy and other characteristics, including the side-effect profile, of telaprevir relative to existing and future treatments for HCV infection;
- the effect of new health care legislation currently being considered in the United States;
- our ability to increase awareness of the benefits of early treatment for HCV infection if telaprevir is approved, and to increase the rates of diagnosis of currently undiagnosed patients with HCV infection; and
- the acceptance of telaprevir by patients, the medical community and with third-party payors.

If the data from our ongoing clinical trials or nonclinical studies regarding the safety or efficacy of telaprevir are not favorable, we may be forced to delay or terminate the clinical development of telaprevir, which would materially harm our business. Further, even if we gain marketing approvals from the FDA and comparable foreign regulatory authorities in a timely manner, we cannot be sure that telaprevir will be commercially successful in the pharmaceutical market. If the results of clinical trials of telaprevir, the anticipated or actual timing of marketing approvals for telaprevir, or the market acceptance of telaprevir, if approved, including treatment reimbursement levels agreed to by third-party payors, do not meet the expectations of investors or public market analysts, the market price of our common stock would likely decline.

# All of our drug candidates remain subject to clinical testing and regulatory approval. If we are unable to successfully develop and test our drug candidates, we will not be successful.

The success of our business depends primarily upon our ability, and the ability of our collaborators, if any, to develop and commercialize our drug candidates, including telaprevir and VX-770, successfully. Due to the development efforts of our competitors, in order to be successful in a therapeutic area it is often necessary to develop follow-on compounds and/or new combination therapies. Our drug candidates are in various stages of development and must satisfy rigorous standards of safety and efficacy before they can be approved by the FDA or comparable foreign regulatory authorities for sale. To satisfy these standards, we and/or our collaborators must allocate resources among our various development programs and must engage in expensive and lengthy testing of our drug candidates. These discovery and development efforts for a new pharmaceutical product, including follow-on compounds, are resource-intensive and may take 10 to 15 years or longer for each drug candidate. Despite our efforts, our drug candidates may not:

- offer therapeutic or other improvement over existing competitive drugs;
- be proven safe and effective in clinical trials;
- meet applicable regulatory standards;
- be capable of being produced in commercial quantities at acceptable costs; or
- if approved for commercial sale, be successfully marketed as pharmaceutical products.

In addition to our ongoing registration programs for telaprevir and VX-770, we have ongoing and planned Phase 2a clinical trials for a number of our earlier-stage drug candidates, including a planned clinical trial of telaprevir in combination with VX-222 in patients infected with HCV, a planned clinical trial of VX-809 in combination with VX-770 in patients with the most common CF mutation, a clinical trial of VX-509 in patients with moderate-to-severe RA and a clinical trial of VX-765 in patients with epilepsy. While we are heavily dependent on the success of our registration programs, the strength of our company's pipeline of drug candidates and potential drug candidates will depend in large part upon the outcomes of these ongoing and planned Phase 2a clinical trials. Findings, including toxicology findings, in nonclinical studies conducted concurrently with clinical trials as well as results of our clinical trials could lead to abrupt changes in our development activities, including the possible cessation of development activities associated with a particular drug candidate or program, including telaprevir or VX-770. Furthermore, results from our clinical trials may not meet the level of statistical significance required by the FDA or other regulatory authorities for approval of a drug candidate.

We and many other companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in earlier-stage clinical trials. Accordingly, the results from the completed preclinical studies and clinical trials, positive results in preclinical studies and early clinical trials may not be replicated in later clinical trials, and ongoing clinical trials for our drug candidates may not be predictive of the results we may obtain in later-stage trials or of the likelihood of approval of a drug candidate for commercial sale. In addition, from time to time we report interim data from our clinical trials, including with respect to our HCV program data regarding patients' HCV RNA levels during treatment, at the end-of-treatment or 12 weeks after completion of treatment. Interim data are subject to change, and there can be no assurances that interim data will be confirmed upon the analysis of final data. In addition, interim data with respect to patients' HCV RNA levels may not be predictive of the final SVR rates that will be achieved in the clinical trial.

# If we are unable to obtain United States and/or foreign regulatory approval, we will be unable to commercialize our drug candidates.

Our drug candidates are subject to extensive governmental regulations relating to their development, clinical evaluation, manufacturing and commercialization. Rigorous nonclinical testing and clinical trials and an extensive regulatory approval process are required in the United States and in most other countries prior to the commercial sale of drug candidates. Satisfaction of these and other regulatory requirements is costly, time-consuming, uncertain and subject to unanticipated delays. It is possible that none of the drug candidates we are developing independently, or in collaboration with others, will be approved for marketing.

We have limited experience in conducting and managing the late-stage clinical trials and NDA process necessary to obtain regulatory approvals, including approval by the FDA. The time required to complete clinical trials and to satisfy the FDA and other countries' regulatory review processes is uncertain and typically takes many years. Our analysis of data obtained from nonclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unanticipated delays or increased costs due to government regulation from future legislation or administrative action or changes in FDA policy during the period of drug development, clinical trials and FDA regulatory review.

Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability to successfully commercialize any drug candidate. Furthermore, any regulatory approval to market a drug may be subject to limitations that we do not currently expect on the indicated uses for which we may market the drug. Any such limitations could limit the size of the market for the drug.

We are also subject to numerous foreign regulatory requirements governing the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process includes all of the risks associated with the FDA approval process described above, as well as risks attributable to the satisfaction of foreign requirements. Approval by the FDA does not ensure approval by regulatory authorities outside the United States. Foreign jurisdictions may have different approval procedures than those required by the FDA and may impose additional testing requirements for our drug candidates.

# If clinical trials for our drug candidates are prolonged or delayed, we will be unable to commercialize our drug candidates as currently planned, which would require us to incur additional costs, would delay our receipt of any product revenue and could harm our competitive position.

We cannot predict whether or not we will encounter problems with any of our completed, ongoing or planned clinical trials that will cause us or regulatory authorities to delay or suspend clinical trials, or delay the analysis of data from our completed or ongoing clinical trials. Any of the following could delay the clinical development of our drug candidates:

- ongoing discussions with the FDA or comparable foreign authorities regarding the scope or design of our clinical trials and the number of clinical trials we must conduct;
- delays in enrolling volunteers or patients into clinical trials, including as a result of low numbers of patients that meet the eligibility criteria for the trial;
- a lower than anticipated retention rate of volunteers or patients in clinical trials;
- the need to repeat clinical trials as a result of inconclusive results, unforeseen complications in testing or clinical investigator error;
- inadequate supply or deficient quality of drug candidate materials or other materials necessary for the conduct of our clinical trials;
- unfavorable FDA or foreign regulatory authority inspection and review of a manufacturing facility for a drug candidate or its relevant manufacturing records or a clinical trial site or records of any clinical or preclinical investigation;
- unfavorable results from clinical trials of our drug candidates;
- serious and unexpected drug-related side-effects experienced by participants in our clinical trials;
- favorable results in testing of our competitors' drug candidates, or FDA or foreign regulatory authority approval of our competitors' products; or
- action by the FDA or a foreign regulatory authority to place a clinical hold on a trial.

Our ability to enroll patients in our clinical trials in sufficient numbers and on a timely basis will be subject to a number of factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the availability of effective treatments for the relevant disease, the number of other clinical trials ongoing and competing for patients in the same indication and the eligibility criteria for the clinical trial. In addition, subjects may drop out of our clinical trials or may be lost to follow-up medical evaluation after treatment ends, and this could possibly impair the validity or statistical significance of the trials. Delays in patient enrollment or unforeseen drop-out rates may result in increased costs and longer development times. We are currently investing large amounts of money in research and development, the building of our commercial organization and the building of commercial supplies of telaprevir. Our revenues constitute only a small fraction of our total investment, which is being funded from various sources, including the sale of shares and convertible debt and payments from collaborators. Any significant delay in our planned timetable for launch of telaprevir, or disappointing sales post-launch would require us to either seek additional financing, which might not be available, or attempt to reduce costs through terminating existing programs, or the sale of assets, either of which might be difficult or insufficient.

We, our collaborators, the FDA or other applicable regulatory authorities may suspend clinical trials of a drug candidate at any time if we or they believe the subjects or patients participating in such clinical trials are being exposed to unacceptable health risks or for other reasons. Any such suspension could materially adversely affect the development of a particular drug candidate and our business.

In addition, it is impossible to predict whether legislative changes will be enacted, or whether FDA or other applicable regulatory authority regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be. If we experience any such problems, we may not have the financial resources to continue development of the drug candidate that is affected or the development of any of our other drug candidates. Any delay in the approval of any of our drug candidates, including telaprevir, could also have a material adverse impact on our ability to effectively commercialize the drug candidate after approval if one or more of our competitors are able to bring competing therapies to market before or in closer proximity to the launch date for our drug candidates.

## The results from our and our collaborators' clinical development activities and the clinical development activities of our competitors are released periodically, and have often resulted in significant volatility in the price of our common stock.

Any new information regarding our drug candidates or potentially competitive drugs or drug candidates, and in particular any new information regarding telaprevir and potentially competitive HCV drug candidates, can substantially affect investors' perceptions regarding our future prospects. We, our collaborators and our competitors periodically provide updates regarding drug development programs, typically through press releases, conference calls and presentations at medical conferences. These periodic updates often include interim or final results from clinical trials conducted by us, our collaborators or our competitors and/or information about our or our competitors' expectations regarding future clinical development of our drug candidates or potentially competitive drugs or drug candidates. The timing of the release of information by us regarding our drug development programs is often beyond our control and is influenced by when we receive data from our clinical trials and by the general preference among pharmaceutical companies to disclose clinical data during medical conferences. In addition, because clinical trials of drug candidates for the treatment of HCV infection often occur over more than one year, the information that we, our collaborators and our competitors disclose may be based on interim rather than final data that may involve interpretation difficulties and may in any event not accurately reflect final results.

#### If our competitors bring superior drugs to market or bring their drugs to market before we do, we may be unable to find a market for our drug candidates.

Our drug candidates in development may not be able to compete effectively with drugs that are currently on the market or new drugs that may be developed by others. There are many other companies developing drugs for the same indications that we are pursuing in development, in particular for the treatment of HCV infection. In order to compete successfully in these areas, we must demonstrate improved safety, efficacy and ease of manufacturing and gain market acceptance over competing drugs, such as Merck's boceprevir, that may receive regulatory approval before or after our drug candidates, and over those that currently are marketed. Many of our competitors, including major pharmaceutical companies such as Merck, Bristol-Myers Squibb, GlaxoSmithKline, Pfizer, Roche, Amgen, Novartis and Johnson & Johnson, possess substantially greater financial, technical and human resources than we possess. In addition, many of our competitors have significantly greater experience than we have in conducting nonclinical testing and human clinical trials of drug candidates, scaling up manufacturing operations and obtaining regulatory approvals of drugs and manufacturing facilities. Accordingly, our competitors may succeed in obtaining regulatory approval for drugs more rapidly than

35

we do. No assurances can be given that telaprevir will be approved for marketing prior to boceprevir. If we obtain regulatory approval and launch commercial sales of our drug candidates, we also will compete with respect to manufacturing efficiency and sales and marketing capabilities, areas in which we currently have limited experience.

We are aware of a number of companies that are developing new treatments for HCV infections including protease inhibitor compounds like telaprevir and boceprevir, polymerase inhibitor compounds, NS5A inhibitor compounds and advanced interferons. Even if we are able to obtain marketing approval for telaprevir, it is possible that one or more of these competing therapies could be approved prior to or shortly after we obtain such approval for telaprevir, or may be approved later but with an equal or better safety and efficacy profile, which we believe may negatively impact telaprevir sales.

## If we are unable to develop effective independent sales and marketing capabilities or establish third-party relationships for the commercialization of our drug candidates, we will not be able to successfully commercialize our drug candidates, particularly telaprevir, even if we are able to obtain regulatory approval.

We currently have limited experience as a company in sales and marketing or with respect to pricing and obtaining adequate third-party reimbursement for drugs. We are developing marketing capabilities and will need to develop an independent sales force in order to market telaprevir in North America and have entered into collaborations in order to market telaprevir in the rest of the world if it is approved. We will need to expand these capabilities and/or enter into additional arrangements with third parties to sell and market our other drug candidates, if they are approved for sale by regulatory authorities.

In order to market telaprevir in North America if it is approved, we are building a marketing organization and will need to build a specialized sales force, which requires substantial efforts and significant management and financial resources. In addition, if VX-770 is approved, we would also need to establish a sales force in North America and Europe for VX-770. While we intend to stage our commitments to the extent possible in consideration of the development timelines, in order to support an effective launch of telaprevir, we will need to make significant financial commitments to our marketing organization prior to receiving regulatory approval. We will need to devote significant effort, in particular, to recruiting individuals with experience in the sales and marketing of pharmaceutical products. Competition for personnel with these skills is very high and may be particularly difficult for us since telaprevir is still an investigational drug candidate and we will be competing with companies that are currently marketing successful drugs. As a result, difficulties in successfully developing our own marketing capabilities or independent sales force for telaprevir in North America may adversely affect an effective launch of telaprevir if it is approved for sale.

We have granted commercialization rights to other pharmaceutical companies with respect to certain of our drug candidates, including telaprevir, in specific geographic locations. To the extent that our collaborators have commercial rights to our drugs, any revenues we receive from sales of any approved drugs in those locations will depend primarily on the sales and marketing efforts of others, which we do not control and may not be able to effectively influence.

# We are investing significant resources in our development program for VX-770, based primarily on data from a relatively small clinical trial in which patients received VX-770 over a short duration. If we are unable to show the safety and efficacy of VX-770, or experience delays in doing so, our business could be materially harmed.

We are increasing the resources that we are investing in the development of VX-770 and began a registration program for VX-770 in the first half of 2009 focused on CF patients with the G551D mutation. We initiated this registration program based primarily on data from a Phase 2a clinical trial of VX-770 in 39 patients with CF, in which patients received VX-770 over 14-day and 28-day periods.

This is a relatively small database from which to project the final outcomes of a drug development program. In order to receive approval for VX-770, we will need to show that VX-770 is safe and effective in a larger number of patients than were involved in the Phase 2a clinical trial, over significantly longer dosing periods. In addition, our registration program for VX-770 includes pediatric patient populations in which VX-770 has not previously been studied. Since a substantial portion of the CF population is under age 18, VX-770's potential commercial success will be dependent not only on marketing approval for adult patients, but also on approval for pediatric patients. If we are unable to show the safety and efficacy of VX-770 in the relevant patient populations, or experience delays in doing so, our business could be materially harmed.

### If physicians, patients and third-party payors do not accept our future drugs, we may be unable to generate significant revenues, if any.

Even if we obtain regulatory approval for our drug candidates, our approved drugs may not gain market acceptance among physicians and patients. We believe that effectively marketing telaprevir, if it is approved, and our other drug candidates, if any of them are approved, will require substantial efforts, both prior to launch and after approval. Physicians may elect not to prescribe our drugs, and patients may elect not to request or take them, for a variety of reasons including:

- lower demonstrated clinical safety and efficacy compared to other drugs;
- prevalence and severity of adverse side-effects;
- lack of cost-effectiveness;
- lack of reimbursement availability from third-party payors;
- a decision to wait for the approval of other therapies that have significant perceived advantages over our drug candidates;
- convenience and ease of administration;
- other potential advantages of alternative treatment methods; and
- ineffective marketing and distribution support.

If our approved drugs fail to achieve market acceptance, we will not be able to generate significant revenues.

#### Government and other third-party payors seek to contain costs of health care through legislative and other means and if they fail to provide coverage and adequate payment rates for our future drugs, our revenues and prospects for profitability will be harmed.

In both domestic and foreign markets, our sales of any future drugs will depend in part upon the availability of reimbursement from third-party payors. Third-party payors include government health programs such as Medicare and Medicaid, managed care providers, private health insurers and other organizations. Governments and other third-party payors generally seek to contain or reduce the costs of health care through various means. For example, in certain foreign markets, pricing or profitability of therapeutic and other pharmaceutical products is subject to governmental control. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental control. Additional and broad health care proposals currently are being considered by the United States Congress. While we cannot predict whether any legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and potential profitability.

In addition, these third-party payors are increasingly attempting to contain health care costs by demanding price discounts or rebates and limiting both the types and variety of drugs that they will

cover and the amounts that they will pay for these drugs. As a result, they may not cover or provide adequate payment for our future drugs. We might need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future drugs to such payors' satisfaction. Such studies might require us to commit a significant amount of management time and financial and other resources. Our future drugs might not ultimately be considered cost-effective. Adequate third-party reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for lower-cost products that are already reimbursed, may be incorporated into existing payments for other products or services, and may reflect budgetary constraints and/or imperfections in Medicare or Medicaid data used to calculate these rates. Net prices for drugs may be reduced by mandatory discounts or rebates required by government health care programs. Such legislation, or similar regulatory changes or relaxation of laws that restrict imports of drugs from other countries, could reduce the net price we receive for our marketed drugs.

## If our processes and systems are not compliant with regulatory requirements, we could be subject to delays in submitting NDAs or restrictions on marketing of drugs after they have been approved.

We currently are developing drug candidates for regulatory approval for the first time since our inception, and are in the process of implementing regulated processes and systems required to obtain and maintain regulatory approval for our drug candidates. Certain of these processes and systems for conducting clinical trials and manufacturing material must be compliant with regulatory requirements before we can apply for regulatory approval for our drug candidates. These processes and systems will be subject to continual review and periodic inspection by the FDA and other regulatory bodies. If we are unable to achieve compliance in a timely fashion, or if compliance issues are identified at any point in the development and approval process, we may experience delays in filing for regulatory approval for our drug candidates, or delays in obtaining regulatory approval after filing. In addition, any later discovery of previously unknown problems or safety issues with approved drugs or manufacturing processes, or failure to comply with regulatory requirements, may result in restrictions on such drugs or manufacturing processes, withdrawal of drugs from the market, the imposition of civil or criminal penalties or a refusal by the FDA and/or other regulatory bodies to approve pending applications for marketing approval of new drugs or supplements to approved applications, any of which could have a material adverse effect on our business. In addition, we are a party to agreements that transfer responsibility for complying with specified regulatory requirements, such as filing and maintenance of marketing authorizations and safety reporting or compliance with manufacturing requirements, to our collaborators and third-party manufacturers. If our collaborators or third-party manufacturers do not fulfill these regulatory obligations, any drugs for which we or they obtain approval may be subject to later restrictions on manufacturing or sale, or may even risk withdrawal, which could have a material adverse effect on our business.

## We depend on our collaborators to work with us to develop, manufacture and commercialize many of our drug candidates.

We have granted development and commercialization rights for telaprevir to Janssen (worldwide other than North America and Far East) and to Mitsubishi Tanabe (Far East). We expect to receive significant financial support under our Janssen collaboration agreement, as well as meaningful technical and manufacturing contributions to the telaprevir program. The success of some of our key programs, such as for telaprevir, is dependent upon the continued financial and other support that our collaborators have agreed to provide. Each of our collaborators has significant discretion in determining the efforts and resources that it will apply to the collaboration. The risks that we face in connection with these existing and any future collaborations include the following:

- Our collaboration agreements are subject to termination under various circumstances, including, as in the case of our agreement with Janssen, termination without cause. Any such termination by Janssen could have a material adverse effect on our financial condition and/or delay the development and commercial sale of telaprevir.
- Our collaborators may change the focus of their development and commercialization efforts or may have insufficient resources to effectively develop our drug candidates. Pharmaceutical and biotechnology companies historically have re-evaluated their development and commercialization priorities following mergers and consolidations, which have been common in recent years in these industries. The ability of some of our drug candidates to reach their potential could be limited if our collaborators decrease or fail to increase development or commercialization efforts related to those drug candidates.
- Our collaboration agreements may have the effect of limiting the areas of research and development that we may pursue, either alone or in collaboration with third parties.
- Our collaborators may develop and commercialize, either alone or with others, drugs that are similar to or competitive with the drugs or drug candidates that are the subject of their collaborations with us.

### Our investment in the clinical development and manufacture of a commercial supply of telaprevir may not result in any benefit to us if telaprevir is not approved for commercial sale.

We are investing significant resources in the clinical development of telaprevir. Telaprevir is the first drug candidate for which we expect to perform all activities related to late-stage development, drug supply, registration and commercialization in a major market. We are planning for and investing significant resources now in preparation for submitting an application for marketing approval, continuing to build our commercial supply inventories of drug product, and completing our scale-up of sales and marketing capacity. Our costs to obtain a commercial supply of telaprevir have included approximately \$20 million, \$17 million and \$75 million in 2009, 2008 and 2007, respectively, and we expect these costs to increase as we near the potential launch of telaprevir. Our engagement in these resource-intensive activities puts significant investment at risk if we do not obtain regulatory approval and successfully commercialize telaprevir in North America. There is no assurance that our development of telaprevir will lead successfully to regulatory approval, or that obtaining regulatory approval will lead to commercial success of telaprevir. If telaprevir is not approved for commercial sale or if its development is delayed for any reason, our full investment in telaprevir may be at risk, we may face significant costs to dispose of unusable inventory, and our business and financial condition could be materially adversely affected.

# We depend on third-party manufacturers, including sole source suppliers, to manufacture materials for clinical trials and expect to continue to rely on them to meet our commercial supply needs for any drug candidate that is approved for sale. We may not be able to maintain these relationships and could experience supply disruptions outside of our control.

We currently rely on a worldwide network of third-party manufacturers to manufacture and distribute our drug candidates for clinical trials, and we expect that we will continue to rely on third parties for the foreseeable future to meet our commercial supply needs for any of our drug candidates that are approved for sale. As a result of our reliance on these third-party manufacturers and suppliers, including sole source suppliers of certain components of our drug candidates, we may be subject to significant supply disruptions outside of our control. Our supply chain for sourcing raw materials and manufacturing drug product ready for distribution is a multi-step international endeavor. Third-party contract manufacturers, including some in Asia, supply us with raw materials, and contract manufacturers in the European Union and the United States convert these raw materials into drug substance and convert the drug substance into final dosage form. Establishing and managing this global supply chain requires a significant financial commitment and the creation and maintenance of numerous third-party contractual relationships. Although we attempt to effectively manage the business relationships with companies in our supply chain, we do not have control over their operations. There can be no assurance that we will be able to establish and maintain commercial supply chains on commercially reasonable terms, or at all, in order to support a timely launch of telaprevir or any of our other drug candidates.

We require a supply of telaprevir for our clinical trials, and have agreed to exercise our contractual rights from our third-party manufacturers to provide a supply of telaprevir to Janssen and Mitsubishi Tanabe for their clinical trials. We will require a supply of telaprevir for sale in North America if we are successful in obtaining marketing approval. We have completed the transfer of technical information regarding the manufacture of telaprevir to Janssen so that Janssen will be able to manufacture telaprevir, if approved, for sale in Janssen's territories and as a secondary supply source of drug substance for us. We believe there are multiple third parties capable of providing most of the materials and services we need in order to manufacture and distribute telaprevir. We also believe that supply of materials which cannot be second-sourced can be managed with inventory planning. However, there is a risk that we may underestimate or overestimate demand, and the manufacturing capacity for which we planned and contracted with third-party manufacturers may not be sufficient or may result in more inventory than is necessary. In addition, because of the significant lead times involved in our supply chain for telaprevir, we may have less flexibility to adjust our supply in response to changes in demand than if we had shorter lead times.

We require a supply of VX-770 for clinical trials in North America and Europe, and will require a supply of VX-770 for sale in North America and Europe if we obtain marketing approval. We obtain VX-770 to meet our clinical supply needs through a third-party manufacturer network and are focused on completing the technical development work to produce VX-770 at a commercial scale. We are in the process of expanding our existing relationships with our third-party manufacturers and establishing new relationships with third-party manufacturers, in order to establish the supply chain for VX-770 that would be required to support the potential commercial launch of VX-770.

Even if we successfully establish arrangements with third-party manufacturers, supply disruptions may result from a number of factors, including shortages in product raw materials, labor or technical difficulties, regulatory inspections or restrictions, shipping or customs delays or any other performance failure by any third-party manufacturer on which we rely.

Any supply disruptions could impact the timing of our clinical trials and the commercial launch of any approved drugs. Furthermore, we may be required to modify our production methods to permit us to economically manufacture our drugs for commercial launch and sale. These modifications may require us to re-evaluate our resources and the resources of our third-party manufacturers, which could result in abrupt changes in our production methods and supplies. Upon approval of a drug for sale, if any, we similarly may be at risk of supply chain disruption for our commercial drug supply.

In the course of its services, a contract manufacturer may develop process technology related to the manufacture of our drug candidates that the manufacturer owns, either independently or jointly with us. This would increase our reliance on that manufacturer or require us to obtain a license from that manufacturer in order to have our products manufactured by other suppliers utilizing the same process.

#### We may need to raise additional capital that may not be available.

We expect to incur substantial expenses as we design and develop existing and future compounds, undertake clinical trials, and build our drug supply, regulatory, development and commercial capabilities. We also expect to incur substantial administrative and commercialization expenses. As a result, we may raise additional capital in order to maintain adequate working capital and cash reserves to continue our diversified research, discovery and development efforts and expect we would need additional capital if the development of telaprevir were materially delayed. We anticipate that we would finance any additional cash needs with some combination of:

- public offerings or private placements of our debt or equity securities or other methods of financing;
- cash received from existing and future collaborative agreements; and
- future product sales.

While we believe that our current cash, cash equivalents and marketable securities, will be sufficient to fund our operations for the next twelve months, we may raise additional capital through public offerings or private placements of our debt or equity securities. Any such capital transactions may or may not be similar to the transactions that we have completed in the past. Any debt financing may be on terms that, among other things, include conversion features that could result in dilution to our then-existing security holders and restrict our ability to pay interest and dividends—although we do not intend to pay dividends for the foreseeable future. Any equity financings would result in dilution to our then-existing security holders. If adequate funds are not available on acceptable terms, or at all, we may be required to curtail significantly or discontinue one or more of our research, drug discovery or development programs, including clinical trials, incur significant cash exit costs, or attempt to obtain funds through arrangements with collaborators or others that may require us to relinquish rights to certain of our technologies, drugs or drug candidates. Based on many factors, including general economic conditions, additional financing may not be available on acceptable terms, if at all.

## We may not be successful in developing any of the drug candidates we acquired in our March 2009 acquisition of ViroChem and, as a result, we may not realize any benefits from this acquisition and could be subject to significant impairment charges in future periods.

In March 2009, we acquired ViroChem for \$100.0 million in cash and 10.7 million shares of our common stock. We acquired ViroChem primarily in order to secure rights to two HCV polymerase inhibitors, VX-222 and VX-759, as part of our strategy to pursue drug candidates that could potentially be developed in combination with telaprevir and/or our earlier-stage drug candidates. VX-222 and VX-759 were still in Phase 1 clinical development at the time of the acquisition and have only been evaluated in nonclinical studies and in a limited number of patients infected with HCV. While we believe the data from the clinical trials to date, together with studies in animal models and *in vitro* data, support the development of combination therapies, there are numerous reasons why we may not be able to successfully develop a combination therapy involving either VX-222 or VX-759, including:

- data from trials involving drug candidates evaluated separately may not predict possible outcomes, such as unforeseen drug interactions, from drug candidates dosed in combination, which could negatively impact the efficacy and safety profile of the combination product candidate;
- positive results in small clinical trials and nonclinical studies may not be predictive of results in clinical trials involving large numbers of patients; and
- favorable results of testing or earlier FDA or foreign regulatory approval of competitors' products.

There can be no assurance that we will be able to successfully develop either VX-222 or VX-759 alone or in combination with telaprevir or our other HCV protease inhibitors, and if we are not successful in developing VX-222 or VX-759, we may not realize any benefits from our March 2009 acquisition of ViroChem.

At the time of acquisition, we allocated \$525.9 million to intangible assets related to the in-process research and development associated with the ViroChem drug candidates. In the fourth quarter of 2009, we recorded expense of \$7.2 million in connection with an impairment of the intangible assets related to VCH-286, a drug candidate for the treatment of HIV infection that we acquired from ViroChem. At December 31, 2009, our consolidated balance sheet included \$518.7 million of intangible assets related to in-process research and development, approximately 80% of which related to VX-222 and approximately 20% of which related to VX-759. If the value of these drug candidates, and in particular VX-222, becomes impaired, we may incur significant impairment charges, including potentially the entire amount of the intangible assets reflected on our consolidated balance sheet associated with the drug candidate, in the period in which the impairment becomes known. An impairment could result from, among other things, unfavorable safety or efficacy results from clinical trials or nonclinical studies or competitive factors affecting the potential market for the drug candidate. VX-759, which is considered a backup compound to VX-222, could be impaired by data pertaining to the potential successful development of VX-222, which could result in a significant impairment charge in the period in which that determination is made. If we incur a significant impairment charge in a future period related to the intangible assets acquired in the ViroChem transaction, the value of our common stock could decrease.

## We rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet established deadlines for the completion of such trials.

We do not have the ability to independently conduct clinical trials for our drug candidates, and we rely on third parties such as contract research organizations to help manage our clinical trial process and on medical institutions and clinical investigators to enroll qualified patients and conduct our clinical trials. Our reliance on these third parties for clinical development activities reduces our control over these activities. Accordingly, these third-party contractors may not complete activities on schedule, or may not conduct our clinical trials in accordance with regulatory requirements or our trial design. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be required to replace them. Although we believe that there are a number of other third-party contractors we could engage to continue these activities, it may result in a delay of the affected trial. If clinical trials are not conducted in accordance with our contractual expectations or regulatory requirements, action by regulatory authorities might significantly and adversely affect the conduct or progress of these trials or in specific circumstances might result in a requirement that a trial be redone. Accordingly, our efforts to obtain regulatory approvals for and commercialize our drug candidates could be delayed.

### Issuances of additional shares of our common stock could cause the price of our common stock to decline.

As of December 31, 2009, we had 200.0 million shares of common stock issued and outstanding. As of December 31, 2009, we also had outstanding options to purchase 19.2 million shares of common stock with a weighted-average exercise price of \$31.38 per share. Outstanding vested options are likely to be exercised if the market price of our common stock exceeds the applicable exercise price. In addition, we may issue additional common stock or restricted securities in the future as part of our financing activities or business development activities and any such issuances may have a dilutive effect on existing shareholders. Sales of substantial amounts of our common stock in the open market, or the availability of such shares for sale, could adversely affect the price of our common stock. In addition, the issuance of restricted common stock or common stock upon exercise of any outstanding options would be dilutive, and may cause the market price for a share of our common stock to decline.

## Outstanding indebtedness may make it more difficult to obtain additional financing or reduce our flexibility to act in our best interests.

As of December 31, 2009, we had outstanding \$32.1 million in aggregate principal amount of our 4.75% Convertible Senior Subordinated Notes due 2013, or 2013 Notes. In February 2010, we announced that we will redeem the 2013 Notes on March 19, 2010 and will be obligated to redeem the 2013 Notes at the redemption price if the 2013 Notes are not earlier converted by the holders, as expected, into shares of our common stock. We also are obligated to repay an aggregate of \$155.0 million no later than October 31, 2012 as a result of our issuance of our secured notes due 2012, or the 2012 Notes. We have issued significant amounts of convertible debt in the past and may issue additional convertible debt or incur other types of indebtedness in the future. The level of our indebtedness could affect us by:

- making it more difficult to obtain additional financing for working capital, capital expenditures, debt service requirements or other purposes;
- constraining our ability to react quickly in an unfavorable economic climate or to changes in our business or the pharmaceutical industry; or
- requiring the dedication of substantial cash to service the repayment of any outstanding debt, including periodic interest payments, thereby reducing the amount of cash available for other purposes.

### If we acquire or license technologies, resources or drug candidates, we will incur a variety of costs and may never realize benefits from the transaction.

If appropriate opportunities become available, we might attempt to license or acquire technologies, resources and drugs or drug candidates, including potentially complimentary HCV therapies. The process of negotiating the license or acquisition might result in operating difficulties and expenditures and, whether or not any such transaction is ever consummated, might require significant management attention that would otherwise be available for ongoing development of our business. Moreover, even if we complete a license or other transaction, we might never realize the anticipated benefits of the transaction or we may incur impairment charges related to assets acquired in any such transaction. For example, in the fourth quarter of 2009, we recorded expense of \$7.2 million in connection with an impairment of the intangible assets related to VCH-286, a drug candidate for the treatment of HIV infection that we acquired from ViroChem. Future licenses or acquisitions could result in potentially dilutive issuances of equity securities, the incurrence of debt, the creation of contingent liabilities, impairment expenses related to goodwill, and impairment or amortization expenses related to other intangible assets, which could harm our financial condition.

## If we obtain regulatory approvals, our drug candidates will be subject to ongoing regulatory review. If we fail to comply with continuing United States and applicable foreign regulations, we could lose those approvals, and our business would be seriously harmed.

If we receive regulatory approval of any drug candidates that we are developing, we will be subject to continuing regulatory review, including the review of clinical results that are reported after our drug candidates become commercially available. Drugs are more widely used by patients once approval has been obtained, and therefore side-effects and other problems may be observed after approval that were not seen or anticipated during pre-approval clinical trials. In addition, the manufacturers and the manufacturing facilities we engage to make any of our drug candidates will also be subject to periodic review and inspection by the FDA. The subsequent discovery of previously unknown problems with the drug, manufacturers or manufacturing facilities may result in restrictions on the drug, manufacturers or manufacturing facilities, including withdrawal of the drug from the market, our inability to use the facilities to make our drug or a determination that drug inventories are not safe for commercial sale. If we fail to comply with applicable continuing regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approval, product recalls and seizures, operating restrictions and/or criminal prosecutions.

## Our drug development efforts are data-driven and therefore potentially subject to abrupt changes in expected outcomes.

Small molecule drug discovery and development involve, initially, the identification of chemical compounds that may have promise as treatments for specific diseases. Once identified as drug candidates, compounds are subjected to years of testing in a laboratory setting, in animals and in humans. Our ultimate objective is to determine whether the drug candidates have physical characteristics, both intrinsically and in animal and human systems, and a toxicological profile, that are compatible with clinical and commercial success in the treatment of the disease being targeted. Throughout this process, experiments are conducted and data are gathered that could reinforce a decision to move to the next step in the investigation process for a particular drug candidate, could result in uncertainty over the proper course to pursue or could result in the termination of further drug development efforts with respect to the compound being evaluated. We monitor the results of our discovery research and our nonclinical studies and clinical trials and regularly evaluate and re-evaluate our portfolio investments with the objective of balancing risk and potential return in view of new data and scientific, business and commercial insights. This process can result in relatively abrupt changes in focus and priority as new information comes to light and we gain additional insights into ongoing programs and potential new programs.

#### We may not have the resources to develop and commercialize all the drug candidates for which we have rights and we may not be able to attract collaborators for the development and commercialization of these drug candidates

As part of our ongoing strategy, we expect to seek additional collaborative arrangements. We have a number of research programs and early-stage and mid-stage clinical development programs. Depending on how these programs progress, we may not have the funding and/or the personnel to continue the development and commercialization of all of these programs internally. At any time, we may make the determination that in order to continue development of a drug candidate or program we need to identify a collaborator. Potentially, and depending on the circumstances, we may desire that a collaborator either agree to fund portions of a drug development program led by us, or agree to provide all the funding and directly lead the development and commercialization of a program. No assurance can be given that any efforts we make to seek additional collaborative arrangements will be successfully completed on a timely basis or at all. If we are unable to enter into acceptable collaborative relationships, one or more of our development programs could be delayed or terminated, and the possibility of our receiving a return on our investment in the program could be impaired.

### Risks associated with our international business relationships could materially adversely affect our business.

We have manufacturing, collaborative and clinical trial relationships, and we and our collaborators are seeking approval for our drug candidates, outside the United States. In addition, we expect that if telaprevir is approved for commercial sale, a significant portion of our commercial supply chain, including sourcing of raw materials and manufacturing, will be located in Asia and the European Union. Consequently, we are, and will continue to be, subject to risks related to operating in foreign countries. Risks associated with conducting operations in foreign countries include:

- differing regulatory requirements for drug approvals in foreign countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;

- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses or reduced revenues, and other obligations incident to doing business or operating a subsidiary in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations could materially adversely affect our business.

## If we fail to expand our human resources, and in particular our commercial organization, and manage our growth effectively, our business may suffer.

We expect that if our clinical drug candidates continue to progress in development and our drug discovery efforts continue to generate drug candidates, we will require significant additional investment in personnel, management systems and resources, particularly in the build out of our commercial capabilities. In advance of the potential approval of telaprevir we will need to build the commercial organization that will be responsible for the commercial launch of telaprevir, if it receives marketing approval, in the United States. The number of our full-time employees increased by 6% in 2009 and 18% in 2008, and we expect to experience additional growth in 2010. Because our drug discovery and development activities are highly technical in nature, we require the services of highly qualified and trained scientists who have the skills necessary to conduct these activities. In addition, as we attempt to grow our capabilities with respect to clinical development, regulatory affairs, quality control and sales and marketing, we need to attract and retain employees with experience in these fields. We face intense competition for our personnel from our competitors, our collaborators and other companies throughout our industry. Moreover, the growth of local biotechnology companies and the expansion of major pharmaceutical companies into the Boston area have increased competition for the available pool of skilled employees, especially in technical fields, and the high cost of living in the Boston and San Diego areas makes it difficult to attract employees from other parts of the country to these areas. Our ability to commercialize our drug candidates, achieve our research and development objectives, and satisfy our commitments under our collaboration agreements depends on our ability to respond effectively to these demands and expand our internal organization to accommodate additional anticipated growth. If we are unable to hire qualified personnel or manage our growth effectively, there could be a material adverse effect on our business.

## The loss of the services of key employees or the failure to effectively integrate key employees could negatively impact our business and future growth.

Our future success will depend in large part on our ability to retain the services of our key scientific and management personnel and to integrate new scientific and management personnel into our business. As we expand our capabilities in anticipation of the possible launch of commercial products, a loss of key personnel or a failure to properly integrate new personnel could be disruptive.

We have entered into employment agreements with some individuals and provide compensation-related benefits to all of our key employees that vest over time and therefore induce them to remain with us. However, the employment agreements can be terminated by the employee on relatively short notice. The value to employees of stock-related benefits that vest over time—such as options and restricted stock—will be significantly affected by movements in our stock price that we cannot control, and may at any point in time be insufficient to counteract more lucrative offers from other companies. A failure to retain, as well as hire, train and effectively integrate into our organization a sufficient number of qualified scientists, professionals, sales personnel and senior management would negatively affect our business and our ability to grow our business.

## If our patents do not protect our drugs, or our drugs infringe third-party patents, we could be subject to litigation and substantial liabilities.

We have numerous issued patents and patent applications pending in the United States, as well as foreign counterparts in other countries. Our success will depend, in significant part, on our ability to obtain and maintain United States and foreign patent protection for our drugs, their uses and our processes, to preserve our trade secrets and to operate without infringing the proprietary rights of third parties. In particular, we believe that composition-of-matter claims are generally the most significant patent claims for companies in our segment of the pharmaceutical industry that focus on small molecule drug candidates that are new chemical compounds. While we currently have patents or patent applications with composition-of-matter claims for each of our more advanced clinical drug candidates, only a portion of these patents have been granted at this time. We cannot be certain that any patents will issue from our patent applications or, even if patents issue or have issued, that the issued claims will provide us with any significant protection against competitive products or otherwise be valuable commercially.

Legal standards relating to the validity of patents and the proper scope of their claims in the pharmaceutical field are still evolving, and there is no consistent law or policy regarding the valid breadth of claims in biopharmaceutical patents or the effect of prior art on them. If we are not able to obtain adequate patent protection, our ability to prevent competitors from making, using and selling similar drugs will be limited. Furthermore, our activities may infringe the claims of patents held by third parties. Defense and prosecution of infringement or other intellectual property claims, as well as participation in other inter-party proceedings, can be expensive and time-consuming, regardless of whether or not the outcome is favorable to us. If the outcome of any such litigation or proceeding were adverse, we could be subject to significant liabilities to third parties, could be required to obtain licenses from third parties or could be required to cease sales of affected drugs, any of which outcomes could have a material adverse effect on our business.

## Our business has a substantial risk of product liability claims. If we are unable to obtain appropriate levels of insurance, a product liability claim could adversely affect our business.

Our business exposes us to significant potential product liability risks that are inherent in the development, clinical testing, manufacturing and sales and marketing of human therapeutic products. We currently have clinical trial insurance and will seek to obtain product liability insurance prior to the sales and marketing of any of our drug candidates. However, our insurance may not provide adequate coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to maintain current amounts of insurance coverage or obtain additional or sufficient insurance at a reasonable cost to protect against losses that could have a material adverse effect on us. If a claim is brought against us, we might be required to pay legal and other expenses to defend the claim, as well as uncovered damages awards resulting from a claim brought successfully against us. Furthermore, whether or not we are ultimately

successful in defending any such claims, we might be required to direct significant financial and managerial resources to such defense, and adverse publicity is likely to result.

## If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

Our research and development efforts involve the controlled use of hazardous materials, chemicals and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials. Although we maintain workers' compensation insurance to cover us for costs we may incur due to injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. Due to the small amount of hazardous materials that we generate, we have determined that the cost to secure insurance coverage for environmental liability and toxic tort claims far exceeds the benefits. Accordingly, we do not maintain any insurance to cover pollution conditions or other extraordinary or unanticipated events relating to our use and disposal of hazardous materials. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

#### We have adopted anti-takeover provisions and are subject to Massachusetts corporate laws that may frustrate any attempt to remove or replace our current management or effectuate a business combination involving Vertex.

Our corporate charter and by-law provisions, Massachusetts state laws and our stockholder rights plan may discourage certain types of transactions involving an actual or potential change of control of Vertex that might be beneficial to us or our security holders. Our charter provides for staggered terms for the members of the Board of Directors. Our by-laws grant the directors a right to adjourn annual meetings of stockholders, and certain provisions of our by-laws may be amended only with an 80% stockholder vote. Pursuant to our stockholder rights plan, each share of common stock has an associated preferred share purchase right. The rights will not trade separately from the common stock until, and are exercisable only upon, the acquisition or the potential acquisition through tender offer by a person or group of 15% or more of the outstanding common stock. We may issue shares of any class or series of preferred stock in the future without stockholder approval and upon such terms as our Board of Directors may determine. The rights of the holders of common stock will be subject to, and may be adversely affected by, the rights of the holders of any class or series of preferred stock that may be issued in the future. Massachusetts state law prohibits us from engaging in specified business combinations, unless the combination is approved or consummated in a prescribed manner, and prohibits voting by any stockholder who acquires 20% or more of our voting stock without stockholder approval. As a result, stockholders or other parties may find it more difficult to remove or replace our current management.

#### Our stock price may fluctuate based on factors beyond our control.

Market prices for securities of companies such as ours are highly volatile. From January 1, 2008 to December 31, 2009, our common stock traded between \$13.84 and \$44.04 per share. The market for our stock, like that of other companies in the biotechnology field, has from time to time experienced

significant price and volume fluctuations that are unrelated to our operating performance. The future market price of our securities could be significantly and adversely affected by factors such as:

- announcements of results of clinical trials or nonclinical studies relating to our drug candidates or those of our competitors;
- announcements of financial results and other operating performance measures, or capital structuring or financing activities;
- technological innovations or the introduction of new drugs by our competitors;
- government regulatory action;
- public concern as to the safety of drugs developed by others;
- developments in patent or other intellectual property rights or announcements relating to these matters;
- developments in domestic and international governmental policy or regulation, for example relating to intellectual property rights;
- developments relating specifically to other companies and market conditions for pharmaceutical and biotechnology stocks or stocks in general; and
- general worldwide or national economic, political and capital market conditions.

### Our estimates of our liability under our Kendall Square lease may be inaccurate.

We leased a 290,000 square foot facility in Kendall Square, Cambridge, Massachusetts in January 2003 for a 15-year term. We currently are not occupying the entire facility. We have sublease arrangements in place for the remaining rentable square footage of the facility. In determining our obligations under the lease for the part of the facility that we are not occupying, we have made certain assumptions relating to the time necessary to sublease the space after the expiration of the initial subleases, projected future sublease rental rates and the anticipated durations of future subleases. Our estimates have changed in the past, and may change in the future, resulting in additional adjustments to the estimate of liability, and the effect of any such adjustments could be material.

### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K and, in particular, the description of our Business set forth in Item 1, the Risk Factors set forth in this Item 1A and our Management's Discussion and Analysis of Financial Condition and Results of Operations set forth in Item 7 contain or incorporate a number of forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding:

- our expectations regarding clinical trials, development timelines and regulatory authority filings and submissions for telaprevir, VX-770, VX-809, VX-509, VX-222, VX-765 and other drug candidates under development by us and our collaborators, including our intention to submit an NDA for telaprevir in the United States in the second half of 2010, the potential of submitting an NDA for VX-770 in the second half of 2011 and the potential commercial launch of telaprevir in the United States in 2011;
- our expectations regarding the expected date by which SVR data will be available and/or publicly announced for our ADVANCE, REALIZE and ILLUMINATE trials, and our expectations regarding the number of patients that will be evaluated, the trial design that will be utilized, the anticipated date by which enrollment will be completed and the expected date

interim data and/or final data will be available and/or publicly announced for our ongoing clinical trials in the ENDEAVOR registration program for VX-770, including the STRIVE, ENVISION and DISCOVER trials, and for the planned and ongoing clinical trials of VX-809, VX-222, VX-509, VX-765 and other drug candidates under development by us;

- expectations regarding the amount of, timing of and trends with respect to our revenues, our costs and expenses and other gains and losses, including those related to the intangible assets associated with the ViroChem acquisition and to the liabilities we recorded in connection with the financial transactions that we entered into in September 2009;
- our belief that if we are able to successfully commercialize telaprevir in accordance with current development timelines, we will begin receiving cash flows from the sale of telaprevir in 2011;
- the data that will be generated by ongoing and planned clinical trials, and the ability to use that data for the design and initiation of further clinical trials and to support regulatory filings, including potentially applications for marketing approval for telaprevir and VX-770;
- our plan to begin clinical evaluation of novel combination regimens of telaprevir with VX-222 in the first quarter of 2010, and the possibility that we will begin evaluation of combination regimens of VX-770 and VX-809 in patients with CF in the second half of 2010;
- our expectations regarding the future market demand and medical need for telaprevir and our other drug candidates;
- our beliefs regarding the support provided by clinical trials and preclinical and nonclinical studies of our drug candidates for further investigation, clinical trials or potential use as a treatment of those drug candidates;
- our ability to successfully market telaprevir and VX-770 or any of our other drug candidates if we are able to obtain regulatory approval;
- the focus of our drug development efforts and our financial and management resources and our plan to invest significant resources in telaprevir and our other drug candidates;
- the establishment, development and maintenance of collaborative relationships;
- potential business development activities, including with respect to our JAK3 program;
- our ability to use our research programs to identify and develop new drug candidates to address serious diseases and significant unmet medical needs;
- our expectation that holders of our 2013 Notes will convert the 2013 Notes into shares of our common stock;
- our estimates regarding obligations associated with a lease of a facility in Kendall Square, Cambridge, Massachusetts; and
- our liquidity and our expectations regarding our needs for and ability to raise additional capital.

Any or all of our forward-looking statements in this Annual Report on Form 10-K may turn out to be wrong. They can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. Many factors mentioned in this Annual Report on Form 10-K will be important in determining future results. Consequently, no forward-looking statement can be guaranteed. Actual future results may vary materially from expected results. We also provide a cautionary discussion of risks and uncertainties under "Risk Factors" above in this Item 1A. These are factors and uncertainties that we think could cause our actual results to differ materially from expected results. Other factors and uncertainties besides those listed there could also adversely affect us. Without limiting the foregoing, the words "believes," "anticipates," "plans," "intends," "expects" and similar expressions are intended to identify forward-looking statements. There are a number of factors and uncertainties that could cause actual events or results to differ materially from those indicated by such forward-looking statements, many of which are beyond our control, including the factors and uncertainties set forth under "Risk Factors" above in this Item 1A. In addition, the forward-looking statements contained herein represent our estimate only as of the date of this filing and should not be relied upon as representing our estimate as of any subsequent date. While we may elect to update these forward-looking statements at some point in the future, we specifically disclaim any obligation to do so to reflect actual results, changes in assumptions or changes in other factors affecting such forward-looking statements.

#### ITEM 1B. UNRESOLVED STAFF COMMENTS

We did not receive any written comments from the Securities and Exchange Commission prior to the date 180 days before the end of the fiscal year ended December 31, 2009 regarding our filings under the Securities Exchange Act of 1934, as amended, that have not been resolved.

#### ITEM 2. PROPERTIES

We lease an aggregate of approximately 1,000,000 square feet of laboratory and office space in facilities located in Cambridge, Massachusetts, San Diego, California, Washington, DC, Coralville, Iowa, Montreal, Canada, and the United Kingdom. We believe our facilities are adequate for our current needs.

#### Cambridge, Massachusetts

We lease an aggregate of 815,000 square feet of space in ten facilities situated in close proximity to our corporate headquarters located at 130 Waverly Street in Cambridge, Massachusetts. We lease approximately 100,000 square feet of laboratory and office space in our 130 Waverly Street corporate headquarters and approximately 192,000 square feet of laboratory and office space at 200 Sidney Street, located adjacent to our corporate headquarters. The 130 Waverly Street and 200 Sidney Street leases expire on December 31, 2015, with two options to extend for additional consecutive five-year terms. The lease for 21,000 square feet of office space at 21 Erie Street, also located adjacent to our corporate headquarters, expires in May 2012, with an option to extend for two additional consecutive five-year terms.

The lease for our Kendall Square, Cambridge, Massachusetts facility will expire in 2018. We have the option to extend this lease for two consecutive ten-year terms. We have subleased approximately 145,000 square feet of the Kendall Square facility, and are using the remaining square feet of space leased in the facility for our research operations. The subleases are for terms ending in 2011 and 2012 with extension options to 2015 and 2018. One of the subleases has certain termination provisions beginning in 2010.

We sublease approximately 145,000 square feet at 88 Sidney Street as subtenant to Alkermes, Inc. who is the prime tenant in the building. The sublease expires in June 2012 with an option to extend through 2014.

#### San Diego, California

We lease approximately 81,000 square feet of laboratory and office space in San Diego, California. The lease for this space will expire on September 30, 2013. We have the option to extend this lease for one additional term of five years.

#### United Kingdom

We lease approximately 22,000 square feet of laboratory and office space in Milton Park, Abingdon, England, for our United Kingdom business and research and development activities, under a lease expiring in 2013. We also lease an additional 41,000 square feet of laboratory and office space in Milton Park under a lease with a term that expires in 2024. This lease has certain termination provisions in 2014 and 2019.

#### ITEM 3. LEGAL PROCEEDINGS

We are not a party to any material legal proceedings. We are not a party to any litigation in any court with any governmental authority, and management is not aware of any contemplated proceeding by any governmental authority against us.

#### ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

There were no matters submitted to a vote of security holders during the quarter ended December 31, 2009.

#### PART II

#### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

#### **Market Information**

Our common stock is traded on The Nasdaq Global Select Market under the symbol "VRTX." The following table sets forth for the periods indicated the high and low sale prices per share of our common stock as reported by Nasdaq:

Year Ended December 31, 2008:	High	Low
First quarter	\$24.67	\$13.84
Second quarter	34.97	23.40
Third quarter	35.00	24.62
Fourth quarter	33.19	18.43

#### Year Ended December 31, 2009:

First quarter	\$35.97	\$26.67
Second quarter	36.30	25.94
Third quarter	38.50	31.85
Fourth quarter	44.04	31.83

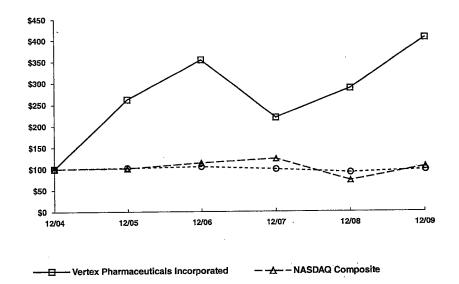
#### Stockholders

As of February 16, 2010, there were 1,655 holders of record of our common stock.

#### **Performance Graph**

#### CUMULATIVE TOTAL RETURN

Based on Initial Investment of \$100 on December 31, 2004 with dividends reinvested (fiscal years ended December 31)



---- O---- NASDAQ Pharmaceutical

#### Dividends

We have never declared or paid any cash dividends on our common stock, and we currently expect that future earnings, if any, will be retained for use in our business.

### **Issuer Repurchases of Equity Securities**

The table set forth below shows all repurchases of securities by us during the three months ended December 31, 2009:

Detember 51, 2005.	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Yet be Purchased under the Plans or Programs
Period	47.958	\$0.01		
Oct. 1, 2009 to Oct. 31, 2009		\$0.01		
Nov. 1, 2009 to Nov. 30, 2009		\$0.01		
Dec. 1. 2007 to Dec. 51, 2007 11				

The repurchases were made under the terms of our 1996 Stock and Option Plan and 2006 Stock and Option Plan. Under these plans, we may award shares of restricted stock to our employees and consultants that typically are subject to a lapsing right of repurchase by us. We may exercise this right of repurchase in the event that a restricted stock recipient's service to us is terminated. If we exercise this right, we are required to repay the purchase price paid by or on behalf of the recipient for the repurchased restricted shares, which typically is the par value per share of \$0.01. Repurchased shares are returned to the applicable Stock and Option Plan under which they were issued. Shares returned to the 2006 Stock and Option Plan are available for future awards under the terms of that plan.

53

#### ITEM 6. SELECTED FINANCIAL DATA

The following unaudited selected consolidated financial data are derived from our audited consolidated financial statements. These data should be read in conjunction with our audited consolidated financial statements and related notes that are included elsewhere in this Annual Report on Form 10-K and with "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in Item 7 below.

Operations included in Rein 7 below.		Year E	nded Decembe	r 31.	
	2009	2008	2007	2006	2005
		(in thousands,	except per sha	re amounts)	<u></u>
Consolidated Statements of Operations Data:					
Revenues: Royalty revenues	\$ 28,320 73,569	\$ 37,483 138,021	\$ 47,973 151,039	\$ 41,208 175,148	\$ 32,829 128,061
Total revenues	101,889	175,504	199,012	216,356	160,890
Costs and expenses:         Royalty expenses         Research and development expenses         Sales, general and administrative expenses         Restructuring expense         Intangible asset impairment charge(1)         Acquisition-related expenses(1)	14,202 550,274 130,192 6,240 7,200 7,793	15,686 516,912 101,290 4,324	13,904 519,227 78,554 7,119 	12,170 379,715 49,858 3,651	10,098 248,540 43,990 8,134 
Total costs and expenses	715,901	638,212	618,804	445,394	310,762
Loss from operations Interest income/(expense), net Other gain/(losses)(2)(3)(4)	(614,012) (8,182) (19,984)	(462,708) 2,857 	(419,792) 28,513 	(229,038) 15,069 7,078	(149,872) (5,332) (48,213)
Net loss(2)	\$(642,178)	\$(459,851)	\$(391,279)	\$(206,891)	\$(203,417)
Net loss per share, basic and diluted(2)	\$ (3.71)	\$ (3.27)	\$ (3.03)	\$ (1.83)	<u>\$ (2.28)</u>
Weighted-average shares, basic and diluted	173,259	140,556	128,986	113,221	89,241
х х		•	December 31		
	2009	2008	2007	2006	2005
			(in thousands	)	
Consolidated Balance Sheets Data:         Cash, cash equivalents and marketable securities         Intangible assets(1)         Goodwill(1)	. 518,7	700 —		\$761,752 	\$407,510 
Total assets	. \$1,955,4	\$980,479	<u>\$601,477</u>	\$921,579	\$548,998
Total current liabilities	. \$ 284,8	\$216,564	\$199,279	\$251,014	\$100,243
Convertible senior subordinated notes (due 2013), net of current portion		287,500	) —	·	
Secured notes (due 2012)(3)	. 121,7				
Liability related to sale of potential future milestone payments(3). Other long term-debt, net of current portion	. 38,2	<u> </u>		19,997	180,097
Other liabilities, net of current portion         Other liabilities, net of current portion         Stockholders' equity	. 160,2	009 237,54			29,482 239,176
Total liabilities and stockholders' equity		488 \$980,47	9 \$601,477	\$921,579	\$548,998

(1) The acquisition-related expenses, the intangible assets, the goodwill, the deferred tax liability and intangible asset impairment charge reflected in the selected financial data relate to our acquisition of ViroChem in 2009. See Note Q to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

(2) We recorded a \$1.0 million benefit in 2006 due to the cumulative effect of estimating forfeitures on the grant date rather than recording them as they occur, which decreased the basic and diluted net loss per common share by \$0.01.

(3) The loss on derivative instruments, secured notes (due 2012), net and liability related to sale of potential future milestone payments reflected in the selected financial data relate to two financial transactions that we entered into in September 2009 relating to future milestone payments under our collaboration agreement with Janssen. See Note R to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

(4) Other gain/losses includes losses on exchanges of convertible notes of \$18.1 million in 2009, \$5.2 million in 2006 and \$48.2 million in 2005 and a realized gain on sale of investment of \$11.2 million in 2006.

#### ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

#### Overview

We are in the business of discovering, developing and commercializing small molecule drugs for the treatment of serious diseases. Telaprevir, our lead drug candidate, is being evaluated in a fullyenrolled registration program focused on treatment-naïve and treatment-failure patients with genotype 1 HCV infection. We currently intend to submit an NDA for telaprevir in the United States in the second half of 2010, assuming the successful completion of the registration program. If we are able to obtain marketing approval for telaprevir in accordance with our current development and regulatory timelines, we expect to initiate sales of telaprevir in the United States in 2011. We are pursuing a number of other clinical development programs, including a registration program for VX-770, the lead drug candidate in our cystic fibrosis program. We plan to continue investing in our research and development programs and to develop selected drug candidates that emerge from those programs, alone or with third-party collaborators.

#### **Business** Focus

Over the last several years, we have invested significant financial and management resources in the late-stage development of telaprevir and in strengthening our pipeline of drug candidates, through research and development activities and the acquisition of ViroChem Pharma Inc. To fund these investments, we have raised an aggregate of approximately \$1.9 billion over the three years ended December 31, 2009, through sales of common stock and convertible debt, other financial transactions and one-time license fees. In order to execute our business plan and achieve profitability, we will need to complete the development of telaprevir on a timely basis and effectively commercialize telaprevir in the United States, where we have retained marketing rights to telaprevir.

Over the next several years we believe that in addition to telaprevir we will need to further investigate other potential therapies for the treatment of HCV and to research, develop and commercialize additional drug candidates in other therapeutic areas with significant unmet need. As a result, we are committed to advancing the other clinical drug candidates in our pipeline and investing in our preclinical research programs. In HCV, we are planning on evaluating telaprevir in combination with VX-222, an investigational polymerase inhibitor that we obtained in 2009 through our acquisition of ViroChem, in a Phase 2a clinical trial that will involve a number of combination regimens. The objective of our ongoing clinical trials of HCV drug candidates and our earlier-stage activities with respect to potential treatments for HCV is to significantly improve the treatment options for genotype 1 HCV infection. The most advanced of our other drug candidates is VX-770, which we are evaluating in a registration program that focuses on patients with CF who have the G551D mutation in the gene responsible for CF. We also are planning on evaluating VX-770 in combination with VX-809 in a Phase 2a clinical trial of VX-509 in patients with moderate-to-severe RA and a Phase 2a clinical trial of VX-765 in patients with treatment-resistant epilepsy.

#### Drug Discovery and Clinical Development

Discovery and development of a new pharmaceutical product is a difficult and lengthy process that requires significant financial resources along with extensive technical and regulatory expertise and can take 10 to 15 years or more. Throughout this entire process, potential drug candidates are subjected to rigorous evaluation, driven in part by stringent regulatory considerations, designed to generate information concerning efficacy, side-effects, proper dosage levels and a variety of other physical and chemical characteristics that are important in determining whether a drug candidate should be approved for marketing as a pharmaceutical product. Most chemical compounds that are investigated

as potential drug candidates never progress into formal development, and most drug candidates that do advance into formal development never become commercial products. A drug candidate's failure to progress or advance may be the result of any one or more of a wide range of adverse experimental outcomes including, for example, the lack of sufficient efficacy against the disease target, the lack of acceptable absorption characteristics or other physical properties, difficulties in developing a cost-effective manufacturing or formulation method, or the discovery of toxicities or side-effects that are unacceptable for the disease indication being targeted or that adversely affect the competitive commercial profile of the drug candidate.

Throughout the development process for a drug candidate we must work collaboratively with regulatory authorities, including the FDA, in order to identify the specific scientific issues that need to be addressed in the clinical trials to support continued development and approval of the drug candidate. If the data from our ongoing clinical trials or nonclinical studies regarding the safety or efficacy of a drug candidate are not favorable or regulatory authorities request additional clinical trials or changes to existing clinical trial protocols, we may be forced to delay or terminate the clinical development program for that candidate, which, particularly in the case of telaprevir, could materially harm our business.

Because our investments are subject to considerable risks, we closely monitor the results of our clinical trials, discovery research and our nonclinical studies and frequently evaluate our portfolio investments in light of new data and scientific, business and commercial insights, with the objective of balancing risk and potential. This process can result in relatively abrupt changes in focus and priority as new information becomes available and we gain additional insights into ongoing programs and potential new programs. Although we believe that our development activities and the clinical trial data we have obtained regarding telaprevir have reduced the risks associated with obtaining regulatory approval, we cannot be sure that our development of telaprevir will lead to such regulatory approval of telaprevir or that such approval, if obtained, will occur in 2011. With respect to our other drug candidates, including VX-770, we have more limited data from clinical trials and nonclinical studies and as a result it is difficult to predict which, if any, of these drug candidates ultimately will result in pharmaceutical products.

#### Commercialization

We plan to market telaprevir in North America, and we hold worldwide commercial rights to the other drug candidates in our pipeline. Over the past several years, we have expanded our commercial organization with a focus on building our understanding of the HCV market, developing our commercial strategy for the potential launch of telaprevir, and planning the infrastructure necessary to support future commercial activities. In the period prior to the anticipated launch of telaprevir, we will expand our commercial organization to an even more significant extent. This expansion will include implementation of internal systems and infrastructure in order to support commercial sales, incorporation of appropriate compliance policies and procedures, establishment of patient-focused programs and hiring a sales force to promote telaprevir, if approved, to health care providers. We are assembling a group of executives with broad experience in marketing, sales, distribution, and cost reimbursement of drugs. We will continue to build our commercial infrastructure by hiring a sales management team followed by a commercial sales force in the United States. If we obtain approval, we may market and sell one or more of our other drug candidates in markets outside North America, which would require additional expansion of our commercial organization.

#### Manufacturing

We will require a supply of telaprevir for sale in North America and a supply of VX-770 for sale worldwide if we are successful in obtaining marketing approval for either or both of these drug candidates. We rely on an international network of third parties to manufacture and distribute our drug

candidates for clinical trials, and we expect that we will continue to rely on third parties for the foreseeable future to meet our commercial supply needs for any of our drug candidates that are approved for sale. Third-party contract manufacturers, including some in Asia, supply us with raw materials, and contract manufacturers in the European Union and the United States convert these raw materials into drug substance, and convert the drug substance into final dosage form. Establishing and managing this global supply chain requires a significant financial commitment and the creation and maintenance of numerous third-party relationships. Although we attempt to effectively manage the business relationships with companies in our supply chain, we do not have complete control over their activities.

#### Corporate Collaborations

Corporate collaborations have been and will continue to be an important component of our business strategy. Historically, we have not had the resources to develop and commercialize all of the drug candidates that we have identified or for which we have rights. Therefore we have relied on collaborations with third parties for the development and commercialization of some or all of our drug candidates. We have been successful in initiating productive collaborations with Janssen and Mitbsubishi Tanabe relating to telaprevir, and our collaboration with Cystic Fibrosis Foundation Therapeutics Incorporated contributed to the discovery of VX-770 and VX-809. Our early collaborations with GlaxoSmithKline plc resulted in two marketed drugs for the treatment of HIV. Collaborations continue to be an important part of our strategy going forward, although the structure and scope of available collaborative opportunities has changed in the past and may change in the future based on prevailing economic and competitive conditions.

#### Financing Strategy

We have incurred losses from our inception and expect to continue to incur losses at least until we obtain approval for and successfully commercialize a product, if we ever do. Therefore, we have been dependent in large part on our ability to raise significant funding to finance our research and development operations, to create a commercial infrastructure, and to meet our overhead costs and long-term contractual commitments and obligations. To date, we have secured funds principally through capital market transactions, strategic collaborative agreements, investment income and the issuance of common stock under our employee benefit plans. As an element of our financial strategy we have from time to time transferred to third parties future financial rights under specific collaborations in exchange for one-time cash payments. For example, in 2009 we entered into two financial transactions that related to potential future milestone payments under our collaboration with Janssen that resulted in aggregate payments to us of \$155.0 million. Also in 2009, we received a one-time cash payment of \$105.0 million from Mitsubishi Tanabe and the right to a potential future milestone payment of up to \$65.0 million, as part of an amendment to an existing agreement with Mitsubishi Tanabe. This amendment provided Mitsubishi Tanabe with a fully-paid license to commercialize telaprevir in Japan and specified other countries in the Far East and the right and obligation to manufacture telaprevir for sale in their territory. In 2008, for a one-time cash payment to us of \$160.0 million, we sold our right to receive royalty payments, net of subroyalty amounts payable to a third party, arising from sales of Lexiva/Telzir and Agenerase under our 1993 agreement with GlaxoSmithKline.

We expect that we will incur substantial expenses in order to complete the development and commercialization of telaprevir while at the same time continuing the development of our other drug candidates and building our other capabilities. As a result, we may raise additional capital in order to maintain adequate working capital and cash reserves to continue both our development and commercialization of telaprevir and our diversified research, discovery and development efforts. We expect we would need to raise additional capital if the development of telaprevir was materially delayed. We may raise additional capital from public offerings or private placements of our securities or other methods of financing. We cannot be sure that financing opportunities will be available on acceptable terms, if at all. If adequate funds are not available on acceptable terms, or at all, we may be required to significantly curtail or discontinue one or more of our research, drug discovery or development programs, including clinical trials, incur significant cash exit costs, or attempt to obtain funds through arrangements with collaborators or others that may require that we relinquish rights to certain of our drug candidates.

#### **Critical Accounting Policies and Estimates**

Our discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these financial statements requires us to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of revenues and expenses during the reported periods. We monitor and analyze changes in facts and circumstances that might have a material effect on our estimates and assumptions in the future. Changes in estimates are reflected in reported results for the period in which they become known. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from our estimates if past experience or other assumptions do not turn out to be substantially accurate.

We believe that our application of the following accounting policies, each of which requires significant judgments and estimates on the part of management, are the most critical to aid in fully understanding and evaluating our reported financial results: business combinations; derivative instruments and embedded derivatives; revenue recognition; research and development expenses; restructuring expense; and stock-based compensation expense. Our accounting polices, including the ones discussed below, are more fully described in the Notes to our consolidated financial statements, including Note B "Accounting Policies," included in this Annual Report on Form 10-K.

#### **Business** Combinations

In March 2009, we acquired ViroChem for \$100.0 million in cash and common stock with a fair market value of \$290.6 million. We assigned the value of the consideration transferred to acquire a business to the tangible assets and identifiable intangible assets acquired and liabilities assumed, on the basis of their fair values at the date of acquisition. The difference between the purchase price and the fair value of assets acquired and liabilities assumed was allocated to goodwill. This goodwill related to the potential synergies from the possible development of combination therapies involving telaprevir and the acquired drug candidates. The allocations recorded on our consolidated balance sheet as of the acquisition date included \$525.9 million of intangible assets related to in-process research and development and a \$162.5 million of intangible assets related to in-process research and development and a \$160.3 million deferred tax liability.

The intangible assets acquired were in-process research and development assets relating to the drug candidates being developed by ViroChem, primarily VX-222 and VX-759, each of which was in Phase 1 clinical development at the date of acquisition. VX-222 and VX-759 had estimated fair values on the acquisition date of \$412.9 million and \$105.8 million, respectively. In addition, we considered ViroChem's other clinical drug candidates and determined that VCH-286, ViroChem's lead HIV drug candidate, had an estimated fair value on the acquisition date of \$7.2 million, based on development costs through the acquisition date, and that the other clinical drug candidates had no fair value because the clinical and nonclinical data for those drug candidates did not support further development as of the acquisition date. We also considered ViroChem's preclinical programs and other technologies and determined that because of uncertainties related to the safety, efficacy and commercial viability of the potential drug candidates, market participants would not ascribe value to those assets.

We assess the fair value of assets, including intangible assets such as in-process research and development, using a variety of methods, including present-value models that are based upon multiple probability-weighted scenarios involving the development and potential commercialization of the acquired drug candidates. The present-value models used to estimate the fair values of VX-222 and VX-759 required us to make significant assumptions regarding the estimates market participants would make in evaluating a drug development asset, including the probability of successfully completing clinical trials and obtaining regulatory approval for marketing of the associated drug candidate, the timing of and the expected costs to complete in-process research and development projects, future cash flows from potential product sales, and appropriate discount rates. The estimated fair value ascribed to VX-222 and VX-759 was based on the estimated fair value that would be ascribed to each of these compounds by a market participant that acquired both compounds in a single transaction. The assumed probability of advancing VX-222 and VX-759 through various phases of development reflects the understanding among market participants that most drug candidates that enter Phase 2 clinical trials are not ultimately approved for commercial sale. While, on the date of acquisition, VX-222 and VX-759 were each at a similar stage of development, we attributed a significantly higher value to VX-222 than to VX-759 because the clinical and nonclinical data from the VX-222 research program was significantly more promising than the clinical and nonclinical data from the VX-759 research program. In addition, the fair value estimate incorporates our determination that a market participant would not be likely to continue development of VX-759 unless future data from clinical trials or nonclinical studies of VX-222 resulted in a delay or discontinuation of the VX-222 development program. Projections of the duration and cost of nonclinical studies and clinical trials vary significantly over the life of a project depending on developments in the program over time, but in order to estimate the fair market value on the acquisition date we made the following assumptions from the perspective of market participants regarding the potential timing and costs to develop VX-222 and/or VX-759. We assumed if a drug candidate were successfully developed in the United States it would take approximately five to nine years from the date of the acquisition in order to obtain marketing approval. In addition, for the valuation, we assumed an estimate of cost from acquisition to launch to develop a drug candidate that was within a range of \$400 million to \$700 million. Future cash flows, if any, would not be generated until a drug candidate completed all required phases of clinical trials and obtained regulatory approval. The risk-adjusted discount rate for each of these projects was approximately 28%.

The in-process research and development assets were recorded at fair value and accounted for as indefinite-lived intangible assets. We maintain each of these assets on our consolidated balance sheet until either the research and development project underlying it is completed or the asset becomes impaired. If we complete a project, we will amortize the carrying value of the related intangible asset over the remaining estimated life of the asset. If we determine that a project has become impaired or we abandon a project, we will write down the carrying value of the related intangible asset to its fair value and will take an impairment charge in the period in which the impairment occurs. In order to complete an acquired research and development project, the related drug candidate must be evaluated in later-stage clinical trials, which are subject to all of the risks and uncertainties associated with the development of pharmaceutical products. If the fair value of any of these drug candidates, and in particular VX-222, becomes impaired as the result of unfavorable safety or efficacy data from any ongoing or future clinical trial or because of any other information regarding the prospects of successfully developing or commercializing the drug candidate, we could incur significant charges in the period in which the impairment occurs. VX-759, which is considered a backup compound to VX-222, could be impaired by data pertaining to the potential successful development of VX-222, which could result in significant charges in the period in which that data is analyzed and the determination is made. These intangible assets are tested for impairment on an annual basis as of October 1, or earlier if impairment indicators are present. Post-acquisition research and development expenses related to the in-process research and development projects will be expensed as incurred. In the fourth quarter of

2009, we evaluated VX-222, VX-759, VCH-286 and goodwill for impairment. No impairment was found with respect to VX-222, VX-759 or goodwill. We recorded an impairment charge of \$7.2 million related to VCH-286, which reduced the intangible assets reflected on our consolidated balance sheet by \$7.2 million and also resulted in an adjustment to our deferred tax liability.

#### Derivative Instruments and Embedded Derivatives-September 2009 Financial Transactions

In connection with the two financial transactions that we entered into in September 2009, we issued the 2012 Notes, which have a face value of \$155.0 million and do not carry an explicit interest rate, for \$122.2 million in cash. The 2012 Notes are secured by \$155.0 million of potential future telaprevir milestone payments that we expect to receive from Janssen. We also sold \$95.0 million in additional potential future telaprevir milestone payments that we expect that we expect will be payable by Janssen for a cash payment of \$32.8 million. The 2012 Notes contain an embedded derivative related to their potential early repayment or redemption. The separate sale of the potential \$95.0 million in future milestone payments is accounted for as a free-standing derivative instrument.

In order to account for the 2012 Notes and the sale of the rights to the potential future milestone payments, we were required to estimate the fair value of the derivative embedded in the 2012 Notes and of the derivative associated with the \$95.0 million in potential future milestone payments. The models we used to estimate these fair values require, among other things, estimates of the assumptions market participants would make regarding the timing and probability of achieving the milestones and the appropriate discount rates. In the fourth quarter of 2009, we recorded interest expense of \$3.1 million related to the 2012 Notes and an additional net expense of \$1.8 million related to the changes in estimated fair value of the derivative related to the \$95.0 million in potential future milestone payments and the derivative embedded in the 2012 Notes.

#### 2012 Notes

The 2012 Notes had a residual value at issuance of \$108.2 million, excluding the fair value of the embedded derivative. That embedded derivative had a fair value at issuance of \$10.7 million. We record a quarterly interest expense with respect to the 2012 Notes that is determined using the effective interest rate method, which increases the amount of the liability for our 2012 Notes each quarter by an amount corresponding to this interest expense through the stated maturity date, unless redeemed or repaid earlier. In addition, we evaluate the embedded derivative for changes in fair value on at least a quarterly basis. As of December 31, 2009, the value of the 2012 Notes was \$111.3 million and the fair value of the embedded derivative was \$10.5 million. We expect that the net expense related to the 2012 Notes that we will recognize based on interest expense and gains and losses on the embedded derivative over the period between December 31, 2009 and October 31, 2012 will equal \$33.2 million, which is the difference between the \$155.0 million face value of the 2012 Notes and the fair value of the 2012 Notes with their embedded derivative on December 31, 2009. However, the timing of these expenses or any gains will depend on a number of factors, including factors related to the probability and timing of achieving the relevant milestone events and to applicable discount rates, and could result in material expenses or gains in any quarterly period.

#### Sale of Future Milestone Payments

The fair value on the sale date of the free-standing derivative instrument created by the sale of \$95.0 million of future milestone rights was \$36.2 million. As of December 31, 2009, the fair value of the free-standing derivative was \$38.2 million. We will evaluate this free-standing derivative for changes in fair value on at least a quarterly basis. Any change in the fair value will be recorded as a loss or gain in the period in which it becomes known. If these milestone events are achieved, we expect that we will recognize net expenses over the period between December 31, 2009 and the date the milestones are achieved equal to \$56.8 million, which is the difference between the \$95.0 million the purchaser will

receive if all the milestone events are achieved and the fair value of the free-standing derivative on December 31, 2009. Because our estimate of the fair value of the free-standing derivative includes the application of a discount rate, we expect to record costs to reflect the time-value of money each quarter. However, the timing of any other expenses or any gains will depend on a number of factors, including, among other things, factors related to the probability and timing of achieving the relevant milestone events and to applicable discount rates, and could result in material losses or gains in any quarterly period.

#### Revenue Recognition

Our revenues are generated primarily through collaborative research, development and/or commercialization agreements. The terms of these agreements typically include payment to us of one or more of the following: nonrefundable, up-front license fees; milestone payments; and royalties on product sales. In addition, we sold our rights to receive future royalties from our HIV assets and have been recognizing revenues in connection with that transaction since the date of the sale in May 2008.

#### **Up-front License Fees**

We recognize revenues from nonrefundable, up-front license fees related to collaboration agreements, including the \$165.0 million we received from Janssen in 2006 and the \$105.0 million we received from Mitsubishi Tanabe in the third quarter of 2009, on a straight-line basis over the contracted or estimated period of performance. The period of performance over which the revenues are recognized is typically the period over which the research and/or development is expected to occur. As a result, we often are required to make estimates regarding drug development and commercialization timelines for compounds being developed pursuant to a collaboration agreement. Because the drug development process is lengthy and our collaboration agreements typically cover activities over several years, this approach often has resulted in the deferral of significant amounts of revenue into future periods. In addition, we periodically evaluate our estimates in light of changes in the development plans for our drug candidates. Because of the many risks and uncertainties associated with the development of drug candidates, our estimates regarding the period of performance have changed in the past and may change in the future. Our estimates regarding the period of performance under the Janssen collaboration agreement were adjusted in 2007, and again in the third quarter of 2009, as a result of changes in the global development plan for telaprevir, which contemplates the conduct of certain development activities in the post-approval period if telaprevir is approved for marketing. These adjustments were made on a prospective basis beginning in the periods in which the changes were identified. These adjustments resulted in a decrease in the amount of revenues we recognized from the Janssen collaboration by \$2.6 million per quarter for the first adjustment and by \$1.1 million per quarter for the second adjustment. Any future adjustment in our estimates of the period of performance under any of our collaborations could result in substantial changes to the period over which the revenues from an up-front license fee related to that collaboration are recognized. For example, if we adjust our estimates as of January 1, 2010 to increase the period of performance under the Janssen agreement by one year, it would result in a decrease in the amount of deferred revenues we recognize from our Janssen collaboration of \$0.8 million per quarter beginning in the first quarter of 2010.

#### **Milestone Payments**

At the inception of each agreement that includes contingent milestone payments, we evaluate whether the contingencies underlying each milestone event are substantive, specifically reviewing factors such as the scientific and other risks that must be overcome to achieve the milestone event, as well as the level of successful effort and investment required. If we do not consider a milestone event to be substantive, the revenues from the related milestone payment cannot be recognized when the milestone event is achieved, but must be recognized on a straight-line basis over the remaining performance period.

Where a substantive milestone event is achieved in a collaboration arrangement and the corresponding payment is reasonably assured, the payment is recognized as earned subject to specific policies applicable where we have obligations remaining after achievement of the milestone. Because achievement of a substantive milestone event under a collaboration agreement typically requires the completion of a number of activities conducted over a significant period of time, the expenses related to achieving the milestone event often are incurred prior to the period in which the milestone payment is recognized. All of the milestones that have been achieved under our Janssen collaboration agreement during the three years ended December 31, 2009 have been considered substantive. In the past, significant quarterly and annual fluctuations in our revenues from milestone payments have contributed to significant fluctuations in our overall collaborative revenues.

#### **Royalty Revenues**

In May 2008, we entered into a purchase agreement with Fosamprenavir Royalty, L.P. pursuant to which we sold, and Fosamprenavir Royalty purchased for a one-time cash payment to us of \$160.0 million, our right to receive royalty payments, net of subroyalty amounts payable to a third party, arising from sales of Lexiva/Telzir and Agenerase under our 1993 agreement with GlaxoSmithKline. We deferred the recognition of \$155.1 million of revenues in connection with this sale. On May 31, 2008, we began recognizing these deferred revenues under the units-of-revenue method. Under this method, the amount of deferred revenues to be recognized as royalty revenues in each period is calculated by multiplying the following: (1) the net royalty payments due from GlaxoSmithKline to Fosamprenavir Royalty for the period by (2) the ratio of the revenues we received from the sale of our rights to HIV royalty payments that we have not yet recognized to the total estimated remaining net royalties that we expect GlaxoSmithKline to pay Fosamprenavir Royalty over the remaining term of the agreement. Estimating the total remaining net royalties that GlaxoSmithKline will pay to Fosamprenavir Royalty requires the use of subjective estimates and assumptions, including estimates regarding the size of the potential market for HIV protease inhibitors, the competitive position of Lexiva/Telzir specifically and HIV protease inhibitors generally with respect to currently approved drugs and drugs that may be approved in the future, and the pricing of Lexiva/ Telzir. Changes to our estimate of the total remaining net royalties that GlaxoSmithKline will pay to Fosamprenavir Royalty could have a material effect on the amount of royalty revenues we recognize in a particular period.

Prior to May 2008, royalty revenues typically were recognized based upon actual and estimated net sales of licensed products in licensed territories and generally were recognized in the period the sales occurred. We reconciled and adjusted for differences between actual royalty revenues and estimated royalty revenues in the quarter any differences became known. These differences were not significant.

#### Research and Development Expenses

All research and development expenses, including amounts funded through research and development collaborations, are expensed as incurred. Research and development expenses are comprised of costs incurred in performing research and development activities, including salary and benefits; stock-based compensation expense; laboratory supplies and other direct expenses; contractual services, including clinical trial and pharmaceutical development costs; expenses associated with the commercial supply investment in our drug candidates, which are considered research and development expenses due to the drug candidates' stages of development; and infrastructure costs, including facilities costs and depreciation.

When third-party service providers' billing terms do not coincide with our period-end, we are required to make estimates of our obligations to those third parties, including clinical trial and pharmaceutical development costs, contractual services and costs for commercial supply of our drug candidates, incurred in a given accounting period and record accruals at the end of the period. We base our estimates on our knowledge of the research and development programs, services performed for the period, past history for related activities and the expected duration of the third-party service contract, where applicable.

We are incurring significant costs related to commercial supplies of telaprevir, which entered into Phase 3 development in the first quarter of 2008. We also are beginning to incur costs related to commercial supplies of VX-770, although these have been considerably less than the costs related to commercial supplies of telaprevir. After a drug candidate enters into Phase 3 clinical development, determining whether to continue to classify all of these costs as research and development expenses or to capitalize some of them as inventory involves significant judgments. Generally, inventory may be capitalized if it is probable that future revenues exceeding the costs of the inventory will be generated from the sale of the inventory. While we believe that the development activities and clinical trial data to date have reduced the risks associated with obtaining marketing approval for telaprevir, for accounting purposes we continue to expense all of our costs related to commercial supplies of telaprevir because of the inherent risks of drug development. To the extent that we continue to consider these costs as research and development expenses as we continue development of telaprevir, we expect that if and when we receive marketing approval for telaprevir the costs of our initial commercial supplies of telaprevir will have already been expensed. A consequence of the application of this accounting policy is that during the initial period after the potential launch of telaprevir our cost of goods sold will not reflect costs recorded as research and development expenses in prior periods.

#### Restructuring Expense

We record liabilities associated with restructuring activities based on estimates of fair value in the period the liabilities are incurred. The liability for accrued restructuring expense of \$34.0 million at December 31, 2009 is related to that portion of our facility in Kendall Square, Cambridge, Massachusetts that we are not occupying and do not intend to occupy. This liability is calculated by applying our best estimate of the net amount of our ongoing obligation. We use a discounted cash-flow analysis to calculate the amount of this liability. The probability-weighted discounted cash-flow analysis is based on management's assumptions and estimates of our ongoing lease obligations, including contractual rental commitments, build-out commitments and building operating costs, and estimates of income from subleases, based on the term and timing of the subleases. We discount the estimated cash flows using a discount rate of approximately 10%. These cash flow estimates are reviewed and may be adjusted in subsequent periods. Adjustments are based, among other things, on management's assessment of changes in factors underlying the estimates. Because our estimate of the liability includes the application of a discount rate to reflect the time-value of money, the estimate will increase simply as a result of the passage of time, even if all other factors remain unchanged.

Our estimates of our restructuring liability have changed in the past, and it is possible that our assumptions and estimates will change in the future, resulting in additional adjustments to the amount of the estimated liability. The effect of any such adjustments could be material. For example, we currently have two subleases for portions of the Kendall Square facility with remaining terms of one and three years, respectively, and we have made estimates and assumptions relating to future sublease terms following the expiration of the current subleases. Market variability may require adjustments to those assumptions in the future. We will review our assumptions and judgments related to the lease restructuring on at least a quarterly basis until the Kendall Square lease is terminated or expires, and make whatever modifications we believe are necessary, based on our judgments, to reflect any changed circumstances.

#### Stock-based Compensation Expense

We measure the compensation cost of stock-based compensation at the grant date, based on the fair value of the award, including estimated forfeitures, and we recognize that cost as an expense ratably over the associated employee service period, which generally is the vesting period of the equity award, or the derived service period for awards with market conditions. For our awards with performance conditions, we make estimates regarding the likelihood of satisfaction of the performance condition which affect the period over which the expense is recognized. We calculate the fair value of stock options and shares purchased pursuant to the Employee Stock Purchase Plan using the Black-Scholes option pricing model. The Black-Scholes option pricing model requires us to make certain assumptions and estimates concerning our stock price volatility, the rate of return of risk-free investments, the expected term of the awards, and our anticipated dividends. In determining the amount of expense to be recorded, we also are required to exercise judgment to estimate forfeiture rates for awards, based on the probability that employees will complete the required service period. If actual forfeitures differ significantly from our estimates, if any of our estimates or assumptions prove incorrect, or if the likelihood of achievement of a performance condition changes, our results could be materially affected.

#### **RESULTS OF OPERATIONS**

		•		09/08 Comparison		08/ Comp	/07 arison
	2009	2008	2007	Increase/ (Decrease)	Increase/ (Decrease)	Increase/ (Decrease)	Increase/ (Decrease)
	(i	n thousands)	)	(in th	iousands, ex	cept percent	ages)
Revenues	\$ 101.889	\$ 175,504	\$ 199,012	\$(73,615)	(42)%	\$(23,508)	(12)%
Operating costs and expenses	715.901	638.212	618,804	77,689	12%	19,408	3%
Net interest income (expense)	(8,182)	2,857	28,513	(11,039)	n/a	(25,656)	(90)%
Other loss, net	19,984		·	19,984	n/a		
Net loss	A (CAO 400)	\$(459,851)	\$(391,279)	\$182,327	40%	\$ 68,572	18%

#### Net Loss

In 2009 as compared to 2008, our net loss increased by \$182.3 million, or 40%. The increased net loss in 2009 as compared to 2008 was the result of significant increases in our costs and expenses combined with significant decreases in our revenues. Our lower revenues in 2009 were primarily the result of our receipt and recognition of milestone payments in 2008 for which there were no corresponding milestone payments in 2009. The increased expenses included increased operating expenses related to the growth in size of our workforce and to our late-stage clinical programs and increased stock-based compensation expense. We currently expect that our net loss for 2010 will exceed our net loss for 2009, primarily as a result of activities to prepare for the potential commercial launch of telaprevir in 2011.

In 2008 as compared to 2007, our net loss increased by \$68.6 million, or 18%. The increased net loss in 2008 as compared to 2007 was the result of a combination of factors, including lower revenues from royalties as a result of the sale of our HIV royalty stream and decreases in revenues from our collaborations, an increase in our overall expenses and a decrease in our net interest income as a result of lower yields on invested funds and higher levels of outstanding debt. In 2008, we increased our workforce, particularly in our development and commercialization organizations, leading to increased employee-related expenses. In 2008, these increased expenses, as compared to 2007, were largely offset by decreased expenses related to our commercial supply investment in telaprevir, resulting in an overall 3% increase in our operating costs and expenses.

#### Net Loss Per Share

Our net loss for 2009 was \$3.71 per basic and diluted common share compared to a net loss for 2008 of \$3.27 per basic and diluted common share. Our net loss per basic and diluted common share increased in 2009 from 2008 as a result of a 40% increase in net loss, partially offset by an increase in the number of basic and diluted weighted-average common shares outstanding from 140.6 million shares in 2008 to 173.3 million shares in 2009.

Our net loss for 2008 was \$3.27 per basic and diluted common share compared to a net loss for 2007 of \$3.03 per basic and diluted common share. Our net loss per basic and diluted common share increased in 2008 from 2007 as a result of an 18% increase in net loss, partially offset by an increase in the number of basic and diluted weighted-average common shares outstanding from 129.0 million shares in 2007 to 140.6 million shares in 2008.

#### Stock-based Compensation and Certain Other Expenses

The comparison of our operating costs and expenses and other losses in the three years ended December 31, 2009, and particularly the comparison between 2009 and 2008, is affected by increases in our stock-based compensation expense in 2009 as well as expenses and an impairment of intangible

assets related to our acquisition of ViroChem, and the loss on exchanges of a portion of the 2013 Notes for our common stock in 2009.

	2009	2008	2007
	(i	in thousand	s)
Stock-based compensation expense	\$86,722	\$57,987	\$59,407
Restructuring expense	6,240	4,324	7,119
Acquisition-related expenses	7,793		—
Intangible asset impairment charges	7,200		—
Loss on exchanges of a portion of the 2013 Notes			

#### Revenues

	2009	2008	2007	09/08 Comparis	son	08/07 Comparis	on
-		in thousands				pt percentage	
Royalty revenues	\$ 28,320	\$ 37,483	\$ 47,973	\$ (9,163)	(24)%	\$(10,490)	(22)%
Collaborative revenues	73,569	138,021	151,039	(64,452)	(47)%	(13,018)	(9)%
Total revenues	\$101,889	\$175,504	\$199,012	<u>\$(73,615)</u>	(42)%	\$(23,508)	(12)%

Our total revenues in recent periods have been comprised primarily of collaborative revenues, which decreased in both 2009 and 2008 in comparison with the preceding year. On a quarterly and annual basis our collaborative revenues have fluctuated significantly, due to the timing of recognition of significant milestone payments. In 2010, we expect to recognize approximately \$75 million of deferred revenues currently reflected on our consolidated balance sheet and additional collaborative revenues from our collaborative relationships and other sources. We do not expect to have any revenues from the sale of telaprevir in 2010. If we are able to successfully commercialize telaprevir in accordance with current development timelines, product revenues from the sales of telaprevir would commence in 2011.

#### Collaborative Revenues

The table presented below is a summary of revenues from collaborative arrangements for 2009, 2008 and 2007:

	2009	2008	2007
	(	s)	
Collaborative revenues:	+	<b>***</b>	<b>6445 500</b>
Janssen	\$54,640	\$120,122	\$117,739
Mitsubishi Tanabe	18,711	9,852	4,359
Cystic Fibrosis Foundation Therapeutics Incorporated	523	764	15,883
Merck		6,000	9,000
Other	(305)	1,283	4,058
Total collaborative revenues	\$73,569	\$138,021	\$151,039

Our revenues from the Janssen collaboration in each period consist of:

- development milestone payments, if any, recognized in the period;
- net reimbursements from Janssen for development costs of telaprevir,
- sales of materials, if any, to Janssen in the period; and
- an amortized portion of the \$165.0 million up-front payment received from Janssen in 2006.

Amounts that Janssen pays us for reimbursement of our telaprevir clinical development expenses, after we offset reimbursement amounts owed by us to Janssen for reimbursements of Janssen's telaprevir clinical development expenses, are recorded as revenues.

The \$65.5 million, or 55%, decrease in our revenues from Janssen in 2009 compared to 2008 was primarily the result of a decrease in milestone revenues. We recognized a total of \$55.0 million from the achievement of milestones in 2008 for which there were no corresponding milestones achieved in 2009. The \$55.0 million in milestone revenue from the Janssen collaboration in 2008 was an increase of \$25.0 million in comparison to 2007. In the third quarter of 2009, we entered into two financial transactions related to \$250.0 million in potential future milestone payments related to the regulatory filing with and approval of telaprevir by the European Medicines Evaluation Agency, and the launch of telaprevir in the European Union. If Janssen is able to successfully commercialize telaprevir in accordance with current development timelines, we anticipate these milestones will be earned prior to April 2012. We expect that, when and if earned, these milestones will result in collaborative revenues of which the proceeds from the first \$155.0 million would be used to redeem the 2012 Notes and the remaining \$95.0 million would be paid by Janssen to the purchaser of these milestones.

In 2009, our collaborative revenues from sources other than Janssen primarily related to our collaboration with Mitsubishi Tanabe. On July 30, 2009, we entered into an amendment to our license, development and commercialization agreement with Mitsubishi Tanabe that provided for a \$105.0 million payment in connection with the execution of the amendment. This payment was initially classified as deferred revenues and is being recognized over our expected period of performance. In 2009, we recognized a total of \$18.7 million of revenues from Mitsubishi Tanabe, including the amortized portion of the \$105.0 million up-front payment. In 2008, our collaborative revenue from sources other than Janssen primarily related to \$9.9 million of revenue from Mitsubishi Tanabe relating to reimbursements for development costs, milestone payments and the sale of materials to Mitsubishi Tanabe, and the \$6.0 million milestone we achieved pursuant to our collaboration with Merck, for which there was no corresponding milestone payment in 2009.

The decrease in our total collaborative revenues from sources other than Janssen in 2008 as compared to 2007 was primarily attributable to decreased revenues from our collaboration with CFFT. In early 2008, we completed our reimbursable activities under our collaboration with CFFT, which resulted in the \$15.1 million decrease in revenues from this collaboration in 2008 as compared to 2007.

#### Royalty Revenues

Our royalty revenues relate to sales of the HIV protease inhibitors Lexiva/Telzir and Agenerase by GlaxoSmithKline. On May 30, 2008, we sold our right to receive future royalties from GlaxoSmithKline with respect to these products, excluding the portion allocated to pay a subroyalty on these net sales to a third party, in return for a one-time cash payment of \$160.0 million. On May 30, 2008, we deferred the recognition of \$155.1 million of revenues from this sale. We are recognizing these deferred revenues over the term of our agreement with GlaxoSmithKline under the units-of-revenue method. We will continue to recognize royalty revenues equal to the amount of the third-party subroyalty and an offsetting royalty expense for the third-party subroyalty payment.

The \$9.2 million, or 24%, decrease in royalty revenues in 2009 compared to 2008, and the \$10.5 million, or 22%, decrease in royalty revenues in 2008 compared to 2007, resulted primarily from this sale of our future HIV royalties in the second quarter of 2008. In 2010, we expect that we will recognize as royalty revenues a portion of the remaining deferred revenues from the sale of the royalty stream plus the full amount of the third-party subroyalty.

#### **Costs and Expenses**

• •	2009	2008	2007	09/08 Comparis	on	08/07 Comparis	on
	(	in thousands	s)	(in thous	ands, exc	pt percentages)	
Royalty expenses	\$ 14.202	\$ 15,686	\$ 13,904	\$ (1,484)	(9)%	\$ 1,782	13%
Research and development expenses	550,274		519,227	33,362	6%	(2,315)	0%
Sales, general and administrative	130,192	101,290	78,554	28,902	29%	22,736	29%
expenses	6,240	4,324	7,119	1,916	44%	(2,795)	(39)%
Intangible asset impairment charges	7,200	<u> </u>		7,200	n/a		
Acquisition-related expense				7,793	n/a		—
Total costs and expenses	\$715,901	\$638,212	\$618,804	\$ 77,689	12%	<u>\$ 19,408</u>	3%

Our operating costs and expenses primarily relate to our research and development expenses and our sales, general and administrative expenses. Our research and development expenses fluctuate on a quarterly basis due to the timing of activities related to the development of clinical drug candidates. Our sales, general and administrative expenses generally have been increasing as we expand our commercial capabilities in preparation for the potential commercial launch of telaprevir.

#### Research and Development Expenses

	2009	2008	2007	09/08 Compari		08/07 Comparis	on
	(in thousands)			(in thous	ages)		
Research expenses	\$174,267 376,007	\$165,381 351,531	\$162,471 356,756	\$ 8,886 24,476	5% 7%	\$ 2,910 (5,225)	2% (1)%
Total research and development expenses	\$550,274	\$516,912	\$519,227	\$33,362	6%	<u>\$(2,315)</u>	0%

The \$33.4 million increase in our total research and development expenses in 2009 compared to 2008 was primarily the result of increases in expenses related to our workforce as we continued to advance telaprevir and our other drug candidates through clinical development, partially offset by decreases in contractual services expenses. Our research and development expense levels were similar in 2008 and 2007 as fluctuations in development expenses, including increases in expenses related to our workforce and a decrease in expenses related to commercial supply investment for telaprevir, resulted in a small decrease in research and development expenses. In 2010, we expect that our total research and development expenses will increase as we increase our investment in commercial supplies of telaprevir in order to prepare for the potential commercial launch of telaprevir in 2011.

Our research and development expenses include internal and external costs incurred for our drug candidates, including telaprevir and VX-770. We do not assign our internal costs, such as salary and benefits, stock-based compensation expense, laboratory supplies and infrastructure costs, to individual drug candidates, because the employees within our research and development groups typically are deployed across multiple research and development programs. These internal costs are significantly greater than our external costs, such as the costs of services provided to us by clinical research organizations and other outsourced research, which we do allocate by individual drug development program. All research and development costs for our drug candidates are expensed as incurred.

To date, we have incurred in excess of \$3.3 billion in research and development expenses associated with drug discovery and development. The successful development of our drug candidates is highly uncertain and subject to a number of risks. In addition, the duration of clinical trials may vary substantially according to the type, complexity and novelty of the drug candidate and the disease indication being targeted. The FDA and comparable agencies in foreign countries impose substantial requirements on the introduction of therapeutic pharmaceutical products, typically requiring lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures. Data obtained from nonclinical and clinical activities at any step in the testing process may be adverse and lead to discontinuation or redirection of development activity. Data obtained from these activities also are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The duration and cost of discovery, nonclinical studies and clinical trials may vary significantly over the life of a project and are difficult to predict. Therefore, accurate and meaningful estimates of the ultimate costs to bring our drug candidates to market are not available.

Over the three year period ended December 31, 2009, telaprevir has represented the largest portion of the development costs for our clinical drug candidates. We anticipate that our ongoing Phase 3 clinical trials of telaprevir will be completed in mid-2010, but that development costs associated with other clinical trials of telaprevir may continue after the completion of the registration trials. If we are able to successfully commercialize telaprevir in accordance with current development timelines, we anticipate revenues and cash flows from the sales of telaprevir to commence in 2011. If our registration program for VX-770 is successful and completed on the timeline that we currently anticipate, we could submit an NDA for VX-770 in the second half of 2011. Our other drug candidates are less advanced and as a result any estimates regarding development timelines for these drug candidates are highly subjective and subject to change, and we cannot at this time make a meaningful estimate when, if ever, these drug candidates, including the drug candidates we acquired from ViroChem, will generate revenues and cash flows.

#### Research Expenses

	2009	2008	2007	09/08 Compari		08/07 Compari	son
	(	in thousands	s)	(in thousands, except percenta			
Research Expenses:		•	÷				
Salary and benefits	\$ 63,422	\$ 55,755	\$ 51,383	\$ 7,667	14%	\$ 4,372	9%
Stock-based compensation expense	23,802	18,764	21,572	5,038	27%	(2,808)	(13)%
Laboratory supplies and other direct				,			
expenses	28,136	24,284	22,705	3,852	16%	1,579	7%
Contractual services	5,406	8,725	7,555	(3,319)	(38)%	1,170	15%
Infrastructure costs	53,501	57,853	59,256	(4,352)	(8)%	(1,403)	(2)%
Total research expenses	\$174,267	\$165,381	\$162,471	\$ 8,886	5%	<u>\$ 2,910</u>	2%

Over the past three years we have maintained a relatively level investment in research activities with fluctuations in various categories of expense resulting in a 5% increase in research expenses in 2009 as compared to 2008 and a 2% increase in research expenses in 2008 as compared to 2007. Our research expenses primarily are related to expenses for our workforce and generally are not dependent on the timing of clinical development activities. We expect to continue to invest in our research programs in an effort to continue identifying additional drug candidates.

#### Development Expenses

	2009	2008	2007	09/08 Comparis	on	08/07 Comparis	on
	(	in thousands	;)	(in thous	ands, exc	ept percentage	es)
Development Expenses:							
Salary and benefits	\$ 98,830	\$ 78,947	\$ 56,340	\$19,883	25%	\$ 22,607	40%
Stock-based compensation expense	40,326	27,380	27,396	12,946	47%	(16)	0%
Laboratory supplies and other direct	· .						
expenses	27,682	30,281	25,462	(2,599)	(9)%	4,819	19%
Contractual services	111,579	121,062	114,475	(9,483)	(8)%	6,587	6%
Commercial supply investment	21,591	17,559	75,463	4,032	23%	(57,904)	(77)%
Infrastructure costs	75,999	76,302	57,620	(303)	0%	18,682	32%
Total development expenses	\$376,007	\$351,531	\$356,756	\$24,476	7%	\$ (5,225)	(1)%

Our development expenses increased by \$24.5 million, or 7%, in 2009 as compared to 2008 primarily as a result of increased expenses related to our workforce partially offset by decreases in our contractual services expenses. The number of employees in our development group increased by approximately 16% from 2008 to 2009. Our investment in commercial supply of drug candidates, which has fluctuated significantly over the past three years, also increased by \$4.0 million, or 23%, in 2009 as compared to 2008. Overall, we expect development expenses to be significantly higher in 2010 than 2009 because of significant projected increases in commercial supply investment in telaprevir, and expenses related to the VX-770 registration program and our earlier-stage clinical trials, partially offset by decreases in expenses related to our telaprevir registration program.

Our development expenses decreased by \$5.2 million, or 1%, in 2008 as compared to 2007. This decrease in our development expenses was the result of a \$57.9 million decrease in expenses for commercial supply of drug candidates partially offset by increases in the other categories of development expenses, including expenses related to our increased headcount and infrastructure.

#### Sales, General and Administrative Expenses

	2009			09/08 Compari		08/07 Compari	son
· · · · · · · · · · · · · · · · · · ·	(i	)	(in thousands, except percentages)				
Sales, general and administrative expenses	\$130,192	\$101,290	\$78,554	\$28,902	29%	\$22,736	29%

Sales, general and administrative expenses increased substantially in each of 2009 and 2008 as compared to the preceding year as a result of increases in workforce expenses as we advance our drug candidates, particularly telaprevir, into late-stage development. We expect that sales, general and administrative expenses will increase significantly in 2010 as we continue to increase headcount in our commercial organization to prepare for the potential launch of telaprevir in 2011.

#### Royalty Expenses

Royalty expenses decreased \$1.5 million, or 9%, in 2009 compared to 2008. Royalty expenses increased \$1.8 million, or 13%, in 2008 compared to 2007. Royalty expenses primarily relate to a subroyalty payable to a third party on net sales of Lexiva/Telzir and Agenerase. The subroyalty expense offsets a corresponding amount of royalty revenues. We expect to continue to recognize this subroyalty as an expense in future periods.

#### Restructuring Expense

As of December 31, 2009, our lease restructuring liability was \$34.0 million. In 2009, 2008 and 2007, we recorded restructuring expense of \$6.2 million, \$4.3 million and \$7.1 million, respectively. The restructuring expense in all periods included imputed interest cost related to the restructuring liability associated with our Kendall Square lease. In 2009 and 2007, there were also adjustments of certain estimates and assumptions for the remaining period of the lease commitment that increased the restructuring expense in those periods.

#### Acquisition-related Expenses

We incurred \$7.8 million of expenses in 2009 in connection with our acquisition of ViroChem, including \$5.7 million in transaction expenses and \$2.1 million related to a restructuring of ViroChem's operations that we undertook in March 2009 in order to focus ViroChem's activities on its HCV assets. We did not have corresponding acquisition-related expenses in 2008 or 2007.

#### Impairment of Intangible Assets

In 2009, we recorded an expense of \$7.2 million in connection with an impairment of the intangible assets related to ViroChem's development program for VCH-286, a drug candidate for the treatment of HIV infection. This intangible asset was estimated to have a fair value on the acquisition date of \$7.2 million, based on development costs through the acquisition date. In the fourth quarter 2009, we determined that VCH-286 was impaired and recorded an impairment charge of \$7.2 million.

## **Non-Operating Items**

#### Interest Income

Interest income decreased by \$11.3 million, or 69%, to \$5.0 million in 2009 from \$16.3 million in 2008. The decrease was a result of lower portfolio yields during 2009 as compared to 2008. Our cash, cash equivalents and marketable securities yielded approximately 1% on an annual basis in 2009 compared to approximately 2% on an annual basis in 2008.

Interest income decreased \$14.5 million, or 47%, to \$16.3 million in 2008 from \$30.8 million in 2007. The decrease was a result of lower portfolio yields during 2008, partially offset by higher average levels of invested funds in 2008. Our cash, cash equivalents and marketable securities yielded approximately 2% on an annual basis in 2008 compared to approximately 5% in 2007.

#### Interest Expense

Interest expense decreased by \$0.3 million, or 2%, to \$13.2 million in 2009 from \$13.5 million in 2008 as a result of a decrease in interest expenses related to our 2013 Notes from \$12.0 million in 2008 to \$8.8 million in 2009 partially offset by the interest expenses related to the 2012 Notes that we issued in September 2009. In 2010, we expect the interest expenses related to our 2013 Notes will be significantly lower than in 2009 as a result of the lower outstanding principal amounts of our 2013 Notes, but that interest expenses related to our 2012 Notes will be significantly higher in 2010 than in 2009.

Interest expense increased \$11.2 million to \$13.5 million in 2008 compared to \$2.3 million in 2007. This increase in 2008 as compared to 2007 resulted from the issuance in February 2008 of \$287.5 million in aggregate principal amount of 2013 Notes.

# Expense on Exchanges of 2013 Notes into Common Stock

In 2009, we incurred non-cash charges of \$18.1 million in connection with the exchanges of \$255.4 million in aggregate principal amount of the 2013 Notes for 11.6 million newly-issued shares of our common stock. The charges related to the additional 542,937 shares of common stock that we issued in excess of the number of shares of common stock into which such 2013 Notes were convertible prior to the exchanges. There were no corresponding expenses in 2008 or 2007.

#### Losses on Derivative Instruments, Net

In the fourth quarter of 2009, we recorded net losses of \$1.8 million in connection with the embedded and free-standing derivatives associated with our September 2009 financial transactions. These net losses primarily are based on a time value of money adjustment to the estimated fair value of the free-standing derivative. We expect to continue to record losses and/or gains related to these derivatives in 2010.

#### LIQUIDITY AND CAPITAL RESOURCES

We have incurred operating losses since our inception and have financed our operations principally through public and private offerings of our equity and debt securities, strategic collaborative agreements that include research and/or development funding, development milestones and royalties on the sales of products, strategic sales of assets or businesses, financial transactions, investment income and proceeds from the issuance of common stock under our employee benefit plans. We expect that we will incur substantial expenses in order to complete the development and commercialization of telaprevir while at the same time continuing the development of our other drug candidates and building our other capabilities. As a result, we may raise additional capital in order to maintain adequate working capital and cash reserves to continue our diversified research, discovery and development efforts. We expect we would need to raise additional capital if the development of telaprevir were materially delayed.

At December 31, 2009, we had cash, cash equivalents and marketable securities of \$1.3 billion, which was an increase of \$452.8 million from \$832.1 million at December 31, 2008. The increase was primarily the result of financing activities, financial transactions and payments from collaborators that occurred in 2009, including an aggregate of \$801.4 million of net proceeds from the offerings of common stock that we completed in February and December 2009, \$155.0 million we received from two financial transactions that we entered into in September 2009, \$105.0 million we received from Mitsubishi Tanabe in the third quarter of 2009 and \$47.9 million from the issuance of common stock under our employee benefit plans. These cash inflows were partially offset by cash expenditures we made in 2009 related to, among other things, research and development expenses, sales, general and administrative expenses and \$100.0 million in cash that was included as part of the consideration to acquire ViroChem. Capital expenditures for property and equipment during 2009 were \$23.5 million.

During 2009, we reduced the aggregate principal amount of our 2013 Notes outstanding from \$287.5 million to \$32.1 million. The 2013 Notes bear interest at the rate of 4.75% per annum, and we were required to make semi-annual interest payments on the outstanding principal balance of the 2013 Notes on February 15 and August 15 of each year. The 2013 Notes would have matured on February 15, 2013. The 2013 Notes are convertible, at the option of the holder, into our common stock at a price equal to approximately \$23.14 per share, subject to adjustment. In February 2010, we announced that we would redeem the 2013 Notes on March 19, 2010 at the redemption prices stated in the indenture related to the 2013 Notes, plus accrued and unpaid interest through March 18, 2010. We expect that the 2013 Notes will be converted into common stock by the holders prior to the redemption date.

As a result of a financial transaction entered into in September 2009, we had \$155.0 million in aggregate principal amount of 2012 Notes outstanding on December 31, 2009. The 2012 Notes mature on October 31, 2012, subject to earlier mandatory redemption as specified milestone events under our collaboration with Janssen are achieved prior to October 31, 2012. In addition, in September 2009, we sold our rights to receive an additional \$95.0 million of potential future milestone payments that we expect to receive from Janssen for the launch of telaprevir in the European Union. As a result of these transactions, the \$250.0 million of potential milestone payments from Janssen related to the filing, approval and launch of telaprevir in the European Union will not provide us with liquidity in the future, if and when earned, except to the extent that they fund redemption of \$155.0 million in principal amount of our 2012 Notes.

Our accrued restructuring expense of \$34.0 million at December 31, 2009 relates to the portion of the facility that we lease in Kendall Square that we do not intend to occupy and includes other related lease obligations, recorded at net present value. In 2009, we made cash payments of \$14.9 million against the accrued expense and received \$8.6 million in sublease rental payments. During 2010, we expect to make additional cash payments of \$14.9 million against the accrued expense and receive \$8.6 million against the accrued expense and receive \$8.6 million in sublease rental payments.

We expect to continue to make significant investments in our development pipeline, particularly for clinical trials of telaprevir and VX-770, in our effort to prepare for potential registration, regulatory approval and commercial launch of telaprevir and VX-770, and in clinical trials for our other drug candidates, including VX-809, VX-222, VX-509 and VX-765. We also expect to maintain our substantial investment in research. As a result, we expect to incur future losses on a quarterly and annual basis at least until we obtain marketing approval and successfully commercialize a product. The adequacy of our available funds to meet our future operating and capital requirements will depend on many factors, including the number, breadth and prospects of our discovery and development programs, the costs and timing of obtaining regulatory approvals for any of our drug candidates and our decisions regarding manufacturing and commercial investments.

We believe that our current cash, cash equivalents and marketable securities will be sufficient to fund our operations for at least the next twelve months. We may raise additional capital in order to maintain adequate working capital and cash reserves to continue our diversified research, discovery and development efforts through public offerings or private placements of our securities, securing new collaborative agreements, or other methods of financing. Any such capital transactions may or may not be similar to transactions in which we have engaged in the past. We will continue to manage our capital structure and consider all financing opportunities, whenever they may occur, that could strengthen our long-term liquidity profile. There can be no assurance that any such financing opportunities will be available on acceptable terms, if at all. If adequate funds are not available, we may be required to curtail significantly or discontinue one or more of our research, drug discovery or development programs or attempt to obtain funds through arrangements that may require us to relinquish rights to certain of our technologies or drug candidates.

#### CONTRACTUAL COMMITMENTS AND OBLIGATIONS

The first part of the following table sets forth commitments and obligations that have been recorded on our consolidated balance sheet at December 31, 2009. Certain other obligations and commitments, while not required under GAAP to be included in the consolidated balance sheet, may

have a material impact on liquidity. We have presented these items, in the remaining rows of the table below in order to present a more complete picture of our financial position and liquidity.

	2010	2011-2012	2013-2014	2015 and later	Total
			(in thousan	nds)	
Commitments and Obligations Recorded on the					
Consolidated Balance Sheet at December 31, 2009:					
Convertible senior subordinated notes (due					A. A. A. A. M.
February 2013)—principal payment	\$32,071	\$	\$	\$ —	\$ 32,071
Convertible senior subordinated notes (due					
February 2013)—interest payments	571			—	571
Secured notes due October 2012		121,765			121,765
Liability related to sale of potential future					
milestone payments		38,207			38,207
Additional Commitments and Obligations at			· .		
December 31, 2009 (as adjusted for redemption of					· ·
2013 Notes):					
Convertible senior subordinated notes (due					
February 2013)—interest payments and					
redemption price	1,248				1,248
Facility operating leases	40,469	88,911	74,373	84,093	287,846
Secured notes due October 2012, net of amounts					~~~~~
reflected on consolidated balance sheet		33,235			33,235
Liability related to sale of potential future					
milestone payments, net of amounts reflected on					
consolidated balance sheet		56,793			56,793
Research, development and commercial supply					11.050
investment	10,789	264			11,053
Total contractual commitments and obligations	\$85,148	\$339,175	\$74,373	\$84,093	\$582,789

# Commitments and Obligations Recorded on the Consolidated Balance Sheet at December 31, 2009

As of December 31, 2009, we had outstanding an aggregate of \$32.1 million in principal amount of our 2013 Notes. The principal and interest accrued as of December 31, 2009 under these notes was included on our consolidated balance sheet as of December 31, 2009. In February 2010, we announced that we will redeem the 2013 Notes on March 19, 2010. We expect that the 2013 Notes will be converted into common stock by the holders prior to the redemption date, based on the current stock price.

As a result of our September 2009 financial transactions, we are obligated to pay \$155.0 million in October 2012 to retire the 2012 Notes. If specified milestone events under our Janssen collaboration relating to the filing, approval and launch of telaprevir in the European Union are achieved prior to October 31, 2012, we will be required to redeem a portion of the 2012 Notes equal to each milestone payment as each such milestone payment is earned under the Janssen collaboration, until the 2012 Notes are redeemed in full. The holders of the 2012 Notes will have the right to cause us to repurchase all or any part of the 2012 Notes at 100% of the principal amount if we experience a change of control. In addition, as a result of our September 2009 financial transactions, we sold \$95.0 million in additional potential future milestone payments. The liability related to this sale is reflected on the consolidated balance sheet at its fair value of \$38.2 million. The difference between the fair value and \$95.0 million is reflected on the table above as an additional commitment.

# Additional Commitments and Obligations Not Required to be Recorded on Consolidated Balance Sheet at December 31, 2009

Our future minimum commitments and contractual obligations include facility operating leases and contractual commitments related to our research, development and commercial supply investment, and future interest payments through March 18, 2010 due on the 2013 Notes that we are obligated to redeem in March, including the redemption premium that we are obligated to pay in connection with the redemption and liabilities related to our September 2009 financial transactions. These items are not required under GAAP to be recorded on our consolidated balance sheets. They are disclosed in the table presented above to provide a more complete picture of our financial position and liquidity.

Our future minimum commitments under our Kendall Square lease for the period commencing on January 1, 2010 are \$18.3 million for 2010, \$36.5 million for 2011 and 2012, \$36.5 million for 2013 and 2014, and \$60.9 million from 2015 through the expiration of the lease in 2018. These amounts are included in the table above as part of our facility operating leases. Rent payments for our Kendall Square lease will be subject to increase in May 2013, based on changes in an inflation factor. We are using approximately 40% of the Kendall Square facility for our operations. We have entered into two subleases for the remaining rentable square footage at the Kendall Square facility to offset our on-going contractual lease obligations. The subleases will expire in 2011 and 2012 and contain options to extend through 2015 and 2018, respectively. One of the subleases has certain termination provisions beginning in 2010. The future minimum committed income from the subleases is \$6.5 million for 2010 and \$5.7 million for 2011 and 2012. These amounts are not offset against our obligations set forth in the table above. See Note F, "Restructuring Expense," to our consolidated financial statements included in this Annual Report on Form 10-K.

Commitments under research, development and commercial supply investment represent contractual commitments entered into for materials and services in the normal course of business.

Our table detailing contractual commitments and obligations does not include severance pay obligations to certain of our executive officers in the event of a not-for-cause employment termination under existing employment contracts.

#### **Recent Accounting Pronouncements**

Refer to Note B, "Accounting Policies," in the accompanying notes to the consolidated financial statements for a discussion of recent accounting pronouncements.

## ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As part of our investment portfolio, we own financial instruments that are sensitive to market risks. The investment portfolio is used to preserve our capital until it is required to fund operations, including our research and development activities. None of these market risk-sensitive instruments are held for trading purposes. We do not have derivative financial instruments in our investment portfolio.

#### Interest Rate Risk

We invest our cash in a variety of financial instruments, principally securities issued by the United States government and its agencies, investment grade corporate bonds and commercial paper, and money market funds. These investments are denominated in United States dollars. All of our interest-bearing securities are subject to interest rate risk, and could decline in value if interest rates fluctuate. Substantially all of our investment portfolio consists of marketable securities with active secondary or resale markets to help ensure portfolio liquidity, and we have implemented guidelines limiting the term-to-maturity of our investment instruments. Due to the conservative nature of these instruments, we do not believe that we have a material exposure to interest rate risk.

# ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this Item 8 is contained on pages F-1 through F-45 of this Annual Report on Form 10-K.

# ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

# ITEM 9A. CONTROLS AND PROCEDURES

(1) Evaluation of Disclosure Controls and Procedures. The Company's chief executive officer and chief financial officer, after evaluating the effectiveness of the Company's disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this Annual Report on Form 10-K, have concluded that, based on such evaluation, the Company's disclosure controls and procedures were effective. In designing and evaluating the disclosure controls and procedures, the Company's management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and the Company's management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

(2) Management's Annual Report on Internal Control Over Financial Reporting. The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) and Rule 15d-15(f) promulgated under the Securities Exchange Act of 1934, as amended, as a process designed by, or under the supervision of, the Company's principal executive and principal financial officers and effected by the Company's Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. The Company's internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The Company's management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2009. In making this assessment, it used the criteria set forth in the Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on its assessment, the Company's management has concluded that, as of December 31, 2009, the Company's internal control over financial reporting is effective based on those criteria.

The Company's independent registered public accounting firm, Ernst & Young LLP, issued an attestation report on the Company's internal control over financial reporting. See Section 4 below.

(3) Changes in Internal Controls. During the quarter ended December 31, 2009, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

# (4) Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Vertex Pharmaceuticals Incorporated

We have audited Vertex Pharmaceuticals Incorporated's internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Vertex Pharmaceuticals Incorporated's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Vertex Pharmaceuticals Incorporated maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Vertex Pharmaceuticals Incorporated as of December 31, 2009 and 2008, and the related consolidated statements of operations, stockholders' equity and comprehensive loss, and cash flows for each of the three years in the period ended December 31, 2009 of Vertex Pharmaceuticals Incorporated and our report dated February 19, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts February 19, 2010

# ITEM 9B. OTHER INFORMATION

As described in Note V to the consolidated financial statements included in this Annual Report on Form 10-K, on February 16, 2009, we announced we will redeem the remaining \$32.1 million in aggregate principal amount of our 2013 Notes on March 19, 2009. The description in Note V is incorporated herein by reference in satisfaction of our obligations under Item 2.04 of Form 8-K.

# ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information regarding directors required by this Item 10 will be included in the definitive Proxy Statement for our 2010 Annual Meeting of Stockholders, or the 2010 Proxy Statement, under "Election of Directors," "Information Regarding our Board of Directors and its Committees," "Stockholder Proposals for the 2011 Annual Meeting and Nominations for Director" and is incorporated herein by reference. Other information required by this Item 10 will be included in the 2010 Proxy Statement under "Section 16(a) Beneficial Ownership Reporting Compliance" and "Code of Conduct and Ethics" and is incorporated herein by reference. The information regarding executive officers required by this Item 10 as well as certain information regarding our directors is included in Part I of this Annual Report on Form 10-K.

## ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 will be included in the 2010 Proxy Statement under "Compensation Committee Interlocks and Insider Participation," "Executive Compensation" and/or "Information Regarding our Board of Directors or Committees" and is incorporated herein by reference.

# ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item 12 will be included in the 2010 Proxy Statement under "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" and is incorporated herein by reference.

# ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item 13 will be included in the 2010 Proxy Statement under "Election of Directors" and "Executive Compensation-Approval of Related Person Transactions and Transactions with Related Persons" and is incorporated herein by reference.

# ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item 14 will be included in the 2010 Proxy Statement under "Independent Registered Public Accounting Firm" and is incorporated herein by reference.

# PART IV

# ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) The Financial Statements required to be filed by Items 8 and 15(c) of Form 10-K, and filed herewith, are as follows:

	Page Number in this Form 10-K
Report of Independent Registered Public Accounting Firm	F-1
Consolidated Balance Sheets as of December 31, 2009 and 2008	F-2
Consolidated Statements of Operations for the years ended December 31, 2009, 2008 and 2007	F-3
Consolidated Statements of Stockholders' Equity and Comprehensive Loss for the years ended December 31, 2009, 2008 and 2007	F-4
Consolidated Statements of Cash Flows for the years ended December 31, 2009, 2008 and 2007	F-5
Notes to Consolidated Financial Statements	F-6

(a)(2) Financial Statement Schedules have been omitted because they are either not applicable or the required information is included in the consolidated financial statements or notes thereto listed in (a)(1) above.

# (a)(3) Exhibits.

The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

Exhibit Number	Exhibit Description	Filed with this report	Incorporated by Reference herein from-Form or Schedule	Filing Date/ Period Covered	SEC File/ Reg. Number
2.1	Share Purchase Agreement, dated March 3, 2009, by and among Vertex Pharmaceuticals Incorporated, Vertex Pharmaceuticals (Canada) Incorporated, ViroChem Pharma Inc. and the ViroChem Securityholders named therein.		8-K (Exhibit 2.1)	March 13, 2009	000-19319
3.1	Restated Articles of Organization of Vertex Pharmaceuticals Incorporated, as amended.		10-Q (Exhibit 3.1)	August 11, 2008	000-19319
3.2	By-laws of Vertex Pharmaceuticals Incorporated, as amended and restated as of May 11, 2005.		10-Q (Exhibit 3.1)	August 9, 2005	000-19319
4.1	Specimen stock certificate.		S-1 (Exhibit 4.1)	July 18, 1991	33- 40966
4.2	Rights Agreement, dated as of July 1, 1991.		S-1 (Exhibit 4.2)	July 5, 1991	33-40966
4.3	First Amendment to Rights Agreement, dated as of February 21, 1997.		10-K (Exhibit 4.3)	March 28, 1997	000-19319
4.4	Second Amendment to Rights Agreement, dated as of June 30, 2001.		10-Q (Exhibit 4.4)	August 14, 2001	000-19319
4.5	Indenture dated as of February 19, 2008 by and between Vertex Pharmaceuticals Incorporated and U.S. Bank National Association, as trustee.		8-K (Exhibit 4.1)	February 25, 2008	<b>000-19319</b>
4.6	Form of 4.75% Convertible Senior Subordinated Note due 2013.		8-K (Exhibit 4.2)	February 25, 2008	000-19319
4.7	Indenture dated as of September 30, 2009 by and between Vertex Pharmaceuticals Incorporated and U.S. Bank National Association, as trustee and collateral	•	10-Q (Exhibit 4.1)	November 9, 2009	000-19319

agent.†

Exhibit Number	Exhibit Description	Filed with this report	Incorporated by Reference herein from—Form or Schedule	Filing Date/ Period Covered	SEC File/ Reg. Number
4.8	Secured Notes due 2012.		10-Q (Exhibit 4.2)	November 9, 2009	000-19319
Collabo	oration Agreements				
10.1	License, Development, Manufacturing and Commercialization Agreement, dated June 30, 2006, by and between Vertex Pharmaceuticals Incorporated and Janssen Pharmaceutica, N.V.†		10-Q (Exhibit 10.1)	August 9, 2006	000-19319
10.2	License, Development and Commercialization Agreement, dated as of June 11, 2004, between Vertex Pharmaceuticals Incorporated and Mitsubishi Pharma Corporation. <sup>†</sup>		10-Q (Exhibit 10.1)	November 9, 2009	000-19319
10.3	Second Amendment to License, Development and Commercialization Agreement, dated July 30, 2009, between Mitsubishi Tanabe Pharma Corporation and Vertex Pharmaceuticals Incorporated. <sup>†</sup>		10-Q (Exhibit 10.2)	November 9, 2009	000-19319
10.4	Research Agreement and License Agreement, both dated December 16, 1993, between Vertex and Burroughs Wellcome Co.†		10-K (Exhibit 10.16)	Year Ended December 31, 1993	000-19319
10.5	Research, Development and Commercialization Agreement, dated as of May 24, 2004, between Vertex Pharmaceuticals Incorporated and Cystic Fibrosis Foundation Therapeutics Incorporated. <sup>†</sup>		8-K/A (Exhibit 99.2)	September 10, 2004	000-19319
10.6	Amendment No. 1 to Research, Development and Commercialization Agreement, dated as of January 6, 2006, between Vertex Pharmaceuticals Incorporated and Cystic Fibrosis Foundation Therapeutics Incorporated.†		10-K (Exhibit 10.9)	March 16, 2006	000-19319
10.7	Amendment No. 2 to Research, Development and Commercialization Agreement, dated as of March 17, 2006, between Vertex Pharmaceuticals Incorporated and Cystic Fibrosis Foundation Therapeutics Incorporated. <sup>†</sup>		10-Q (Exhibit 10.1)	May 10, 2006	000-19319
Financ	cial Transactions				
10.8	Purchase Agreement, dated May 30, 2008, by and between Vertex Pharmaceuticals Incorporated and Fosamprenavir Royalty, L.P.		10-Q (Exhibit 10.2)	August 11, 2008	000-19319
10.9	Note Purchase Agreement dated September 30, 2009 by and between Vertex Pharmaceuticals Incorporated and Olmsted Park S.A. <sup>†</sup>		10-Q (Exhibit 10.3)	November 9, 2009	000-19319
10.10	Security Agreement dated September 30, 2009 between Vertex Pharmaceuticals Incorporated and U.S. Bank National Association, as collateral agent. <sup>†</sup>		10-Q (Exhibit 10.4)	November 9, 2009	000-19319
10.11	Purchase Agreement Regarding Milestone #9 dated September 30, 2009 by and between Vertex Pharmaceuticals Incorporated and Olmsted Park S.A.†		10-Q (Exhibit 10.5)	November 9, 2009	000-19319
10.12			10-Q (Exhibit 10.6)	November 9, 2009	000-19319
Lease					
10.13	Washington Realty Trust and Vertex.			Year Ended December 31, 1994	000-19319
10.14	First Amendment to Lease, dated as of December 29, 1995, between Fort Washington Realty Trust and Vertex Pharmaceuticals Incorporated.		10-K (Exhibit 10.15)	Year Ended December 31, 1995	000-19319

.

Exhibit Number	Exhibit Description	Filed with this report	Incorporated by Reference herein from—Form or Schedule	Filing Date/ Period Covered	SEC File/ Reg. Number
10.15	Second Amendment to Lease, dated as of June 13, 1997, between Fort Washington Realty Trust and Vertex Pharmaceuticals Incorporated.		10-K (Exhibit 10.20)	March 26, 1998	000-19319
10.16	Third, Fourth and Fifth Amendments to Lease between Fort Washington Realty Trust and Vertex Pharmaceuticals Incorporated. <sup>†</sup>		10-K (Exhibit 10.14)	March 26, 2001	000-19319
10.17	Lease, dated as of September 17, 1999, between Trustees of Fort Washington Realty Trust and Vertex Pharmaceuticals Incorporated. <sup>†</sup>		10-Q (Exhibit 10.27)	November 15, 1999	000-19319
10.18	Lease, dated as of January 18, 2001, between Kendall Square, LLC and Vertex Pharmaceuticals Incorporated. <sup>†</sup>		10-K (Exhibit 10.16)	March 26, 2001	000-19319
10.19	Amendment to Lease, dated January 12, 2009, by and between BMR-200 Sidney Street LLC and Vertex Pharmaceuticals Incorporated.		10-Q (Exhibit 10.4)	May 11, 2009	000-19319
10.20	Amendment to Lease, dated January 12, 2009, by and between BMR-40 Erie Street LLC and Vertex Pharmaceuticals Incorporated.		10-Q (Exhibit 10.5)	May 11, 2009	000-19319
10.21	Agreement for Lease, dated as of November 4, 1998, between Milton Park Limited, Vertex Pharmaceuticals Incorporated and Vertex Pharmaceuticals (Europe) Limited.		10-K (Exhibit 10.21)	March 30, 1999	000-19319
10.22	Lease between MEPC Milton Park No.1 Limited and MEPC Milton Park No. 2 Limited, Vertex Pharmaceuticals (Europe) Limited and Vertex Pharmaceuticals Incorporated, dated June 10, 2009.		10-Q (Exhibit 10.1)	August 10, 2009	000-19319
Equity	-				
10.23	1991 Stock Option Plan, as amended and restated as of September 14, 1999.*		10-K (Exhibit 10.1)	March 3, 2000	000-19319
10.24	1994 Stock and Option Plan, as amended and restated as of September 14, 1999.*		10-K (Exhibit 10.2)	March 3, 2000	000-19319
10.25	1996 Stock and Option Plan, as amended and restated as of March 14, 2005.*		10-K (Exhibit 10.3)	March 16, 2005	000-19319
10.26	Form of Stock Option Grant under 1996 Stock and Option Plan.*		8-K (Exhibit 10.1)	February 9, 2005	000-19319
10.27	Form of Restricted Stock Award under 1996 Stock and Option Plan—Annual Vesting.*		8-K (Exhibit 10.2)	February 9, 2005	000-19319
10.28	Form of Restricted Stock Agreement (Performance Accelerated Restricted Stock) under 1996 Stock and Option Plan.*		8-K (Exhibit 10.3)	February 9, 2005	000-19319
10.29	Amended and Restated 2006 Stock and Option Plan.*		10-Q (Exhibit 10.2)	August 10, 2009	000-19319
10.30	Form of Stock Option Grant under 2006 Stock and Option Plan.*		8-K (Exhibit 10.2)	May 15, 2006	000-19319
10.31	Form of Restricted Stock Award (Performance Accelerated Restricted Stock) under 2006 Stock and Option Plan.*		8-K (Exhibit 10.4)	May 15, 2006	000-19319
10.32	Vertex Pharmaceuticals Incorporated Employee Stock Purchase Plan, as amended and restated.*		10-Q (Exhibit 10.8)	August 11, 2008	000-19319
10.33	Form of Stock Option Grant-Performance Accelerated 2009 Stock-Options.	х			
Agreen	nents with Executive Officers and Directors				
10.34	Agreement between Matthew W. Emmens and Vertex, dated February 5, 2009.*		8-K (Exhibit 10.1)	February 10, 2009	000-19319

Exhibit Number	Exhibit Description	Filed with this report	Incorporated by Reference herein from—Form or Schedule	Filing Date/ Period Covered	SEC File/ Reg. Number
10.35	Employee Non-disclosure, Non-competition and Inventions Agreement between Matthew W. Emmens and Vertex, dated February 5, 2009.*		8-K (Exhibit 10.2)	February 10, 2009	000-19319
10.36	Employment Agreement, dated February 11, 2008, between Peter Mueller and Vertex.*		10-Q (Exhibit 10.2)	May 12, 2008	000-19319
10.37	Form of Change of Control Agreement, dated as of March 7, 2003, between Vertex and Peter Mueller.*		10-K (Exhibit 10.32)	March 31, 2003	000-19319
10.38	Form of Amendment to Change of Control Agreement, dated as of November 8, 2004, between Vertex and Peter Mueller.*		10-Q (Exhibit 10.7)	November 9, 2004	000-19319
10.39	Second Amendment to Change of Control Agreement, dated February 11, 2008, between Peter Mueller and Vertex.*		10-K (Exhibit 10.38)	February 11, 2008	000-19319
10.40	Amended and Restated Employment Agreement, dated as of November 8, 2004, between Vertex and Ian F. Smith.*		10-Q (Exhibit 10.13)	November 9, 2004	000-19319
10.41	Amendment No. 1 to Amended and Restated Employment Agreement between Ian F. Smith and Vertex, dated December 29, 2008.*		10-K (Exhibit 10.66)	February 17, 2009	000-19319
10.42	Employment Agreement, dated as of December 9, 2009 between Vertex and Nancy Wysenski.*	х			
10.43	Change of Control letter, dated as of December 9, 2009 between Vertex and Nancy Wysenski.*	Х			
10.44	Amended and Restated Employment Agreement, dated as of November 8, 2004, between Vertex and Kenneth S. Boger.*		10-Q (Exhibit 10.11)	November 9, 2004	000-19319
10.45	Amendment No. 1 to Amended and Restated Employment Agreement, dated February 11, 2008, between Vertex and Kenneth S. Boger.*		10-K (Exhibit 10.32)	February 11, 2008	000-19319
10.46 <sub>.</sub>	Amendment No 2. to Amended and Restated Employment Agreement between Kenneth S. Boger and Vertex, dated December 29, 2008.*		10-K (Exhibit 10.64).	February 17, 2009	000-19319
10.47	Form of Restricted Stock Agreement for 2007 Restricted Stock Awards to Peter Mueller and Ian F. Smith.*		10-Q (Exhibit 10.5)	August 9, 2007	000-19319
10.48	Employment Agreement, dated February 11, 2008, between Lisa Kelly-Croswell and Vertex.*		10-Q (Exhibit 10.3)	May 12, 2008	000-19319
10.49	Change of Control Change of Control entered into between Vertex Pharmaceuticals Incorporated and Lisa Kelly-Croswell on July 12, 2007.*		10-Q (Exhibit 10.2)	November 9, 2007	000-19319
10.50	Amendment to Change of Control Agreement, dated February 11, 2008, between Lisa Kelly-Croswell and Vertex.*		10-K (Exhibit 10.48)	February 11, 2008	000-19319
10.51	Offer Letter, between Vertex and Amit Sachdev, dated June 4, 2007.*		10-Q (Exhibit 10.4)	August 9, 2007	000-19319
10.52	Employment Agreement, dated February 11, 2008, between Amit Sachdev and Vertex.*		10-Q (Exhibit 10.4)	May 12, 2008	000-19319
10.53	Change of Control Agreement, dated February 11, 2008, between Amit Sachdev and Vertex.*		10-K (Exhibit 10.51)	February 11, 2008	000-19319
10.54	Form of Employee Non-Disclosure and Inventions Agreement.*		S-1 (Exhibit 10.4)	May 30, 1991	33-40966
10.55	Vertex Pharmaceuticals Incorporated Executive Compensation Program.*		10-Q (Exhibit 10.6)	May 12, 2008	000-19319
10.56	Form of Restricted Stock Agreement between Vertex and each of the individuals listed on Schedule 1 thereto.*		10-Q (Exhibit 10.8)	November 9, 2004	000-19319

Exhibit Number	Exhibit Description	Filed with this report	Incorporated by Reference herein from—Form or Schedule	Filing Date/ Period Covered	SEC File/ Reg. Number
10.57	Form of Amendment to Employment Agreement and Change of Control Agreement, dated December 2008, entered into by Vertex and each of Amit Sachdev and Lisa Kelly-Croswell.*		10-K (Exhibit 10.67)	February 17, 2009	000-19319
10.58	Vertex Employee Compensation Plan.*	Х			
10.59	Vertex Pharmaceuticals Non-Employee Board Compensation.*	х			
10.60	Executive Employment Agreement, dated as of November 1, 1994, between Vertex and Joshua S. Boger.*		10-K (Exhibit 10.6)	Year Ended December 31, 1994	000-19319
10.61	Amendment to Employment Agreement, dated as of May 12, 1995, between Vertex and Joshua S. Boger.*		10-Q (Exhibit 10.1)	Quarter Ended June 30, 1995	000-19319
10.62	Second Amendment to Employment Agreement, dated as of November 8, 2004, between Vertex and Joshua S. Boger.*		10-Q (Exhibit 10.9)	November 9, 2004	000-19319
10.63	Third Amendment to Employment Agreement, dated December 30, 2008, between Vertex and Joshua S. Boger.*		10-K (Exhibit 10.30)	February 17, 2009	000-19319
10.64	Transition Agreement between Joshua S. Boger and Vertex, dated February 5, 2009.*		8-K (Exhibit 10.3)	February 10, 2009	000-19319
10.65	Employment Agreement, between Vertex Pharmaceuticals Incorporated and Kurt Graves, dated June 29, 2007.*		10-Q (Exhibit 10.3)	August 9, 2007	000-19319
10.66	Amendment No. 1 to Employment Agreement between Kurt Graves and Vertex, dated December 29, 2008.*		10-K (Éxhibit 10.65)	February 17, 2009	000-19319
10.67	Employment Agreement, dated February 11, 2008, between Richard C. Garrison and Vertex.*		10-Q (Exhibit 10.5)	May 12, 2008	000-19319
21.1	Subsidiaries of Vertex Pharmaceuticals Incorporated.	Х			
23.1	Consent of Independent Registered Public Accounting Firm Ernst & Young LLP.	Х			
31.1	Certification of the Chief Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002.	Х			
31.2	Certification of the Chief Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002.	х			
32.1	Certification of the Chief Executive Officer and the Chief Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002.	х			

\* Management contract, compensatory plan or agreement.

Confidential portions of these documents have been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

# SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

# VERTEX PHARMACEUTICALS INCORPORATED

February 19, 2010

/s/ MATTHEW W. EMMENS By:

> Matthew W. Emmens Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Title	Date
/s/ MATTHEW W. EMMENS Matthew W. Emmens	Chief Executive Officer, Chairman of the Board and President (Principal Executive	February 19, 2010
Watthew W. Emmens	Officer)	
/s/ IAN F. SMITH Ian F. Smith	Executive Vice President and Chief Financial Officer (Principal Financial Officer)	February 19, 2010
/s/ PAUL M. SILVA	Vice President and Corporate Controller	February 10, 2010
Paul M. Silva	(Principal Accounting Officer)	February 19, 2010
/s/ CHARLES A. SANDERS	Lead Independent Director	February 19, 2010
Charles A. Sanders	Leau independent Director	rebluary 19, 2010
/s/ JOSHUA S. BOGER	Director	February 19, 2010
Joshua S. Boger	Dictor	1001uary 19, 2010
/s/ Roger W. Brimblecombe	Director	February 19, 2010
Roger W. Brimblecombe	Director	reoluary 19, 2010
/s/ STUART J.M. COLLINSON	Director	February 19, 2010
Stuart J.M. Collinson	Director	1001uary 19, 2010
/s/ Eugene H. Cordes	Director	February 19, 2010
Eugene H. Cordes	Director	10010ary 19, 2010
/s/ Jeffrey M. Leiden	Director	February 19, 2010
Jeffrey M. Leiden	Director	1001daiy 19, 2010
/s/ Bruce I. Sachs	Director	February 19, 2010
Bruce I. Sachs	Director	1001daly 19, 2010
/s/ Elaine S. Ullian	Director	February 19, 2010
Elaine S. Ullian	Director	1001uary 19, 2010
/s/ Dennis L. Winger	Director	February 19, 2010
Dennis L. Winger		1001uary 19, 2010

# **Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders of Vertex Pharmaceuticals Incorporated

We have audited the accompanying consolidated balance sheets of Vertex Pharmaceuticals Incorporated as of December 31, 2009 and 2008, and the related consolidated statements of operations, stockholders' equity and comprehensive loss, and cash flows for each of the three years in the period ended December 31, 2009. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Vertex Pharmaceuticals Incorporated at December 31, 2009 and 2008, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2009, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Vertex Pharmaceuticals Incorporated's internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 19, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts February 19, 2010

# **Consolidated Balance Sheets**

# (in thousands, except share and per share amounts)

Assets         2009         2008           Current assets:         Cash and cash equivalents         \$ 446,658         \$ 389,115           Marketable securities, available for sale         838,255         442,986           Accounts receivable         9,601         23,489           Prepaid expenses and other current assets         12,512         11,991           Total current assets         1,307,026         867,581
Current assets: Cash and cash equivalents.\$ 446,658 838,255\$ 389,115 389,115 442,986 442,986 Accounts receivable\$ 446,658 838,255\$ 389,115 442,986 442,986 23,489 12,512Prepaid expenses and other current assets9,601 12,51223,489 11,991 11,991Total current assets12,512 1,307,02611,307,026
Cash and cash equivalents       \$ 446,658       \$ 389,115         Marketable securities, available for sale       838,255       442,986         Accounts receivable       9,601       23,489         Prepaid expenses and other current assets       12,512       11,991         Total current assets       1,307,026       867,581
Total current assets         1,307,026         867,581
Restricted cash
Liabilities and Stockholders' Equity
Current liabilities:36,989\$ 51,760Accrued expenses and other current liabilities118,75394,203Accrued interest5715,345Deferred revenues, current portion74,95637,678Accrued restructuring expense, current portion6,3166,316Convertible senior subordinated notes (due February 2013), current portion (Note V)32,071Other obligations15,22721,255
Total current liabilities         284,883         216,564
Iotal current habilities       204,863       210,304         Accrued restructuring expense, excluding current portion       27,701       27,745         Convertible senior subordinated notes (due February 2013), excluding current portion       287,500
Secured notes (due October 2012)121,765Liability related to sale of potential future milestone payments38,207Deferred revenues, excluding current portion225,575Deferred tax liability160,278Other liabilities733
Total liabilities
Commitments and contingencies (Note K and Note T) Stockholders' equity: Preferred stock, \$0.01 par value; 1,000,000 shares authorized; none issued and outstanding at December 31, 2009 and 2008
and 2008; 199,953,025 and 151,243,364 shares issued and outstanding at         December 31, 2009 and 2008, respectively       1,982         Additional paid-in capital       3,784,787         Accumulated other comprehensive (loss) income       (640)         Accumulated deficit       (2,689,783)         (2,047,605)
Total stockholders' equity         1,096,346         238,874
Total liabilities and stockholders' equity \$ 1,955,488 \$ 980,479

**Consolidated Statements of Operations** 

(in thousands, except per share amounts)

· · · ·	Years	Ended Decemb	er 31,
	2009	2008	2007
Revenues: Royalty revenues Collaborative revenues Total revenues	\$ 28,320 73,569 101,889	\$ 37,483 <u>138,021</u> <u>175,504</u>	\$ 47,973 <u>151,039</u> 199,012
Costs and expenses: Royalty expenses	14,202	15,686	13,904
Research and development expenses	550,274 130,192 6,240	516,912 101,290 4,324	519,227 78,554 7,119
Restructuring expense       Intangible asset impairment charges         Acquisition-related expenses       Intangible asset	7,200 7,793		
Total costs and expenses	715,901	638,212	618,804
Loss from operations	(614,012) 5,010 (13,192)	(462,708) 16,328 (13,471)	(419,792) 30,798 (2,285)
Loss on exchanges of convertible subordinated notes Loss on derivative instruments, net	(18,137) (1,847)		
Net loss	<u>\$(642,178)</u>	<u>\$(459,851</u> )	<u>\$(391,279</u> )
Basic and diluted net loss per common share	<u>\$ (3.71</u> )	<u>\$ (3.27)</u>	<u>\$ (3.03)</u>
Basic and diluted weighted-average number of common shares outstanding	173,259	140,556	128,986

# Consolidated Statements of Stockholders' Equity and Comprehensive Loss

# (in thousands)

		n Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity	Comprehensive Income (Loss)
Balance, December 31, 2006	126,121	\$1,244	\$1,702,128	\$ (962)	\$(1,196,475)	\$ 505,935	
Unrealized holding gains on márketable securities Reclassification adjustment for realized gain on marketable	·			1,751		1,751	\$ 1,751
securities included in net loss				100		100	100
Translation adjustments	•			(8)	(201 270)	(8)	(8)
Net loss					(391,279)	(391,279)	(391,279)
Comprehensive loss							<b>\$(389,436)</b>
Issuances of common stock: Convertible subordinated notes converted Benefit plans Stock-based compensation expense	3,992 2,763	40 28	59,035 36,286 59,407			59,075 36,314 59,407	
Balance, December 31, 2007	132,876	\$1,312	\$1,856,856	\$ 881	\$(1,587,754)	\$ 271,295	
Unrealized holding gains on marketable securities Reclassification adjustment for				3,683		3,683	\$ 3,683
realized loss on marketable securities included in net loss Translation adjustments				(1,242) (154)	(459,851)	(1,242) (154) (459,851)	(1,242) (154) (459,851)
Comprehensive loss							\$(457,564)
Issuances of common stock:         Equity offerings         Benefit plans         Stock-based compensation expense	2,844	155	329,990 36,986 57,985			330,145 37,013 57,985	
Balance, December 31, 2008	151,245	\$1,494	\$2,281,817	\$ 3,168	\$(2,047,605)	\$ 238,874	
Unrealized holding losses on marketable securities Translation adjustments Net loss				(3,178) (630)	(642,178)	(3,178) (630) (642,178)	\$ (3,178) (630) (642,178)
Comprehensive loss							\$(645,986)
Issuances of common stock:         Convertible subordinated notes         exchanges         Acquisition of ViroChem         Equity offerings         Benefit plans         Stock-based compensation expense         Balance, December 31, 2009	11,582 10,734 23,000 3,394	116 107 230 35 \$1,982	270,776 290,450 801,155 53,867 86,722 \$3,784,787	<del>、(640</del> )	\$(2,689,783)	270,892 290,557 801,385 53,902 86,722 \$1,096,346	
Datance, December 51, 2009		φ1,70Z	φJ,104,101	φ (0+0) 	Ψ(2,005,765)	#1,070,340	

# **Consolidated Statements of Cash Flows**

# (in thousands)

	Years Er	ber 31,	
	2009	2008	2007
Cash flows from operating activities:			
Net loss	\$ (642,178)	) \$(459,851)	\$(391,279)
Adjustments to reconcile net loss to net cash used in operating activities:	20 107	32 106	27,459
Depreciation and amortization expense	30,107 86,722	32,196 57,985	27,439 59,407
Stock-based compensation expense	6,044	5,027	4,340
Intangible asset impairment charges	7,200	5,027	
Secured notes (due 2012) discount amortization expense	3,125		_
Change in fair value of derivatives	1,847		_
Change in deferred tax liability	(2,225)	) —	
Loss on disposal of property and equipment	2,211	11	142
Realized (gain) loss on marketable securities		(633)	155
Loss on exchange of convertible subordinated notes	18,137		_
Changes in operating assets and liabilities, excluding the effect of an acquisition:	12 000	7 021	21 602
Accounts receivable	13,900 2,070		31,603 (803)
Accounts payable	(15,057		17,382
Accrued expenses and other liabilities	8,924	, ,	22,032
Accrued restructuring expense	(47		2,219
Accrued interest	(1,423)		(1,694)
Deferred revenues	53,057	115,094	(23,439)
Net cash used in operating activities	(427,586)	(226,482)	(252,476)
Cash flows from investing activities:			
Purchases of marketable securities	(1,186,701)		(317,470)
Sales and maturities of marketable securities	788,263	427,648	755,620
Payment for the acquisition of ViroChem, net of cash acquired	(87,422) (23,496)	·	(32,415)
Increase in restricted cash			(52,415)
Decrease (increase) in other assets	679		(569)
Net cash (used in) provided by investing activities	(508,732)	′	405,166
Cash flows from financing activities:			
Issuances of common stock from employee benefit plans, net	47,850	31,983	31,965
Issuances of common stock from stock offerings, net	801,385	330,145	
Issuances of convertible senior subordinated notes (due February 2013), net		278,607	
Issuance of secured notes (due October 2012) and sale of potential future milestones			
payments, net	149,902		—
Repayment of collaborator development loan (due May 2008)	—	(19,997)	
Principal payments on convertible subordinated notes (due September 2007)	(121)	、 —	(42,102)
Debt exchange costs	(131)		(53)
Net cash provided by (used in) financing activities	999,006	620,738	(10,190)
Effect of changes in exchange rates on cash	(5,145)	)(154)	(8)
Net increase in cash and cash equivalents	57,543 389,115	33,452 355,663	142,492 213,171
Cash and cash equivalents-end of period	\$ 446,658	\$ 389,115	\$ 355,663
Supplemental disclosure of cash flow information:			
Cash paid for interest	\$ 10,248	\$ 6,676	\$ 3,820
Cash paid for taxes	\$	\$ _	\$
Cash paid for taxes Exchange/conversion of convertible subordinated notes for common stock Accrued interest offset to additional paid-in capital on exchange/conversion of convertible	\$ 255,429	\$ —	\$ 59,648
subordinated notes	\$ 3,355	\$ —	\$ 211
Unamortized debt issuance costs of exchanged/converted convertible subordinated notes offset	\$ 5,899	\$	\$ 730
to additional paid-in capital	\$ 290,557		\$ _
	φ 20,0,001	÷	•

# Notes to Consolidated Financial Statements

#### A. The Company

Vertex Pharmaceuticals Incorporated ("Vertex" or the "Company") is in the business of discovering, developing and commercializing small molecule drugs for the treatment of serious diseases. Telaprevir, the Company's lead drug candidate, is an oral hepatitis C protease inhibitor and one of the most advanced of a new class of antiviral treatments in clinical development that targets hepatitis C virus ("HCV") infection. Telaprevir is being evaluated in a registration program focused on treatment-naïve and treatment-failure patients with genotype 1 HCV infection. The Company also is developing, among other drug candidates, VX-770, which is being evaluated in a registration program focused on patients with cystic fibrosis who have the G551D mutation in the gene responsible for cystic fibrosis.

The Company's net loss for 2009 was \$642.2 million, or \$3.71 per basic and diluted common share, and the Company expects to incur operating losses at least until it obtains marketing approval and successfully commercializes a product. As of December 31, 2009, the Company had cash, cash equivalents and marketable securities of \$1.3 billion. The Company expects that the Company's current cash, cash equivalents and marketable securities will be sufficient to fund its operations for the next twelve months. The Company may seek additional financing and expects that it would need to seek additional financing if the development of telaprevir were terminated or significantly delayed. There can be no assurance that additional financing would be available on acceptable terms, if at all. If adequate funds are not available, the Company may be required to curtail significantly or discontinue one or more of the Company's research, drug discovery or development programs or attempt to obtain funds through arrangements that may require the Company to relinquish rights to certain of the Company's drugs or drug candidates.

Vertex is subject to risks common to companies in its industry including, but not limited to, the dependence on the success of the Company's lead drug candidate, uncertainty about clinical trial outcomes, limited experience in drug development, manufacturing, and sales and marketing, rapid technological change and competition, uncertain protection of proprietary technology, the need to comply with government regulations, share price volatility, uncertainties relating to pharmaceutical pricing and reimbursement, dependence on collaborative relationships and potential product liability.

On March 12, 2009, Vertex acquired ViroChem Pharma Inc. ("ViroChem"). The Company consolidated ViroChem's operating results with those of Vertex beginning on the date of the acquisition. See Note Q, "Acquisition of ViroChem Pharma Inc.," for additional information regarding the acquisition.

The Company has evaluated subsequent events through February 19, 2010, the date of issuance of the consolidated financial statements. During this period, the Company did not have any material recognizable subsequent events. However, the Company did have a nonrecognizable subsequent event related to its decision to redeem \$32.1 million in outstanding principal amount of 4.75% convertible senior subordinated notes due 2013. See Note V, "Subsequent Event," for additional information.

#### **B.** Accounting Policies

#### Basis of Presentation

The consolidated financial statements reflect the operations of the Company and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated. The Company operates in one segment, pharmaceuticals, and all revenues are from United States operations.

## Notes to Consolidated Financial Statements (Continued)

#### **B.** Accounting Policies (Continued)

## Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the amounts of revenues and expenses during the reported periods. Significant estimates in these consolidated financial statements have been made in connection with the calculation of revenues, research and development expenses, stock-based compensation expense, and restructuring expense, the value of intangible assets, derivative instruments and debt securities. The Company bases its estimates on historical experience and various other assumptions, including in certain circumstances future projections, that management believes to be reasonable under the circumstances. Actual results could differ from those estimates. Changes in estimates are reflected in reported results in the period in which they become known.

#### Reclassification in the Preparation of Financial Statements

Certain amounts in prior years' financial statements have been reclassified to conform to the current presentation. The reclassifications had no effect on the reported net loss.

#### Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of money market funds and marketable securities. The Company places these investments with highly rated financial institutions, and, by policy, limits the amounts of credit exposure to any one financial institution. These amounts at times may exceed federally insured limits. The Company has not experienced any credit losses in these accounts and does not believe it is exposed to any significant credit risk on these funds. The Company has no foreign exchange contracts, option contracts or other foreign exchange hedging arrangements.

The Company's revenues have been generated from a limited number of collaborators in the biotechnology and pharmaceuticals industries in the United States, Europe and Japan. In 2009, the Company had significant revenue transactions with Janssen Pharmaceutica, N.V. ("Janssen") and Mitsubishi Tanabe Pharma Corporation ("Mitsubishi Tanabe") that accounted for 54% and 18%, respectively of the Company's total revenues. In 2008, the Company had significant revenue transactions with Janssen that accounted for 68% of the Company's total revenues. In 2007, the Company had significant revenue transactions with Janssen and GlaxoSmithKline plc ("GlaxoSmithKline") that accounted for 59% and 24%, respectively, of the Company's total revenues.

Receivables from Janssen, GlaxoSmithKline and Mitsubishi Tanabe represented 36%, 36% and 15%, respectively, of the Company's accounts receivable balance at December 31, 2009. Receivables from Janssen, GlaxoSmithKline and Mitsubishi Tanabe Pharma Corporation represented 67%, 17% and 11%, respectively, of the Company's accounts receivable balance at December 31, 2008. Management believes that credit risks associated with these collaborators are not significant.

## Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase to be cash equivalents. Cash equivalents consist principally of money

#### Notes to Consolidated Financial Statements (Continued)

## **B.** Accounting Policies (Continued)

market funds and debt securities. Changes in cash and cash equivalents may be affected by shifts in investment portfolio maturities as well as by actual cash receipts and disbursements.

## Marketable Securities

Marketable securities consist of investments in U.S. Treasuries, government-sponsored enterprise securities and high-grade corporate bonds and commercial paper that are classified as available-for-sale. The Company classifies marketable securities available to fund current operations as current assets on the consolidated balance sheets. Marketable securities are classified as long-term assets on the consolidated balance sheets if (i) they have been in an unrealized loss position for longer than one year and (ii) the Company has the ability and intent to hold them (a) until the carrying value is recovered and (b) such holding period may be longer than one year. Marketable securities are stated at fair value with their unrealized gains and losses included as a component of accumulated other comprehensive income (loss), which is a separate component of stockholders' equity, until such gains and losses are realized. The fair value of these securities is based on quoted prices for identical or similar assets. If a decline in the fair value is considered other-than-temporary, based on available evidence, the unrealized loss is transferred from other comprehensive income (loss) to the consolidated statements of operations. There were no charges taken for other than temporary declines in fair value of marketable securities in 2009, 2008 or 2007. Realized gains and losses are determined on the specific identification method and are included in interest income in the consolidated statements of operations. Please refer to Note G, "Marketable Securities," for further information.

#### Stock-based Compensation Expense

The Company expenses the fair value of employee stock options and other forms of stock-based employee compensation over the associated employee service period or for awards with market conditions, the derived service period. For awards with performance conditions, the Company makes estimates regarding the likelihood of satisfaction of the performance conditions that affect the period over which the expense is recognized. Compensation expense is determined based on the fair value of the award at the grant date, including estimated forfeitures, and is adjusted to reflect actual forfeitures and the outcomes of certain market and performance conditions. Please refer to Note D, "Stock-based Compensation Expense," for further information.

#### Research and Development Expenses

All research and development expenses, including amounts funded by research and development collaborations, are expensed as incurred. Effective January 1, 2008, the Company has deferred and capitalized nonrefundable advance payments made by the Company for research and development activities until the related goods are delivered or the related services are performed. Prior to January 1, 2008, the Company expensed nonrefundable advance payments for research and development activities upon payment.

Research and development expenses are comprised of costs incurred by the Company in performing research and development activities, including salary and benefits; stock-based compensation expense; laboratory supplies and other direct expenses; contractual services, including clinical trial and pharmaceutical development costs; commercial supply investment in its drug candidates; and infrastructure costs, including facilities costs and depreciation expense. The Company

# Notes to Consolidated Financial Statements (Continued)

# **B.** Accounting Policies (Continued)

evaluates periodically whether a portion of its commercial supply investment may be capitalized as inventory. Generally, inventory may be capitalized if it is probable that future revenues will be generated from the sale of the inventory and that these revenues will exceed the cost of the inventory. The Company is continuing to expense all of its commercial supply investment due to the high risk inherent in drug development.

The Company's collaborators have funded portions of the Company's research and development programs related to specific drug candidates and research targets, including telaprevir in 2009; telaprevir, certain kinases and certain cystic fibrosis research targets in 2008; and telaprevir, VX-702, VX-770, certain kinases and certain cystic fibrosis research targets in 2007. The Company's collaborative revenues were \$73.6 million, \$138.0 million and \$151.0 million, respectively, for 2009, 2008 and 2007. The Company's research and development expenses allocated to programs in which a collaborator funded at least a portion of the research and development expenses were approximately \$149 million, approximately \$156 million and approximately \$266 million, respectively, for 2009, 2008 and 2007.

#### Restructuring Expense

The Company records costs and liabilities associated with exit and disposal activities based on estimates of fair value in the period the liabilities are incurred. In periods subsequent to initial measurement, changes to the liability are measured using the credit-adjusted risk-free discount rate applied in the initial period. Liabilities are evaluated and adjusted as appropriate at least on a quarterly basis for changes in circumstances. Please refer to Note F, "Restructuring Expense," for further information.

#### Revenue Recognition

#### **Collaborative Arrangements**

The Company's revenues are generated primarily through collaborative research, development and/or commercialization agreements. The terms of these agreements typically include payment to the Company of one or more of the following: nonrefundable, up-front license fees; funding of research and/or development efforts; milestone payments; and royalties on product sales.

Agreements containing multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the collaborator and whether there is objective and reliable evidence of the fair value of the undelivered obligation(s). The consideration received is allocated among the separate units either on the basis of each unit's fair value or using the residual method, and the applicable revenue recognition criteria are applied to each of the separate units.

The Company recognizes revenues from nonrefundable, up-front license fees on a straight-line basis over the contracted or estimated period of performance, which is typically the research or development term. Research and development funding is recognized as earned, ratably over the period of effort.

#### Notes to Consolidated Financial Statements (Continued)

## **B.** Accounting Policies (Continued)

Substantive milestones achieved in collaboration arrangements are recognized as earned when the corresponding payment is reasonably assured, subject to the following policies in those circumstances where the Company has obligations remaining after achievement of the milestone:

- In those circumstances where collection of a substantive milestone payment is reasonably assured, the Company has remaining obligations to perform under the collaboration arrangement and the Company has sufficient evidence of the fair value of its remaining obligations, management considers the milestone payment and the remaining obligations to be separate units of accounting. In these circumstances, the Company uses the residual method to allocate revenues among the milestone and the remaining obligations.
- In those circumstances where collection of a substantive milestone payment is reasonably assured and the Company has remaining obligations to perform under the collaboration arrangement, but the Company does not have sufficient evidence of the fair value for its remaining obligations, management considers the milestone payment and the remaining obligations under the contract as a single unit of accounting. If the collaboration does not require specific deliverables at specific times or at the end of the contract term, but rather, the Company's obligations are satisfied over a period of time, substantive milestone payments are recognized over the period of performance. This typically results in a portion of the milestone payment being recognized as revenue on the date the milestone is achieved equal to the applicable percentage of the performance period that has elapsed as of the date the milestone is achieved, with the balance being deferred and recognized over the remaining period of performance.

At the inception of each agreement that includes milestone payments, the Company evaluates whether each milestone is substantive on the basis of the contingent nature of the milestone, specifically reviewing factors such as the scientific and other risks that must be overcome to achieve the milestone, as well as the level of effort and investment required. Milestones that are not considered substantive and that do not meet the separation criteria are accounted for as license payments and recognized on a straight-line basis over the remaining period of performance.

Payments received or reasonably assured after performance obligations are met completely are recognized as earned.

Royalty revenues typically are recognized based upon actual and estimated net sales of licensed products in licensed territories, as provided by the licensee, and generally are recognized in the period the sales occur. The Company reconciles and adjusts for differences between actual royalty revenues and estimated royalty revenues in the quarter they become known. These differences have not historically been significant.

## Sale of Future Royalties

In the circumstance where the Company has sold its rights to future royalties under a license agreement and also maintains continuing involvement in the royalty arrangement (but not significant continuing involvement in the generation of the cash flows due to the purchaser), the Company defers recognition of the proceeds it receives for the royalty stream and recognizes these deferred revenues over the life of the license agreement. The Company recognizes these deferred revenues pursuant to the units-of-revenue method. Under this method, the amount of deferred revenues to be recognized as royalty revenues in each period is calculated by multiplying the following: (1) the royalty payments due

#### Notes to Consolidated Financial Statements (Continued)

# **B.** Accounting Policies (Continued)

to the purchaser for the period by (2) the ratio of the remaining deferred revenue amount to the total estimated remaining royalty payments due to the purchaser over the term of the agreement.

### Property and Equipment

Property and equipment are recorded at cost. Depreciation and amortization is provided using the straight-line method over the estimated useful life of the related asset, generally four to seven years for furniture and equipment and three to five years for computers and software. Leasehold improvements are amortized using the straight-line method over the lesser of the useful life of the improvements or the remaining life of the associated lease. Major additions and betterments are capitalized; maintenance and repairs to an asset that do not improve or extend its life are charged to operations. When assets are retired or otherwise disposed of, the assets and related allowances for depreciation and amortization are eliminated from the accounts and any resulting gain or loss is reflected in the Company's consolidated statements of operations.

## Income Taxes

Deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the financial statement carrying amounts and the income tax bases of assets and liabilities. A valuation allowance is applied against any net deferred tax asset if, based on the weighted available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

#### Financial Transaction Expenses

Issuance costs incurred to complete the Company's convertible senior subordinated note offering and the financial transactions that the Company entered into in September 2009 are deferred and included in other assets on the Company's consolidated balance sheet. The issuance costs are amortized using the effective interest rate method over the term of the related debt or financing instrument. The amortization expense related to the issuance costs is included in interest expense on the consolidated statements of operations.

The Company defers direct and incremental costs associated with the sale of its rights to future royalties. These costs are included in other assets on the Company's consolidated balance sheet and are amortized in the same manner and over the same period in which the related deferred revenues are recognized as royalty revenues. The amortization expense related to these transaction expenses is included in royalty expenses on the consolidated statements of operations.

Expenses incurred in connection with common stock issuances are recorded as an offset to additional paid-in capital on the consolidated balance sheets.

#### **Business** Combinations

The Company assigns the value of the consideration transferred to acquire a business to the tangible assets and identifiable intangible assets acquired and liabilities assumed on the basis of their fair values at the date of acquisition. The Company assesses the fair value of assets, including intangible assets such as in-process research and development, using a variety of methods including present-value models. Each asset is measured at fair value from the perspective of a market participant.

#### Notes to Consolidated Financial Statements (Continued)

# **B.** Accounting Policies (Continued)

The method used to estimate the fair values of in-process research and development assets incorporates significant assumptions regarding the estimates market participants would make in order to evaluate an asset: including market participants' assumptions regarding the probability of completing in-process research and development projects, which would require obtaining regulatory approval for marketing of the associated drug candidate; market participants' estimates regarding the timing of and the expected costs to complete in-process research and development projects; market participants' estimates of future cash flows from potential product sales; and the appropriate discount rates for market participants. Transaction costs and restructuring costs associated with the transaction are expensed as incurred.

#### In-process Research and Development Assets

In-process research and development assets acquired in a business combination are recorded as of the acquisition date at fair value and accounted for as indefinite-lived intangible assets. These assets are maintained on the Company's consolidated balance sheet until either the project underlying them is completed or the assets become impaired. If a project is completed, the carrying value of the related intangible asset is amortized over the remaining estimated life of the asset beginning in the period in which the project is completed. If a project becomes impaired or is abandoned, the carrying value of the related intangible asset is written down to its fair value and an impairment charge is taken in the period in which the impairment occurs. In-process research and development assets are tested for impairment on an annual basis as of October 1, or earlier if impairment indicators are present.

## Goodwill

The difference between the purchase price and the fair value of assets acquired and liabilities assumed in a business combination is allocated to goodwill. Goodwill is evaluated for impairment on an annual basis as of October 1, or earlier if impairment indicators are present.

#### Derivative Instruments and Embedded Derivatives

The Company has entered into financial transactions involving a free-standing derivative instrument and embedded derivatives. These financial transactions include arrangements involving convertible notes, secured notes and the sale of potential future milestone payments. The embedded derivatives are required to be bifurcated from the host instruments because the derivatives are not clearly and closely related to the host instruments. The Company determines the fair value of each derivative instrument or embedded derivative on the date of issuance. The estimates of the fair value of these derivatives, particularly with respect to derivatives related to the achievement of milestones in the development of specific drug candidates, include significant assumptions regarding the estimates market participants would make in order to evaluate the derivative. Changes in the fair value of these derivatives are evaluated on a quarterly basis. Please refer to Note R, "September 2009 Financial Transactions," for further information.

#### Comprehensive Loss

Comprehensive loss consists of net loss and other comprehensive income (loss), which includes foreign currency translation adjustments and unrealized gains and losses on certain marketable securities. For purposes of comprehensive loss disclosures, the Company does not record tax provisions

#### Notes to Consolidated Financial Statements (Continued)

# **B.** Accounting Policies (Continued)

or benefits for the net changes in foreign currency translation adjustment, as the Company intends to permanently reinvest undistributed earnings in its foreign subsidiaries.

#### Foreign Currency Translation

The functional currency of the Company's foreign subsidiaries is the local currency. Assets and liabilities of the foreign subsidiaries are translated into U.S. dollars at rates of exchange in effect at the end of the year. Revenue and expense amounts are translated using the average exchange rates for the period. Net unrealized gains and losses resulting from foreign currency translation are included in other comprehensive income (loss), which is a separate component of stockholders' equity. Included in accumulated other comprehensive income (loss) is a net unrealized loss related to foreign currency translation of \$604,000 at December 31, 2009, a net unrealized gain related to foreign currency translation of \$127,000 at December 31, 2008 and a net unrealized gain related to foreign currency translation of \$181,000 at December 31, 2007.

#### Basic and Diluted Net Loss per Common Share

Basic net loss per common share is based upon the weighted-average number of common shares outstanding during the period, excluding restricted stock that has been issued but is not yet vested. Diluted net loss per common share is based upon the weighted-average number of common shares outstanding during the period plus additional weighted-average common equivalent shares outstanding during the period when the effect is dilutive. Common equivalent shares result from the assumed exercise of outstanding stock options (the proceeds of which are then assumed to have been used to repurchase outstanding stock using the treasury stock method), the assumed conversion of convertible notes and the vesting of unvested restricted shares of common stock. Common equivalent shares have not been included in the net loss per common share calculations because the effect would have been anti-dilutive. Total potential gross common equivalent shares consisted of the following:

	At December 31,		
	2009	2008	2007
	(in thousands, except per share amounts)		
Stock options	19,232	16,497	15,358
Weighted-average exercise price (per share)	\$31.38	\$29.16	\$28.70
Convertible notes	1,386	12,425	_
Weighted-average conversion price (per share)	\$23.14	\$23.14	n/a
Unvested restricted shares	1,727	1,851	1,676

#### Recent Accounting Pronouncements

In January 2010, the Financial Accounting Standards Board ("FASB") issued updated guidance to amend the disclosure requirements related to recurring and nonrecurring fair value measurements. This update requires new disclosures on significant transfers of assets and liabilities between Level 1 and Level 2 of the fair value hierarchy (including the reasons for these transfers) and the reasons for any transfers in or out of Level 3. This update also requires a reconciliation of recurring Level 3 measurements about purchases, sales, issuances and settlements on a gross basis. In addition to these new disclosure requirements, this update clarifies certain existing disclosure requirements. For example, this update clarifies that reporting entities are required to provide fair value measurement disclosures

#### Notes to Consolidated Financial Statements (Continued)

# **B.** Accounting Policies (Continued)

for each class of assets and liabilities rather than each major category of assets and liabilities. This update also clarifies the requirement for entities to disclose information about both the valuation techniques and inputs used in estimating Level 2 and Level 3 fair value measurements. This update will become effective for the Company with the interim and annual reporting period beginning January 1, 2010, except for the requirement to provide the Level 3 activity of purchases, sales, issuances, and settlements on a gross basis, which will become effective for the Company with the interim and annual reporting period beginning January 1, 2011. The Company will not be required to provide the amended disclosures for any previous periods presented for comparative purposes. Other than requiring additional disclosures, adoption of this update will not have a material effect on the Company's consolidated financial statements.

In September 2009, the FASB provided updated guidance (1) on whether multiple deliverables exist, how the deliverables in a revenue arrangement should be separated, and how the consideration should be allocated; (2) requiring an entity to allocate revenue in an arrangement using estimated selling prices of deliverables if a vendor does not have vendor-specific objective evidence or third-party evidence of selling price; and (3) eliminating the use of the residual method and requiring an entity to allocate revenue using the relative selling price method. The update is effective for fiscal years beginning on or after June 15, 2010, with early adoption permitted. Adoption may either be on a prospective basis or by retrospective application. The Company is currently evaluating the effect of this update to its accounting and reporting systems and processes; however, at this time the Company is unable to quantify the impact on its consolidated financial statements of its adoption or determine the timing and method of its adoption.

In June 2009, the FASB issued an update to the accounting and disclosure requirements for the consolidation of variable interest entities ("VIE"s). This update requires a qualitative approach to identifying a controlling financial interest in a VIE, and requires ongoing assessment of whether an entity is a VIE and whether an interest in a VIE makes the holder the primary beneficiary of the VIE. This update will be effective for the Company on January 1, 2010. The Company is evaluating the effect of the pending adoption of this update, but does not expect this update to have a material effect on the Company's consolidated financial statements.

In June 2009, the FASB issued an update to the accounting and disclosure requirements for transfers of financial assets. This update is intended to improve the relevance, representational faithfulness, and comparability of the information that a reporting entity provides in its financial reports about a transfer of financial assets; the effects of a transfer on its financial position, financial performance, and cash flows; and a transferor's continuing involvement in transferred financial assets. The recognition and measurement provisions of this update shall be applied to transfers that occur on or after January 1, 2010, which is the date upon which this accounting update becomes effective for the Company. The Company is evaluating the effect of the pending adoption of this update, but does not expect this update to have a material effect on the Company's consolidated financial statements.

#### **C. Common and Preferred Stock**

#### Stock and Option Plans

At December 31, 2009, the Company had four stock-based employee compensation plans: the 1991 Stock Option Plan (the "1991 Plan"), the 1994 Stock and Option Plan (the "1994 Plan"), the 1996 Stock and Option Plan (the "1996 Plan") and the 2006 Stock and Option Plan (the "2006 Plan" and

# Notes to Consolidated Financial Statements (Continued)

#### C. Common and Preferred Stock (Continued)

together with the 1991 Plan, the 1994 Plan and the 1996 Plan, collectively, the "Stock and Option Plans") and one Employee Stock Purchase Plan (the "ESPP"). On May 15, 2008, the Company's stockholders approved an increase in the number of shares of common stock authorized for issuance under the 2006 Plan of 6,600,000, to a total of 13,902,380 shares of common stock, and an increase in the number of shares of common stock authorized for issuance under the ESPP of 2,000,000. On May 14, 2009, the Company's stockholders approved an increase in the number of shares of common stock authorized for issuance under the 2006 Plan of 7,700,000, to a total of 21,602,380 shares of common stock authorized for issuance under the Stock and Option Plans, the Company issues stock options and restricted stock awards with service conditions, which are generally the vesting periods of the awards. The Company also issues to certain members of senior management restricted stock awards ("PARS") and option awards that vest upon the earlier of the satisfaction of (i) a market or performance condition.

Under the 2006 Plan, the Company may issue restricted stock and options to its employees, directors and consultants for services. Stock options may be granted under the 2006 Plan either as options intended to qualify as "incentive stock options" ("ISOs") under the Internal Revenue Code or as non-qualified stock options ("NQSOs"). Each option granted under the 2006 Plan has an exercise price equal to the fair market value of the underlying common stock on the date of grant. For options issued to current employees, the date of grant is the date the option award is approved by the Company's Board of Directors. For grants to new employees, the date of grant is the employee's first day of employment. The price per share of restricted stock granted to employees is equal to \$0.01, the par value of the Company's common stock. Vesting of options and restricted stock generally is ratable over specified periods, usually four years, and is determined by the Company's Board of Directors. All options awarded under the 2006 Plan expire not more than ten years from the grant date.

Stock options granted under the 1991 Plan, the 1994 Plan and the 1996 Plan were granted either as ISOs or NQSOs. Under the 1991 Plan, stock options could only be granted to employees (including officers and directors who were employees) and to consultants of the Company (NQSOs only). Under the 1994 Plan and the 1996 Plan, stock rights, which may be (i) ISOs when Internal Revenue Code requirements are met, (ii) NQSOs, or (iii) shares of common stock or the opportunity to make a direct purchase of shares of common stock, could be granted to employees (including officers and directors who are employees) and consultants, advisors and non-employee directors (NQSOs and stock awards only). Under the 1991 Plan and the 1994 Plan, ISOs could only be granted at a price not less than the fair market value of the common stock on the date of the grant, and NQSOs could be granted at an exercise price established by the Board of Directors, which could have been less than, equal to or greater than the fair value of the common stock on the date of the grant. Stock options granted under the 1996 Plan could not have been granted at a price less than the fair market value of the common stock on the date of grant. Vesting is ratable over specified periods for all Stock and Option Plans, is generally four or five years, and was determined by the Board of Directors. All ISOs granted under the 1991 Plan, the 1994 Plan and the 1996 Plan expire not more than ten years from the date of grant.

The ESPP permits eligible employees to enroll in a twelve-month offering period comprising two six-month purchase periods. Participants may purchase shares of the Company's common stock, through payroll deductions, at a price equal to 85% of the fair market value of the common stock on the first day of the applicable twelve-month offering period, or the last day of the applicable six-month purchase period, whichever is lower. Purchase dates under the ESPP occur on or about May 14 and November 14 of each year.

#### Notes to Consolidated Financial Statements (Continued)

# C. Common and Preferred Stock (Continued)

The Company reserved an aggregate of 8,000,000 shares under the 1991 Plan and 1994 Plan. The Company reserved 22,000,000 shares under the 1996 Plan and 21,602,380 shares under the 2006 Plan. At December 31, 2009, the Company had 19,232,000 stock options outstanding and 1,727,000 outstanding and unvested restricted shares. At December 31, 2009, the Company had 6,543,000 shares of common stock available for grants under the 2006 Plan. At December 31, 2009, no shares were available for grants under the 1994 Plan or the 1996 Plan. As of December 31, 2009, 1,433,000 shares remained available for future purchases under the ESPP and approximately 453,000 shares remained available for grant under the 401(k) Plan.

#### Rights

Each Vertex shareholder also holds one share purchase right (a "Right") for each share of common stock owned. Each Right entitles the holder to purchase from the Company one half of one-hundredth of a share of Series A junior participating preferred stock, \$0.01 par value (the "Junior Preferred Shares"), of the Company at a price of \$135 per one half of one-hundredth of a Junior Preferred Share, subject to adjustment (the "Purchase Price"). The Rights are not exercisable until after the acquisition by a person or group of 15% or more of the outstanding common stock (an "Acquiring Person"), or after the announcement of an intention to make or the commencement of a tender offer or exchange offer, the consummation of which would result in the beneficial ownership by a person or group of 15% or more of the outstanding common stock (the earlier of such dates being called the "Distribution Date"). Until the Distribution Date (or earlier redemption or expiration of the Rights will be traded with, and only with, the common stock. Until a Right is exercised, the Right will not entitle the holder thereof to any rights as a stockholder.

If any person or group becomes an Acquiring Person, each holder of a Right, other than Rights beneficially owned by the Acquiring Person, will thereafter have the right to receive upon exercise and payment of the Purchase Price that number of shares of common stock having a market value of two times the Purchase Price and, if the Company is acquired in a business combination transaction or 50% or more of its assets are sold, each holder of a Right will thereafter have the right to receive upon exercise and payment of the Purchase Price that number of shares of common stock of the acquiring company that at the time of the transaction will have a market value of two times the Purchase Price.

At any time after any person becomes an Acquiring Person and prior to the acquisition by such person or group of 50% or more of the outstanding common stock, the Board of Directors of the Company may cause the Rights (other than Rights owned by such person or group) to be exchanged, in whole or in part, for common stock or Junior Preferred Shares, at an exchange rate of one share of common stock per Right or one half of one-hundredth of a Junior Preferred Share per Right.

At any time prior to the acquisition by a person or group of beneficial ownership of 15% or more of the outstanding common stock, the Board of Directors of the Company may redeem the Rights at a price of \$0.01 per Right.

The Rights have certain anti-takeover effects that will cause substantial dilution to a person or group that attempts to acquire a significant interest in Vertex on terms not approved by the Board of Directors.

## Notes to Consolidated Financial Statements (Continued)

# **D.** Stock-based Compensation Expense

The Company recognizes share-based payments to employees as compensation expense using the "fair value" method. The fair value of stock options and shares purchased pursuant to the ESPP is calculated using the Black-Scholes option pricing model. The fair value of restricted stock awards typically is based on intrinsic value on the date of grant. Stock-based compensation, measured at the grant date based on the fair value of the award, is recognized as expense ratably over the service period. The expense recognized over the service period includes an estimate of awards that will be forfeited.

For PARS awards granted in 2006, 2007 and 2008, a portion of the fair value of the common stock on the date of grant is recognized ratably over a derived service period that is equal to the estimated time to satisfy the market condition. The portion of the fair value of the common stock that is recognized over the derived service period is determined on the basis of the estimated probability that the PARS award will vest as a result of satisfying the market condition. For the PARS awards granted in 2008, 2007 and 2006, the derived service period relating to each market condition was shorter than the four-year service-based vesting period of the PARS. The difference between the fair value of the common stock on the date of grant and the value recognized over the derived service period is recognized ratably over the four-year service-based vesting period of the PARS. The stock-based compensation expense recognized over each of the derived service periods and the four-year service periods includes an estimate of awards that will be forfeited prior to the end of the derived service periods or the four-year service periods, respectively. For PARS awards granted in 2009, the shares vest on the fourth anniversary of the grant date, subject to accelerated vesting upon achievement of performance conditions. Stock-based compensation expense associated with the PARS issued in 2009 is being expensed ratably over the four-year service period.

For options to purchase 1.3 million shares that were granted in the fourth quarter of 2009 that vest upon the earlier of the satisfaction of (i) performance conditions or (ii) a service condition, the compensation expense is being recognized ratably over service periods of approximately five years.

The effect of stock-based compensation expense during the three years ended December 31, 2009 was as follows:

2000

2000

2007

	2009	2008	2007	
	(i	(in thousands)		
Stock-based compensation expense by type of award:				
Stock options	\$63,397	\$39,449	\$38,330	
Restricted stock (including PARS)	18,983	15,195	18,419	
ESPP issuances	4,342	3,343	2,658	
Total stock-based compensation expense	\$86,722	\$57,987	\$59,407	
Effect of stock-based compensation expense by line item:				
Research and development expenses	\$64,128	\$46,144	\$48,968	•
Sales, general and administrative expenses	22,594	11,843	10,439	
Total stock-based compensation expense	\$86,722	\$57,987	\$59,407	

F-17

#### Notes to Consolidated Financial Statements (Continued)

#### **D.** Stock-based Compensation Expense (Continued)

# Stock Options

All stock options awarded granted during 2009, 2008 and 2007 have exercise prices equal to the fair market value of the Company's common stock on the date the option was granted by the Company's board of directors. Under amendments to the 2006 Plan adopted on May 15, 2008, no options can be issued under the 2006 Plan with an exercise price less than the fair market value on the date of grant.

The stock options granted during 2008 included options to purchase 536,625 shares of common stock (the "Contingent Options") at an exercise price of \$18.93 per share that were granted to the Company's executive officers on February 7, 2008, subject to ratification by the Company's stockholders. At the Company's 2008 Annual Meeting of Stockholders, the stockholders ratified the Contingent Options as part of the Company's proposal to increase the number of shares authorized for issuance under the 2006 Plan. The Contingent Options are deemed for accounting purposes to have been granted on May 15, 2008 (the date of ratification by the Company's stockholders), and the grant-date fair value of the Contingent Options is calculated using a Black-Scholes option pricing model based on the fair market value of the Contingent Options on May 15, 2008. The options granted during 2009, 2008 and 2007 had a weighted-average grant-date fair value per share, measured on the grant date, of \$19.11, \$14.33 and \$17.45, respectively.

The Company recorded stock-based compensation expense of \$63.4 million, \$39.4 million and \$38.3 million in 2009, 2008 and 2007, respectively, related to stock options. The stock-based compensation expense related to stock options for 2009 included \$12.7 million related to stock options that were accelerated and modified in connection with transition arrangements and severance arrangements with certain of the Company's former executive officers. The stock-based compensation expense related to stock options for 2007 included \$1.9 million related to stock options accelerated in connection with an executive officer's severance arrangement.

As of December 31, 2009, there was \$109.6 million of total unrecognized stock-based compensation expense, net of estimated forfeitures, related to unvested options granted under the Stock and Option Plans. That expense is expected to be recognized over a weighted-average period of 3.07 years.

The Company uses the Black-Scholes option pricing model to estimate the fair value of stock options at the grant date. The Black-Scholes option pricing model uses the option exercise price as well as estimates and assumptions related to the expected price volatility of the Company's stock, the rate of return on risk-free investments, the expected period during which the options will be outstanding, and the expected dividend yield for the Company's stock to estimate the fair value of a stock option on the grant date.

The fair value of each option granted under the Stock and Option Plans during 2009, 2008 and 2007 was estimated on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions:

•	2009	2008	2007
Expected stock price volatility	57.77%	52.78%	51.95%
Risk-free interest rate		3.42%	4.81%
Expected term	6.31 years	5.78 years	5.74 years
Expected annual dividends	_		

#### Notes to Consolidated Financial Statements (Continued)

#### **D.** Stock-based Compensation Expense (Continued)

The weighted-average valuation assumptions were determined as follows:

- *Expected stock price volatility:* Options to purchase the Company's stock with remaining terms of greater than one year are regularly traded in the market. Expected stock price volatility is calculated using the trailing one month average of daily implied volatilities prior to grant date.
- *Risk-free interest rate:* The Company bases the risk-free interest rate on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected option term.
- *Expected term of options:* The expected term of options represents the period of time options are expected to be outstanding. The Company uses historical data to estimate employee exercise and post-vest termination behavior. The Company believes that all groups of employees exhibit similar exercise and post-vest termination behavior and therefore does not stratify employees into multiple groups in determining the expected term of options.
- *Expected annual dividends:* The estimate for annual dividends is \$0.00 because the Company has not historically paid, and does not intend for the foreseeable future to pay, a dividend.

The following table summarizes information related to the outstanding and vested options during 2009:

	Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life	Aggregate Intrinsic Value
	(in thousands)		(in years)	(in thousands)
Outstanding at December 31, 2008	16,497	\$29.16		
Granted	6,085	33.68		
Exercised	(2,069)	18.48		
Forfeited	(989)	30.47		
Expired	(292)	48.12		
Outstanding at December 31, 2009	19,232	\$31.38	6.45	\$260,644
Exercisable at December 31, 2009	11,895	\$31.04	4.96	\$177,979
Total exercisable or expected to vest	18,166	\$31.29	6.28	\$249,669

The aggregate intrinsic value in the table above represents the total pre-tax amount, net of exercise price, which would have been received by option holders if all option holders had exercised all options with an exercise price lower than the market price on December 31, 2009, which was \$43.19 based on the average of the high and low price of the Company's common stock on that date.

The total intrinsic value (the amount by which the fair market value exceeded the exercise price) of stock options exercised during 2009, 2008 and 2007 was \$36.4 million, \$23.7 million and \$28.3 million, respectively. The total cash received from employees as a result of employee stock option exercises during 2009, 2008 and 2007 was \$38.2 million, \$24.1 million and \$26.3 million, respectively.

The Company settles employee stock option exercises with newly issued common shares.

## Notes to Consolidated Financial Statements (Continued)

## **D.** Stock-based Compensation Expense (Continued)

#### Restricted Stock

The Company recorded stock-based compensation expense of \$19.0 million, \$15.2 million and \$18.4 million for 2009, 2008 and 2007, respectively, related to restricted shares outstanding during those periods. The stock-based compensation expense related to restricted stock for 2009 included \$2.2 million related to accelerated vesting of restricted stock awards in connection with transition arrangements and severance arrangements with certain of the Company's former executive officers. The stock-based compensation expense for restricted stock for 2008 included \$0.6 million related to accelerated vesting of restricted stock for 2008 included \$0.6 million related to accelerated vesting of restricted stock awards in connection with an executive officer's separation arrangement. The stock-based compensation expense related to restricted stock for 2007 included \$1.4 million related to accelerated vesting of restricted stock awards in connection with an executive officer's separation after the stock based compensation expense related to restricted stock for 2007 included \$1.4 million related to accelerated vesting of restricted stock awards in connection with an executive officer's separation arrangement. The stock-based compensation expense related to restricted stock for 2007 included \$1.4 million related to accelerated vesting of restricted stock awards in connection with an executive officer's separation arrangement.

As of December 31, 2009, there was \$31.5 million of total unrecognized stock-based compensation expense, net of estimated forfeitures, related to unvested restricted stock granted under the Company's Stock and Option Plans. The Company expects to recognize that expense over a weighted-average period of 2.52 years.

The following table summarizes the restricted stock activity of the Company during 2009:

	Restricted Stock	Weighted-Average Grant-Date Fair Value	
	(in thousands)	(per share)	
Outstanding and unvested at December 31, 2008	1,851	\$25.92	
Granted	951	33.55	
Vested	(839)	22.33	
Cancelled	(236)	30.54	
Outstanding and unvested at December 31, 2009	1,727	\$31.23	

The total fair value of the shares vesting during 2009, 2008 and 2007 (measured on the date of vesting) was \$26.5 million, \$11.0 million and \$22.5 million, respectively.

# Employee Stock Purchase Plan

The stock-based compensation expense related to the ESPP for 2009, 2008 and 2007 was \$4.3 million, \$3.3 million and \$2.7 million, respectively. As of December 31, 2009, there was \$2.3 million of total unrecognized stock-based compensation expense, net of estimated forfeitures, related to ESPP shares. The Company expects to recognize that expense during 2010.

During 2009, the following shares were issued to employees under the ESPP:

	Year Ended December 31, 2009
	(shares in thousands)
Number of shares	412
Average price paid per share	\$23.34

#### Notes to Consolidated Financial Statements (Continued)

# D. Stock-based Compensation Expense (Continued)

The weighted-average fair value of each purchase right granted during 2009, 2008 and 2007 was \$11.31, \$10.14 and \$8.45, respectively. The following table reflects the weighted-average assumptions used in the Black-Scholes option pricing model for 2009, 2008 and 2007:

· ·	2009	2008	2007
Expected stock price volatility	54.22% 0.39%	66.63% 1.16%	
Expected term	0.76 years	0.72 years	0.70 years
Expected annual dividends	—		_

The expected stock price volatility for ESPP offerings is based on implied volatility. The Company bases the risk-free interest rate on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected term. The expected term represents purchases and purchase periods that take place within the offering period. The expected annual dividends estimate is \$0.00 because the Company has not historically paid, and does not for the foreseeable future intend to pay, a dividend.

#### **E.** Fair Value of Financial Instruments

The fair value of the Company's financial assets and liabilities reflects the Company's estimate of amounts that it would have received in connection with the sale of the assets or paid in connection with the transfer of the liabilities in an orderly transaction between market participants at the measurement date. In connection with measuring the fair value of its assets and liabilities, the Company seeks to maximize the use of observable inputs (market data obtained from sources independent from the Company) and to minimize the use of unobservable inputs (the Company's assumptions about how market participants would price assets and liabilities). The following fair value hierarchy is used to classify assets and liabilities based on the observable inputs and unobservable inputs used in order to value the assets and liabilities:

- Level 1: Quoted prices in active markets for identical assets or liabilities. An active market for an asset or liability is a market in which transactions for the asset or liability occur with sufficient frequency and volume to provide pricing information on an ongoing basis.
- Level 2: Observable inputs other than Level 1 inputs. Examples of Level 2 inputs include quoted prices in active markets for similar assets or liabilities and quoted prices for identical assets or liabilities in markets that are not active.
- Level 3: Unobservable inputs based on the Company's assessment of the assumptions that market participants would use in pricing the asset or liability.

The Company's investment strategy is focused on capital preservation. The Company invests in instruments that meet credit quality standards as outlined in the Company's investment policy guidelines. These guidelines also limit the amount of credit exposure to any one issue or type of instrument. Beginning in the fourth quarter of 2007, the Company began to shift its investments to instruments that carry less exposure to market volatility and liquidity pressures. As of December 31,

#### Notes to Consolidated Financial Statements (Continued)

#### E. Fair Value of Financial Instruments (Continued)

2009, the Company's investments are in money market funds and short-term government guaranteed or supported securities.

As of December 31, 2009, all of the Company's financial assets that were subject to fair value measurements were valued using observable inputs. The Company's financial assets that were valued based on Level 1 inputs consist of a money market fund, U.S. Treasuries and government-sponsored enterprise securities, which are government-supported. The Company's money market fund also invests in government-sponsored enterprise securities. During 2009, 2008 and 2007, the Company did not record an other-than-temporary impairment charge related to its financial assets. The Company's financial liabilities that were subject to fair value measurement related to the financial transactions that the Company entered into in September 2009 are valued based on Level 3 inputs. Please refer to Note R, "September 2009 Financial Transactions."

The following table sets forth the Company's financial assets and liabilities subject to fair value measurements as of December 31, 2009:

	Fair Value Measurements as of December 31, 2009				
		Fai	r Value Hiera	rchy	
	Total	Level 1	Level 2	Level 3	
		(in thousands)			
Financial assets carried at fair value:				•	
Cash equivalents	\$ 423,014	\$ 423,014	\$	\$ _	
Marketable securities, available-for-sale	838,255	838,255	. —		
Restricted cash	30,313	30,313	<u></u>	—	
Total	\$1,291,582	\$1,291,582	\$	\$	
Financial liabilities carried at fair value:		<u> </u>			
Embedded derivative related to 2012 Notes	\$ 10,452	\$	\$	\$ 10,452	
Liability related to sale of potential future milestone payments	38,207			38,207	
Total	\$ 48,659	\$	\$	\$ 48,659	

The following table is a reconciliation of financial liabilities measured at fair value using significant unobservable inputs (Level 3):

	2009
·	(in thousands)
Balance, beginning of the year	\$
Issuance of derivative instruments related to September 2009 financial transactions	46,812
Loss on derivative instruments, net	1,847
Balance, end of the year	\$48,659

The Company had \$32.1 million outstanding in aggregate principal amount of 4.75% convertible senior subordinated notes due 2013 included on the consolidated balance sheet as of December 31, 2009. At December 31, 2009, these 2013 Notes had a fair value of \$55.2 million as obtained from a quoted market source.

# VERTEX PHARMACEUTICALS INCORPORATED Notes to Consolidated Financial Statements (Continued)

#### **F.** Restructuring Expense

In June 2003, Vertex adopted a plan to restructure its operations to coincide with its increasing internal emphasis on advancing drug candidates through clinical development to commercialization. The restructuring was designed to re-balance the Company's relative investments in research and development to better support the Company's long-term strategy. The restructuring plan included a workforce reduction, write-offs of certain assets and a decision not to occupy approximately 290,000 square feet of specialized laboratory and office space in Cambridge, Massachusetts under lease to Vertex (the "Kendall Square Lease"). The Kendall Square Lease commenced in January 2003 and has a 15-year term. In the second quarter of 2005, the Company revised its assessment of its real estate requirements and decided to use approximately 120,000 square feet of the facility subject to the Kendall Square Lease (the "Kendall Square Facility") for its operations, beginning in 2006. The remaining rentable square footage of the Kendall Square Facility currently is subleased to third parties.

The Company's initial estimate of its liability for net ongoing costs associated with the Kendall Square Lease obligation was recorded in the second quarter of 2003 at fair value. The restructuring expense incurred from the second quarter of 2003 through the end of the first quarter of 2005 (i.e., immediately prior to the Company's decision to use a portion of the Kendall Square Facility for its operations) relates to the estimated incremental net ongoing lease obligations associated with the entire Kendall Square Facility, together with imputed interest costs relating to the restructuring liability. The restructuring expense incurred in the period beginning in the second quarter of 2005 relates only to the portion of the building that the Company currently does not intend to occupy for its operations. The remaining lease obligations, which are associated with the portion of the Kendall Square Facility that the Company reviews its assumptions and estimates quarterly and updates its estimates of this liability as changes in circumstances require. The expense and liability recorded is calculated using probability-weighted discounted cash-flows of the Company's estimated ongoing lease obligations, including contractual rental and build-out commitments, net of estimated sublease rentals, offset by related sublease costs.

In estimating the expense and liability under its Kendall Square Lease obligation, the Company estimated (i) the costs to be incurred to satisfy rental and build-out commitments under the lease (including operating costs), (ii) the lead-time necessary to sublease the space, (iii) the projected sublease rental rates, and (iv) the anticipated durations of subleases. The Company uses a credit-adjusted risk-free rate of approximately 10% to discount the estimated cash flows. The Company reviews its estimates and assumptions on at least a quarterly basis, and intends to continue such reviews until the termination of the Kendall Square Lease, and will make whatever modifications the Company believes necessary, based on the Company's best judgment, to reflect any changed circumstances. The Company's estimates have changed in the past, and may change in the future, resulting in additional adjustments to the estimate of the liability are recorded as additional restructuring expense/ (credit). In addition, because the Company's estimate of the liability are recorded as additional restructuring expense/ (credit). In addition, because the Company's estimate of the liability includes the application of a discount rate to reflect the time-value of money, the Company will record imputed interest costs related to the liability each quarter. These costs are included in restructuring expense on the Company's consolidated statements of operations.

The restructuring liability of \$34.0 million at December 31, 2009 relates solely to the portion of the Kendall Square Facility that the Company does not intend to use for its operations and includes other related lease obligations, recorded at net present value. The Company classified \$6.3 million of the

# Notes to Consolidated Financial Statements (Continued)

# F. Restructuring Expense (Continued)

total restructuring liability at December 31, 2009 as short-term, and \$27.7 million as long-term. The short-term portion of the restructuring liability represents the net amount the Company expects to pay in 2010.

In 2003, the Company recorded restructuring and other related expenses of \$91.8 million. The \$91.8 million included \$78.7 million of lease restructuring expense, \$6.0 million of lease operating expense incurred prior to the decision not to occupy the Kendall Square Facility, \$2.6 million for severance and related employee transition benefits and \$4.5 million for a write-off of leasehold improvements and other assets. The activity related to restructuring and other liability for 2003 was as follows:

	Charge in 2003	Cash payments in 2003	Non-cash write-off in 2003	Liability as of December 31, 2003
		(in t	housands)	
Lease restructuring and other operating lease expense	\$84,726	\$(15,200)	\$ —	\$69,526
Employee severance, benefits and related costs	2,616	(2,616)	_	
Leasehold improvements and asset impairments	4,482		(4,482)	
Total	\$91,824	\$(17,816)	\$(4,482)	\$69,526

# Notes to Consolidated Financial Statements (Continued)

#### F. Restructuring Expense (Continued)

The activity related to the restructuring since December 31, 2003 is as follows:

	Restructuring Liability
	(in thousands)
Liability: December 31, 2003	\$ 69,526
Cash payments in 2004	(31,550)
Cash received from sublease, net of operating costs, in 2004	293
Additional charge in 2004	17,574
Liability: December 31, 2004	55,843
Cash payments in 2005	(24,229)
Cash received from subleases in 2005	3,234
Credit for portion of facility Vertex decided to occupy in 2005	(10,018)
Additional charge in 2005	18,152
Liability: December 31, 2005	42,982
Cash payments in 2006	(21,607)
Cash received from subleases in 2006	8,047
Additional charge in 2006	3,651
Liability: December 31, 2006	33,073
Cash payments in 2007	(12,854)
Cash received from subleases in 2007	7,954
Additional charge in 2007	7,119
Liability: December 31, 2007	35,292
Cash payments in 2008	(14,017)
Cash received from subleases in 2008	8,465
Additional charge in 2008	4,324
Liability: December 31, 2008	34,064
Cash payments in 2009	(14,924)
Cash received from subleases in 2009	8,637
Additional charge in 2009	6,240
Liability: December 31, 2009	\$ 34,017

In 2004, the Company recorded restructuring expense of \$17.6 million primarily as the result of revising estimates and assumptions about when subtenants would be identified and secured and imputing an interest charge for the related restructuring liability.

In 2005, the Company recorded net restructuring expense of \$8.1 million. This net expense includes a \$10.0 million credit to the restructuring liability made when the Company decided to occupy and use a portion of the Kendall Square Facility, which was offset by (i) the estimated incremental net ongoing lease obligations associated with the portion of the Kendall Square Facility that the Company does not intend to occupy and (ii) imputed interest costs relating to the restructuring liability. The portion of the \$18.2 million additional charge in 2005 that was for incremental lease obligations was related to the revision of certain key estimates and assumptions about operating costs, including real estate taxes associated with the portion of the Kendall Square Facility that the Company does not intend to occupy.

÷.,

#### Notes to Consolidated Financial Statements (Continued)

#### F. Restructuring Expense (Continued)

In 2006, the Company recorded restructuring expense of \$3.7 million, which was primarily attributable to imputed interest relating to the restructuring liability and specific build-out costs.

In 2007, the Company recorded restructuring expense of \$7.1 million, which was primarily the result of revising certain key estimates and assumptions in the first quarter of 2007 about building operating costs for the remaining period of the lease commitment and the imputed interest cost relating to the restructuring liability.

In 2008, the Company recorded restructuring expense of \$4.3 million, which was primarily attributable to imputed interest cost relating to the restructuring liability.

In 2009, the Company recorded restructuring expense of \$6.2 million, which was the result of incremental lease obligations related to the revision of certain key estimates and assumptions as well as the imputed interest cost relating to the restructuring liability.

#### **G.** Marketable Securities

A summary of cash, cash equivalents and marketable securities is shown below:

December 31, 2009	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
		(in tho	usands)	
Cash and cash equivalents				
Cash and money market funds	\$ 251,005	\$	\$	\$ 251,005
U.S. Treasury securities	20,198		(5)	20,193
Government-sponsored enterprise securities	175,455	8	(3)	175,460
Total cash and cash equivalents	\$ 446,658	\$8	\$ (8)	\$ 446,658
Marketable securities	<u> </u>			
U.S. Treasury securities (due within 1 year)	\$ 223,422	\$	\$ (99)	\$ 223,323
Government-sponsored enterprise securities (due within 1 year)	614,869	- 81	(18)	614,932
Total marketable securities		\$ 81		\$ 838,255
	\$ 838,291	♪ 01	<u>(117)</u>	\$ 656,255
Total cash, cash equivalents and marketable securities	\$1,284,949	\$89	\$ (125)	\$1,284,913
	·			
December 31, 2008				
Cash and cash equivalents				
Cash and money market funds	\$ 389,115	\$	\$ —	\$ 389,115
Total cash and cash equivalents	\$ 389,115	\$	· <u>s                                    </u>	\$ 389,115
•				
Marketable securities	¢ 247.002	¢ 0.710	¢	¢ 250.005
Government-sponsored enterprise securities (due within 1 year)	\$ 347,982	\$ 2,713	\$	\$ 350,695
Corporate debt securities (due within 1 year)	91,863	428		92,291
Total marketable securities	\$ 439,845	\$ 3,141	<u>\$                                    </u>	\$ 442,986
Total cash, cash equivalents and marketable securities	\$ 828,960	\$ 3,141	<u>\$                                    </u>	\$ 832,101

The Company has marketable securities classified as current assets of \$838.3 million and \$443.0 million, respectively, on the consolidated balance sheets as of December 31, 2009 and 2008.

#### Notes to Consolidated Financial Statements (Continued)

# G. Marketable Securities (Continued)

The Company reviews investments in marketable securities for other-than-temporary impairment whenever the fair value of an investment is less than amortized cost and evidence indicates that an investment's carrying amount is not recoverable within a reasonable period of time. To determine whether an impairment is other-than-temporary, the Company considers the intent to sell, or whether it is more likely than not that the Company will be required to sell, the investment before recovery of the investment's amortized cost basis. Evidence considered in this assessment includes reasons for the impairment, compliance with the Company's investment policy, the severity and the duration of the impairment and changes in value subsequent to year end.

The Company owned 42 available-for-sale marketable securities at December 31, 2009. Of these 42 securities, there were 16 securities with unrealized losses, none of which was individually significant.

The following table summarizes the fair value and gross unrealized losses related to marketable securities, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position as of December 31, 2009:

	Less than 12 months		12 months or more		Total	
	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss
			(in tho	usands)		
U.S. Treasury securities	\$221,412	\$ (99)	· \$	\$	\$221,412	\$ (99)
Government-sponsored enterprise securities	118,950	(18)			118,950	(18)
Total	\$340,362	\$(117)	<u>\$</u>	<u>\$</u>	\$340,362	\$(117)

As of December 31, 2009, unrealized losses in the portfolio related to various debt securities including U.S. Treasuries and government-sponsored enterprise securities. For these securities, the unrealized losses were primarily due to increases in interest rates. The contractual terms of these investments do not permit the issuer to settle the securities at a price less than the amortized cost bases of the investments. Because the Company does not intend to sell the investments and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost bases, which may be maturity, the Company does not consider those investments to be other-than-temporarily impaired at December 31, 2009.

As of December 31, 2008, there were no securities with unrealized losses.

The Company had proceeds of \$788.3 million, \$427.6 million and \$755.6 million, respectively, from sales and maturities of available-for-sale securities in 2009, 2008 and 2007, respectively.

Realized gains and losses are determined using the specific identification method and are included in interest income on the consolidated statements of operations. There were no gross realized gains and losses for 2009. Gross realized gains and losses for 2008 were \$943,000 and \$310,000, respectively. Gross realized gains and losses for 2007 were \$122,000 and \$277,000, respectively.

#### H. Restricted Cash

At December 31, 2009 and 2008, the Company held \$30.3 million in restricted cash. At December 31, 2009 and 2008, the balance was held in deposit with certain banks predominantly to collateralize conditional stand-by letters of credit in the names of the Company's landlords pursuant to certain operating lease agreements.

#### Notes to Consolidated Financial Statements (Continued)

#### I. Property and Equipment

Property and equipment consist of the following at December 31:

	2009	2008
	(in thousands)	
Furniture and equipment	\$128,920	\$118,292
Leasehold improvements	88,020	84,402
Software	41,910	37,891
Computers	25,155	21,324
Total property and equipment, gross	284,005	261,909
Less accumulated depreciation and amortization	221,726	193,578
Total property and equipment, net	\$ 62,279	\$ 68,331

Depreciation and amortization expense for the years ended December 31, 2009, 2008 and 2007 was \$28.3 million \$30.4 million and \$27.3 million, respectively.

In 2009, 2008 and 2007, the Company wrote-off certain assets that were fully depreciated and no longer utilized. There was no effect on the Company's net property and equipment. Additionally, the Company wrote-off or sold certain assets that were not fully depreciated. The loss on disposal of those assets was \$2,211,000 for 2009, \$11,000 for 2008, \$142,000 for 2007.

#### J. Current Liabilities

Accrued expenses and other current liabilities consist of the following at December 31:

	2009	2008
	(in thou	isands)
Research and development contract costs	\$ 54,912	\$43,615
Payroll and benefits	45,882	39,835
Professional fees	7,801	6,081
Other	10,158	4,672
Total	\$118,753	\$94,203

Other obligations of \$15.2 million and \$21.3 million as of December 31, 2009 and 2008, respectively, consist of a deposit received from a collaborator for potential future obligations of the Company.

#### **K.** Commitments

The Company leases its facilities and certain equipment under non-cancelable operating leases. The Company's leases have terms through July 2019. The leases of the Company's primary facilities in Cambridge were extended in 2009 through December 2015. The term of the Kendall Square Lease began January 1, 2003. Rent payments will be subject to increase in May 2013, based on changes in an inflation index. These increases will be treated as contingent rentals. The Kendall Square Lease will expire in 2018, and the Company has the option to extend the term for two consecutive terms of ten years each, ultimately expiring in 2038. The Company occupies and uses for its operations approximately 120,000 square feet of the Kendall Square Facility. The Company has sublease arrangements in place for the remaining rentable square footage of the Kendall Square Facility, with

#### Notes to Consolidated Financial Statements (Continued)

#### K. Commitments (Continued)

initial terms that expire in April 2011 and August 2012. See Note F, "Restructuring Expense," for further information.

As of December 31, 2009, future minimum commitments under facility operating leases with non-cancelable terms of more than one year are as follows:

Year	Kendall Square Lease	Sublease income for Kendall Square Facility	Other Operating Leases	Total Operating Leases
		(in thous	sands)	
2010	\$ 18,260	\$ (6,493)	\$ 22,209	\$ 33,976
2011	18,260	(3,908)	27,430	41,782
2012	18,260	(1,744)	24,961	41,477
2013	18,260		20,749	39,009
2014	18,260	<del></del>	17,104	35,364
Thereafter	60,866		23,227	84,093
Total minimum lease payments.	\$152,166	\$(12,145)	\$135,680	\$275,701

Rental expense for 2009 was \$39.1 million, which included \$11.5 million related to the Kendall Square Facility. Rental expense for 2008 was \$31.1 million, which included \$10.7 million related to the Kendall Square Facility. Rental expense for 2007 was \$28.1 million, which included \$9.9 million related to the Kendall Square Facility.

The Company has future contractual commitments in connection with its research, development and commercial supply investment. For 2010 and 2011 the amount committed under these contracts is \$10.8 million and \$0.3 million, respectively.

In September 2009, the Company entered into two financial transactions pursuant to which it issued secured notes and sold its rights to future potential milestones. See Note R, "September 2009 Financial Transactions," for further information.

#### L. Convertible Subordinated Notes Due 2007 and 2011 and Collaborator Loan

#### 2011 Notes

On January 1, 2007, the Company had outstanding \$59.6 million in aggregate principal amount of 5.75% Convertible Senior Subordinated Notes due in February 2011 (the "2011 Notes"). The 2011 Notes were convertible, at the option of the holder, into common stock at a price per share equal to \$14.94. In the first quarter of 2007, the Company called all of the remaining outstanding 2011 Notes for redemption. In response and pursuant to the terms of the 2011 Notes, the holders of all the outstanding 2011 Notes converted, at a price equal to \$14.94 per share, their \$59.6 million in aggregate principal amount of 2011 Notes into 3,992,473 shares of the Company's common stock. The following items related to the 2007 conversion were recorded as an offset to additional paid-in capital on the Company's consolidated balance sheet: accrued interest, remaining unamortized issuance costs of the converted notes and issuance costs of the common stock.

#### 2007 Notes

On January 1, 2007, the Company had outstanding \$42.1 million in aggregate principal amount of 5% Convertible Subordinated Notes due in September 2007 (the "2007 Notes"). The 2007 Notes were

#### Notes to Consolidated Financial Statements (Continued)

#### L. Convertible Subordinated Notes Due 2007 and 2011 and Collaborator Loan (Continued)

convertible, at the option of the holder, into common stock at a price per share equal to \$92.26. In the third quarter of 2007, the Company repaid upon maturity the outstanding principal and accrued interest on the remaining \$42.1 million in principal amount of 2007 Notes.

#### Collaborator Loan

On January 1, 2007, the Company had outstanding \$20.0 million in loans under a loan facility established in connection with a collaboration with Novartis that was completed in 2006. In May 2008, the Company repaid the \$20.0 million in loans outstanding under the loan facility.

#### M. Equity and Debt Offerings and Debt Exchanges

#### February 2008 Concurrent Debt and Equity Offering

In February 2008, the Company completed concurrent offerings of \$287.5 million in aggregate principal amount of 4.75% convertible senior subordinated notes due 2013 (the "2013 Notes") and 6,900,000 shares of common stock (the "February 2008 Equity Offering"), which were sold at a price of \$17.14 per share.

The convertible debt offering resulted in net proceeds of \$278.6 million to the Company. The underwriting discount of \$8.6 million and other expenses of \$0.3 million related to the convertible debt offering were recorded as debt issuance costs and are included in other assets on the Company's consolidated balance sheets. The February 2008 Equity Offering resulted in net proceeds of \$112.7 million to the Company. The underwriting discount of \$5.3 million and other expenses of \$0.2 million related to the February 2008 Equity Offering were recorded as an offset to additional paid-in-capital.

The 2013 Notes are convertible, at the option of the holder, into common stock at a price equal to approximately \$23.14 per share, subject to adjustment. The 2013 Notes bear interest at the rate of 4.75% per annum, and the Company is required to make semi-annual interest payments on the outstanding principal balance of the 2013 Notes on February 15 and August 15 of each year. The 2013 Notes would have matured on February 15, 2013.

On or after February 15, 2010, the Company may redeem the 2013 Notes at its option, in whole or in part, at the redemption prices stated in the indenture, plus accrued and unpaid interest, if any, to, but excluding, the redemption date. Holders may require the Company to repurchase some or all of their 2013 Notes upon the occurrence of certain fundamental changes of Vertex, as set forth in the indenture, at 100% of the principal amount of the 2013 Notes to be repurchased, plus any accrued and unpaid interest, if any, to, but excluding, the repurchase date.

If a fundamental change occurs that is also a specific type of change of control under the indenture, the Company will pay a make-whole premium upon the conversion of the 2013 Notes in connection with any such transaction by increasing the applicable conversion rate on such 2013 Notes. The make-whole premium will be in addition to, and not in substitution for, any cash, securities or other assets otherwise due to holders of the 2013 Notes upon conversion. The make-whole premium will be determined by reference to the indenture and is based on the date on which the fundamental change becomes effective and the price paid, or deemed to be paid, per share of the Company's common stock in the transaction constituting the fundamental change, subject to adjustment.

#### Notes to Consolidated Financial Statements (Continued)

#### M. Equity and Debt Offerings and Debt Exchanges (Continued)

The indenture provides the holders of the 2013 Notes with certain remedies if a default occurs under the indenture. If an event of default under the indenture relates solely to the Company's failure to comply with its reporting obligations pursuant to the 2013 Notes, at the election of the Company, the sole remedy of the holders of the 2013 Notes for the first 180 days following such event of default would consist of the right to receive special interest at an annual rate equal to 1.0% of the outstanding principal amount of the 2013 Notes.

Based on the Company's evaluation of the 2013 Notes, the Company determined that the 2013 Notes contain a single embedded derivative. This embedded derivative relates to potential penalty interest payments that could be imposed on the Company for a failure to comply with its reporting obligations pursuant to the 2013 Notes. This embedded derivative required bifurcation because it was not clearly and closely related to the host instrument. The Company has determined that the value of this embedded derivative was nominal as of February 19, 2008, December 31, 2008 and December 31, 2009.

#### September 2008 Equity Offering

In September 2008, the Company completed an offering of 8,625,000 shares of common stock (the "September 2008 Equity Offering"), which were sold at a price of \$25.50 per share. This offering resulted in \$217.4 million of net proceeds to the Company. The underwriting discount of \$2.2 million and other expenses of \$0.3 million related to the September 2008 Equity Offering were recorded as an offset to additional paid-in-capital.

#### February 2009 Equity Offering

In February 2009, the Company completed an offering of 10,000,000 shares of common stock (the "February 2009 Equity Offering"), which were sold at a price of \$32.00 per share. This offering resulted in \$313.3 million of net proceeds to the Company. The underwriting discount of \$6.4 million and other expenses of \$0.3 million related to the February 2009 Equity Offering were recorded as an offset to additional paid-in capital.

#### 2009 Debt Exchanges

In June 2009, the Company exchanged 6,601,000 shares of newly-issued common stock for \$143.5 million in aggregate principal amount of the 2013 Notes, plus accrued interest. In the exchanges, the Company issued 46 shares of common stock for each \$1,000 in principal amount of 2013 Notes. As a result of the exchanges, the Company incurred a non-cash charge of \$12.3 million in the second quarter of 2009. This charge is related to the incremental shares issued in the transaction over the number that would have been issued upon conversion of the 2013 Notes under their original terms, at the original conversion rate of approximately 43.22 shares of common stock per \$1,000 in principal amount of the 2013 Notes. In addition, accrued interest of \$2.1 million and unamortized debt issuance costs of exchanged convertible notes of \$3.5 million were recorded as an offset to additional paid-in capital on the Company's consolidated balance sheet.

In November 2009, the Company exchanged 4,980,838 shares of newly-issued common stock for \$111.9 million in aggregate principal amount of the 2013 Notes, plus accrued interest. In the exchanges, the Company issued 44.5 shares of common stock for each \$1,000 in principal amount of 2013 Notes. As a result of the exchanges, the Company incurred a non-cash charge of \$5.8 million in the fourth

#### Notes to Consolidated Financial Statements (Continued)

#### M. Equity and Debt Offerings and Debt Exchanges (Continued)

quarter of 2009. This charge is related to the incremental shares issued in the transaction over the number that would have been issued upon conversion of the 2013 Notes under their original terms, at the original conversion rate of approximately 43.22 shares of common stock per \$1,000 in principal amount of the 2013 Notes. In addition, accrued interest of \$1.3 million and unamortized debt issuance costs of exchanged convertible notes of \$2.4 million were recorded as an offset to additional paid-in capital on the Company's consolidated balance sheet.

As a result of these exchanges, on December 31, 2009 the outstanding aggregate principal amount of the 2013 Notes has been reduced to \$32.1 million. In February 2010, the Company announced that it will redeem the remaining \$32.1 million in aggregate principal amount of 2013 Notes on March 19, 2010. See Note V, "Subsequent Event," for further information.

#### December 2009 Equity Offering

In December 2009, the Company completed an offering of 13,000,000 shares of common stock (the "December 2009 Equity Offering"), which were sold at a price of \$38.50 per share. This offering resulted in \$488.1 million of net proceeds to the Company. The underwriting discount of \$12.1 million and other expenses of \$0.3 million related to the December 2009 Equity Offering were recorded as an offset to additional paid-in capital.

#### N. Income Taxes

For the years ended December 31, 2009, 2008 and 2007, there is no provision for income taxes included in the consolidated statements of operations.

The Company's federal statutory income tax rate for 2009, 2008 and 2007 was 34%. The Company has incurred losses from operations but has not recorded an income tax benefit for 2009, 2008 and 2007, as the Company has recorded a valuation allowance against its net operating losses and other net deferred tax assets due to uncertainties related to the realizability of these tax assets.

The difference between the Company's "expected" tax provision (benefit), as computed by applying the U.S. federal corporate tax rate of 34% to loss before provision for income taxes, and actual tax is reconciled as follows:

· · · · · · · · · · · · · · · · · · ·	2009	2008	2007
	(in thousands)		
Loss before provision for income taxes	\$(642,178)	\$(459,851)	\$(391,279)
Expected tax benefit at 34%	(218,341)	(156,349)	(133,035)
State taxes, net of federal benefit	(38,965)	(28,833)	(24,533)
Unbenefited operating losses	248,388	185,016	157,337
Non-deductible expenses	8,244	127	91
Other	674	39	140
Income tax provision	\$	\$	\$

For federal income tax purposes, as of December 31, 2009, the Company has net operating loss carryforwards of approximately \$2.4 billion, and \$54 million of tax credits, which may be used to offset future federal income and tax liability, respectively. For state income tax purposes, the Company has net operating loss carryforwards of approximately \$1.8 billion, and \$35 million of tax credits, which may be used to offset future state income and tax liability, respectively. These operating loss carryforwards

# Notes to Consolidated Financial Statements (Continued)

#### N. Income Taxes (Continued)

began to expire in 2005, and the tax credit carryforwards began to expire in 2004. After consideration of all the evidence, both positive and negative, management has established a valuation allowance for the full amount of the 2009 deferred tax asset since it is more likely than not that the deferred tax asset will not be realized. In future periods, if management determines that it is more likely than not that the deferred tax asset will be realized (i) the valuation allowance would be decreased, (ii) a portion or all of the deferred tax asset would be reflected on the consolidated balance sheet and (iii) the Company would record non-cash benefits in its statements of operations related to the reflection of the deferred tax asset on the consolidated balance sheet.

Deferred tax assets and liabilities are determined based on the difference between financial statement and tax bases using enacted tax rates in effect for the year in which the differences are expected to reverse. The components of the deferred taxes at December 31 were as follows:

	2009	2008
	(in thousands)	
Deferred tax assets:		
Net operating loss	\$ 759,687	\$ 534,036
Tax credit carryforwards	83,562	66,320
Property and equipment	22,370	19,086
Deferred revenues	99,207	99,658
Stock-based compensation	59,958	41,097
Inventory	38,714	29,237
Capitalized research and development		3,832
Accrued expenses and other	17,939	11,040
Gross deferred tax assets	1,081,437	804,306
Valuation allowance	(1,081,437)	(804,306)
Total deferred tax assets		
Deferred tax liabilities:		
Acquired intangibles	(160,278)	·
Net deferred tax liabilities	\$ (160,278)	\$

2000

Generally, tax return deductions are allowable on stock-based compensation plans, but, may arise in different amounts and periods from when compensation costs are recognized in the financial statements. If the tax return deduction for an award exceeds the cumulative compensation expense recognized in the financial statements, any excess tax benefit shall be recognized as additional paid-in capital when the deduction reduces income tax payable. The net tax amount of the unrealized excess tax benefits as of December 31, 2009 is approximately \$112 million. The gross amount of this excess tax deduction in the net operating loss carryforward is approximately \$284 million.

The valuation allowance increased by \$288 million during 2009 due primarily to the increase in net operating losses and tax credits.

At December 31, 2009 and December 31, 2008, the Company had no material unrecognized tax benefits and no adjustments to liabilities or operations were required. The Company does not expect that its unrecognized tax benefits will materially increase within the next twelve months. The Company did not recognize any interest or penalties related to uncertain tax positions at December 31, 2009 and December 31, 2008.

#### Notes to Consolidated Financial Statements (Continued)

#### N. Income Taxes (Continued)

The Company files United States federal income tax returns and income tax returns in various state, local, and foreign jurisdictions. The Company is no longer subject to any tax assessment from an income tax examination in the United States before 2007 and any other major taxing jurisdiction for years before 2005, except where the Company has net operating losses or tax credit carryforwards that originate before 2005. The Company completed an examination by the Internal Revenue Service with respect to 2006 in June 2009 with no material change. The Company currently is not under examination by any jurisdiction for any tax year.

#### O. Sale of HIV Protease Inhibitor Royalty Stream

In December 1993, the Company and GlaxoSmithKline entered into a collaboration agreement to research, develop and commercialize HIV protease inhibitors, including Agenerase (amprenavir) and Lexiva/Telzir (fosamprenavir calcium). Under the collaboration agreement, GlaxoSmithKline agreed to pay the Company royalties on net sales of drugs developed under the collaboration.

The Company began earning a royalty from GlaxoSmithKline in 1999 on net sales of Agenerase, in 2003 on net sales of Lexiva, and in 2004 on net sales of Telzir. GlaxoSmithKline has the right to terminate its arrangement with the Company without cause upon twelve months' notice. Termination of the collaboration agreement by GlaxoSmithKline will relieve it of its obligation to make further payments under the agreement and will end any license granted to GlaxoSmithKline by the Company under the agreement. In June 1996, the Company and GlaxoSmithKline obtained a worldwide, non-exclusive license under certain G.D. Searle & Co. ("Searle," now owned by Pharmacia/Pfizer) patents in the area of HIV protease inhibition. Searle is paid royalties based on net sales of Agenerase and Lexiva/Telzir.

On May 30, 2008, the Company entered into a purchase agreement (the "Purchase Agreement") with Fosamprenavir Royalty, L.P. ("Fosamprenavir Royalty") pursuant to which the Company sold, and Fosamprenavir Royalty purchased, the Company's right to receive royalty payments, net of royalty amounts to be earned and due to Searle, arising from sales of Lexiva/Telzir and Agenerase under the Company's 1993 agreement with GlaxoSmithKline, from April 1, 2008 to the end of the term of the collaboration agreement, for a one-time cash payment of \$160.0 million to the Company. In accordance with the Purchase Agreement, GlaxoSmithKline will make all royalty payments, net of the subroyalty amounts payable to Searle, directly to Fosamprenavir Royalty. The Purchase Agreement also contains other representations, warranties, covenants and indemnification obligations. The Company continues to be obligated for royalty amounts earned and that are due to Searle. The Company has instructed GlaxoSmithKline to pay such amounts directly to Searle as they become due.

The Company classified the proceeds received from Fosamprenavir Royalty as deferred revenues, to be recognized as royalty revenues over the life of the collaboration agreement, because of the Company's continuing involvement in the royalty arrangement over the term of the Purchase Agreement. Such continuing involvement, which is required pursuant to covenants contained in the Purchase Agreement, includes overseeing GlaxoSmithKline's compliance with the collaboration agreement, monitoring and defending patent infringement, adverse claims or litigation involving the royalty stream, undertaking to cooperate with Fosamprenavir Royalty's efforts to find a new license partner if GlaxoSmithKline terminates the collaboration agreement, and complying with the license agreement with Searle, including the obligation to make future royalty payments to Searle. Because the transaction was structured as a non-cancellable sale, the Company has no significant continuing

#### Notes to Consolidated Financial Statements (Continued)

#### **O.** Sale of HIV Protease Inhibitor Royalty Stream (Continued)

involvement in the generation of the cash flows due to Fosamprenavir Royalty and there are no guaranteed rates of return to Fosamprenavir Royalty, the Company has recorded the proceeds as deferred revenues.

The Company recorded \$155.1 million, representing the proceeds of the transaction less the net royalty payable to Fosamprenavir Royalty for the period from April 1, 2008 through May 30, 2008, as deferred revenues to be recognized as royalty revenues over the life of the collaboration agreement based on the units-of-revenue method. The amount of deferred revenues to be recognized as royalty revenues in each period is calculated by multiplying the following: (1) the net royalty payments due to Fosamprenavir Royalty for the period by (2) the ratio of the remaining deferred revenue amount to the total estimated remaining net royalties that GlaxoSmithKline is expected to pay Fosamprenavir Royalty over the term of the collaboration agreement. On May 31, 2008, the Company began recognizing these deferred revenues. In addition, the Company continues to recognize royalty revenues for the portion of the royalty earned that is due to Searle.

The Company recognizes royalty expenses in each period based on (i) deferred transaction expenses in the same manner and over the same period in which the related deferred revenues are recognized as royalty revenues plus (ii) the subroyalty paid by GlaxoSmithKline to Searle on net sales of Agenerase and Lexiva/Telzir for the period.

#### **P.** Collaborative Arrangements

The Company has formed strategic collaborations with pharmaceutical companies and other organizations in the areas of drug discovery, development, and commercialization. Research, development and commercialization agreements provide the Company with financial support and other valuable resources for its research programs, for the development of clinical drug candidates, and for the marketing and sales of products. In the Company's collaborative research, development and commercialization programs the Company seeks to discover, develop and commercialize pharmaceutical products in conjunction with and supported by the Company's collaborators. Collaborative research and development arrangements may provide research funding over an initial contract period with renewal and termination options that vary by agreement. The agreements may also include nonrefundable, up-front license fees as well as milestone payments based on the achievement of a pre-agreed objective or the occurrence of a designated event. The agreements may also contain development expense reimbursement provisions, royalty rights or profit-sharing rights, and manufacturing options. The Company has entered into significant research and development collaborations under terms that vary from agreement to agreement.

#### Janssen Pharmaceutica, N.V.

In June 2006, the Company entered into a collaboration agreement with Janssen Pharmaceutica, N.V. for the development, manufacture and commercialization of telaprevir, the Company's lead investigative HCV protease inhibitor. Under the agreement, Janssen has agreed to be responsible for 50% of the drug development costs incurred under the development program for the parties' territories (North America for the Company, and the rest of the world, other than the Far East, for Janssen) and has exclusive rights to commercialize telaprevir in its territories including Europe, South America, the Middle East, Africa and Australia. Under the development program for telaprevir, each party is incurring reimbursable drug development costs. Reimbursable costs incurred by Janssen

#### Notes to Consolidated Financial Statements (Continued)

#### P. Collaborative Arrangements (Continued)

are offset against reimbursable costs incurred by the Company. Amounts that Janssen pays to the Company for reimbursement, after the offset, are recorded as revenues. Accordingly, if Janssen incurs increased costs under the development program, the Company's revenues attributable to the reimbursement are reduced.

Janssen made a \$165.0 million up-front license payment to the Company in July 2006. The up-front license payment is being amortized over the Company's estimated period of performance under the collaboration agreement. The Company's estimates regarding the period of performance under the Janssen collaboration agreement were adjusted in 2007, and again in the third quarter of 2009, as a result of changes in the global development plan for telaprevir, which contemplates the conduct of certain development activities in the post-approval period if telaprevir is approved for marketing. These adjustments were made on a prospective basis beginning in the periods in which the changes were identified. These adjustments resulted in a decrease in the amount of revenues the Company recognized from the Janssen collaboration by \$2.6 million per quarter for the first adjustment and by \$1.1 million per quarter for the second adjustment.

Under the agreement, Janssen agreed to make contingent milestone payments, which could have totalled up to \$380.0 million if telaprevir is successfully developed, approved and launched as a product. As of December 31, 2009, the Company had earned \$100.0 million of these contingent milestone payments under the agreement. The remaining \$280.0 million in milestones under the Company's agreement with Janssen include \$100.0 million related to the regulatory filing with and approval of telaprevir by the European Medicines Evaluation Agency, and \$150.0 million related to the launch of telaprevir in the European Union. On September 30, 2009, the Company entered into two financial transactions related to the \$250.0 million in milestones related to the filing, approval and launch of telaprevir in the European Union. Please refer to Note R, "September 2009 Financial Transactions."

The collaboration agreement with Janssen also provides the Company with royalties on any sales of telaprevir in the Janssen territories, with a tiered royalty averaging in the mid-20% range, as a percentage of net sales in the Janssen territories, depending upon successful commercialization of telaprevir. Each of the parties will be responsible for drug supply in their respective territories. However, the agreement provides for the purchase by Janssen from the Company of materials required for Janssen's manufacture of the active pharmaceutical ingredient. In addition, Janssen will be responsible for certain third-party royalties on net sales in its territories. Janssen may terminate the agreement without cause at any time upon six months' notice to the Company.

During 2009, the Company recognized \$54.6 million in revenues under the Janssen agreement, which included an amortized portion of the up-front payment, the sale of materials to Janssen and net reimbursements from Janssen for telaprevir development costs. During 2008, the Company recognized \$120.1 million in revenues under the Janssen agreement, which includes an amortized portion of the up-front payment, milestone payments of \$55.0 million, and net reimbursements from Janssen for telaprevir development costs. During 2007, the Company recognized \$117.7 million in revenues under the Janssen agreement, which includes an amortized portion of the up-front payment, which includes an amortized portion of the up-front payment of \$30.0 million, and net reimbursements from Janssen for telaprevir development costs.

#### Notes to Consolidated Financial Statements (Continued)

#### **P.** Collaborative Arrangements (Continued)

#### Mitsubishi Tanabe Pharma Corporation

In June 2004, the Company entered into a collaboration agreement (the "MTPC Agreement") with Mitsubishi Tanabe Pharma Corporation, pursuant to which Mitsubishi Tanabe agreed to provide financial and other support for the development and commercialization of telaprevir. Under the terms of the agreement, Mitsubishi Tanabe has the right to develop and commercialize telaprevir in Japan and certain other Far East countries. The MTPC Agreement provided for payments by Mitsubishi Tanabe to the Company through Phase 2 clinical development, including an up-front license fee, development stage milestone payments and reimbursement of certain drug development costs for telaprevir.

On July 30, 2009, the Company amended the MTPC Agreement. Under the amended agreement, the Company received \$105.0 million in the third quarter of 2009, and will be eligible to receive a further contingent milestone payment, which if realized would range between \$15.0 million and \$65.0 million. The amended agreement provides to Mitsubishi Tanabe a fully-paid license to commercialize telaprevir to treat HCV infection in Japan and specified other countries in the Far East, as well as rights to manufacture telaprevir for sale in its territory. Mitsubishi Tanabe is responsible for its own development and manufacturing costs in its territory. Mitsubishi Tanabe may terminate the agreement at any time without cause upon 60 days' prior written notice to the Company.

Prior to the amendment, the Company recognized revenues based on an amortized portion of the up-front payment, milestones, if any, and reimbursement of certain of the Company's expenses incurred in telaprevir development. The \$105.0 million payment that the Company received in the third quarter of 2009 pursuant to the amended agreement is a nonrefundable, up-front license fee and revenues related to this payment are being recognized on a straight-line basis over the Company's estimated period of performance under the amended agreement. In 2009, 2008 and 2007, the Company recognized revenues from Mitsubishi Tanabe of \$18.7 million, \$9.9 million and \$4.4 million, respectively.

#### Cystic Fibrosis Foundation Therapeutics Incorporated

In May 2004, Vertex entered into an agreement, which was amended in 2006, with Cystic Fibrosis Foundation Therapeutics Incorporated ("CFFT") that provided funding for Vertex's cystic fibrosis drug discovery effort. Under the amended agreement, Vertex retains the right to develop and commercialize VX-770, VX-809 and any other compounds discovered in the research collaboration, and will owe royalties to CFFT on net sales of any drug candidate approved and commercialized under the collaboration. Funding under the agreement ended in early 2008. In 2009, 2008 and 2007, Vertex recognized \$0.5 million, \$0.8 million and \$15.9 million, respectively, in revenues related to its agreement with CFFT.

#### Merck & Co., Inc.

In June 2004, Vertex entered into a global collaboration with Merck to develop and commercialize Aurora kinase inhibitors for the treatment of cancer. The Merck collaboration agreement provided for an up-front license payment of \$20 million, which was made in June 2004, and for research funding of \$14 million over two years, ending in June 2006. In 2006, the Company agreed with Merck to extend the research program term and corresponding research funding for the parties' ongoing research collaboration for an additional three months beyond the original research program termination date.

#### Notes to Consolidated Financial Statements (Continued)

#### **P.** Collaborative Arrangements (Continued)

Vertex was eligible to receive as much as \$350 million in milestone payments. As of December 31, 2009, Vertex had received an aggregate of \$70.8 million in milestone payments pursuant to this collaboration. Merck is responsible for worldwide clinical development and commercialization of any compounds developed under the collaboration and would be obligated to pay the Company royalties on any product sales. Merck may terminate the agreement at any time without cause upon 90 days' advance written notice, except that six months' advance written notice is required for termination at any time when a product has marketing approval in a major market and the termination is not the result of a safety issue. Merck is conducting a Phase 1 clinical trial of MK-5108 (VX-689) involving patients with advanced and/or refractory tumors, but has indicated to the Company, based on its analysis of its broader portfolio of drug development programs, that it does not anticipate continuing further development activities with respect to MK-5108 after the completion of dosing of patients currently enrolled in this Phase 1 clinical trial. Merck is not conducting any other clinical trials of drug candidates that resulted from the collaboration. In 2009, 2008 and 2007, Vertex received milestone payments of \$0, \$6.0 million and \$9.0 million.

#### **Q.** Acquisition of ViroChem Pharma Inc.

On March 12, 2009, the Company acquired 100% of the outstanding equity of ViroChem, a privately-held biotechnology company based in Canada, for \$100.0 million in cash and 10,733,527 shares of the Company's common stock. Vertex acquired ViroChem in order to add two clinical-development stage HCV polymerase inhibitors to Vertex's HCV drug development portfolio. At the time of the acquisition, ViroChem was also engaged in research stage activities related to viral diseases and was developing an early-stage drug candidate for the treatment of patients with HIV infection.

The transaction was accounted for under the acquisition method of accounting. All of the assets acquired and liabilities assumed in the transaction were recognized at their acquisition-date fair values, while transaction costs and restructuring costs associated with the transaction were expensed as incurred.

#### Purchase Price

The \$390.6 million purchase price for ViroChem is based on the acquisition-date fair value of the consideration transferred, which was calculated based on the opening price of the Company's common stock of \$27.07 per share on March 12, 2009. The acquisition-date fair value of the consideration consisted of the following:

	Fair Value of Consideration
· · · · ·	(in thousands)
Cash	. \$100,000
Common stock	. 290,557
Total	\$390,557

#### Notes to Consolidated Financial Statements (Continued)

#### Q. Acquisition of ViroChem Pharma Inc. (Continued)

#### Allocations of Assets and Liabilities

The Company allocated the purchase price for ViroChem to net tangible assets and intangible assets, goodwill and a deferred tax liability. The difference between the aggregate purchase price and the fair value of assets acquired and liabilities assumed was allocated to goodwill. The following table summarizes the fair values of the assets acquired and liabilities assumed at the acquisition date:

	Fair Values as of March 12, 2009
	(in thousands)
Cash and cash equivalents	\$ 12,578
Other tangible assets	2,701
Intangible assets	525,900
Goodwill	26,102
Accounts payable and accrued expenses	(14,221)
Deferred tax liability	(162,503)
Net assets	\$ 390,557

All \$525.9 million of the intangible assets acquired in the ViroChem acquisition related to in-process research and development assets. These in-process research and development assets primarily related to ViroChem's two clinical-development stage HCV polymerase inhibitors, VX-222 (formerly VCH-222) and VX-759 (formerly VCH-759), which had estimated fair values at the acquisition date of \$412.9 million and \$105.8 million, respectively. The Company measured the fair values of VX-222 and VX-759 from the perspective of a market participant. In addition, the Company considered ViroChem's other clinical drug candidates and determined that VCH-286, ViroChem's lead HIV drug candidate, had an estimated fair value of \$7.2 million at the acquisition date, based on development costs through the acquisition date, and that the other clinical drug candidates had no fair value because the clinical and nonclinical data for those drug candidates did not support further development as of the acquisition date. The Company also considered ViroChem's preclinical programs and other technologies and determined that because of uncertainties related to the safety, efficacy and commercial viability of the potential drug candidates, market participants would not ascribe value to these assets.

The deferred tax liability primarily relates to the tax impact of future amortization or impairments associated with the identified intangible assets acquired, which are not deductible for tax purposes.

The difference between the consideration transferred to acquire the business and the fair value of assets acquired and liabilities assumed was allocated to goodwill. This goodwill relates to the potential synergies from the possible development of combination therapies involving telaprevir and the acquired drug candidates. None of the goodwill is expected to be deductible for income tax purposes.

#### Intangible Assets and Goodwill Post-acquisition

If the Company completes a project related to an in-process research and development asset, it will amortize the carrying value of the related intangible asset over the remaining estimated life of the asset beginning in the period in which the project is completed. If the Company determines that a project has become impaired or abandons a project, it will write down the carrying value of the related

#### Notes to Consolidated Financial Statements (Continued)

#### Q. Acquisition of ViroChem Pharma Inc. (Continued)

intangible asset to its fair value and will take an impairment charge in the period in which the impairment occurs. The ViroChem intangible assets and goodwill are tested for impairment on an annual basis as of October 1, or earlier if impairment indicators are present.

In the fourth quarter of 2009, the Company evaluated the intangible assets and goodwill related to the ViroChem transaction for impairment. No impairment was found for VX-759, VX-222 or the goodwill. The Company determined that the fair value of VX-286 was zero, resulting in a \$7.2 million impairment charge. In connection with this impairment charge, the Company also recorded an adjustment of \$2.2 million to the deferred tax liability.

#### Acquisition-related Expenses, Including Restructuring

In connection with the acquisition of ViroChem, the Company incurred \$7.8 million in expenses, which are reflected as acquisition-related expenses on the consolidated statements of operations in 2009. These costs include transaction expenses as well as a restructuring charge the Company incurred in March 2009 when it determined it would restructure ViroChem's operations in order to focus on ViroChem's HCV development programs. As a result of this restructuring plan, Vertex recorded a \$2.1 million expense related to employee severance, benefits and related costs in 2009.

#### ViroChem Financial Information

The results of operations of ViroChem have been included in the consolidated financial statements since the acquisition date. ViroChem had no revenues in the period from the acquisition date of March 12, 2009 through December 31, 2009. Pro forma results of operations for the year ended December 31, 2009 and 2008, assuming the acquisition of ViroChem had taken place at the beginning of each period, would not differ significantly from Vertex's actual reported results.

#### **R.** September 2009 Financial Transactions

#### 2012 Notes

On September 30, 2009, the Company sold \$155.0 million in aggregate principal amount of secured notes due 2012 (the "2012 Notes") for an aggregate of \$122.2 million pursuant to a note purchase agreement with Olmsted Park S.A. (the "Purchaser"). The 2012 Notes were issued pursuant to, and the 2012 Notes are governed by the terms of, an indenture entered into on September 30, 2009 between the Company and U.S. Bank National Association, as trustee and collateral agent.

The 2012 Notes were issued at a discount and do not pay current interest prior to maturity. The 2012 Notes will mature on October 31, 2012, subject to earlier mandatory redemption to the extent specified milestone events set forth in the Company's collaboration with Janssen are achieved prior to October 31, 2012. \$100.0 million of these potential milestone payments related to the regulatory filing with and approval of telaprevir by the European Medicines Evaluation Agency, and \$55.0 million relate to the launch of telaprevir in the European Union. The Company will be required to redeem the portion of the 2012 Notes equal to each milestone payment as each such milestone payment is earned under the Janssen collaboration.

The holders of the 2012 Notes have the right to cause the Company to repay all or any part of the 2012 Notes at 100% of the principal amount of the 2012 Notes to be repurchased if a change of control of the Company occurs. The Company may also redeem all or any part of the 2012 Notes at

#### Notes to Consolidated Financial Statements (Continued)

#### R. September 2009 Financial Transactions (Continued)

any time at 100% of the principal amount of the 2012 Notes to be redeemed. Upon certain events of default occurring and continuing, either the trustee or the holders of not less than 25% in aggregate principal amount of the 2012 Notes then outstanding may declare the principal of the 2012 Notes immediately due and payable. In the case of certain events of bankruptcy, insolvency or reorganization relating to the Company, the principal amount of the 2012 Notes shall automatically become immediately due and payable.

The Company has determined that the 2012 Notes contain an embedded derivative related to the potential mandatory redemption or early repayment of the 2012 Notes at the principal amount prior to their maturity date. The Company bifurcated the embedded derivative from the 2012 Notes because the features of the embedded derivative were not clearly and closely related to the 2012 Notes.

In connection with the issuance of the 2012 Notes, the Company granted a security interest to the Purchaser with respect to \$155.0 million of future telaprevir milestone payments that the Company is eligible to receive from Janssen for the potential future filing, approval and launch of telaprevir in the European Union.

The Company determined that the 2012 Notes had an initial residual value upon issuance of \$108.2 million, which excluded the estimated \$10.7 million value of the embedded derivative. The Company determined that the fair value of the embedded derivative as of September 30, 2009 was \$10.7 million based on a probability-weighted model of the discounted value that market participants would ascribe to the potential mandatory redemption and early repayment features of the 2012 Notes. The Company records quarterly interest expense related to the 2012 Notes determined using the effective interest rate method. The fair value of this embedded derivative is evaluated quarterly, with any changes in the fair value of the embedded derivative resulting in a corresponding loss or gain. The liabilities related to the 2012 Notes, including the embedded derivative, are reflected together on the Company's consolidated balance sheet as a long-term liability.

Any expenses incurred after issuance on the 2012 Notes, including losses, if any, related to the embedded derivative, will increase the liability for the 2012 Notes each quarter by an amount corresponding to expense and any gains related to the embedded derivative will decrease the liability for the 2012 Notes. In the fourth quarter of 2009, the Company recorded interest expense of \$3.1 million using the effective interest rate method and a gain of \$0.2 million related to the embedded derivative. As of December 31, 2009, the fair value of the 2012 Notes was \$121.8 million, including the \$10.5 million estimated value of the embedded derivative.

#### Sale of Future Milestone Payments

On September 30, 2009, the Company entered into two purchase agreements with the Purchaser pursuant to which the Company sold its rights to an aggregate of \$95.0 million in potential future milestone payments pursuant to the Janssen collaboration related to the launch of telaprevir in the European Union, for nonrefundable payments totaling \$32.8 million. The \$32.8 million cash payment was received on October 1, 2009. The purchase agreements contain representations, warranties, covenants and indemnification obligations of each party, including the obligation of the Company to make the milestone payments to the Purchaser when the underlying milestone events are achieved if the Janssen collaboration has been terminated.

#### Notes to Consolidated Financial Statements (Continued)

#### **R.** September 2009 Financial Transactions (Continued)

The Company determined that this sale of a potential future revenue stream should be accounted for as a liability related to the sale of the future milestone payments because the Company has significant continuing involvement in the generation of the potential milestone payments pursuant to its collaboration agreement with Janssen. As a result, the Company recorded a liability on its consolidated balance sheet equal to the fair value of the purchase agreements. No revenues or deferred revenues have been recorded on account of the amounts that the Company received from the Purchaser pursuant to these purchase agreements. In addition, the Company determined that the purchase agreements are free-standing derivative instruments. The Company determined that the initial aggregate fair value of the free-standing derivative created by the sale of the rights to future milestone payments to the Purchaser pursuant to the purchase agreements was \$36.2 million based on a probability-weighted model of the discounted value that market participants would ascribe to these rights. The models used to estimate the fair value of the rights sold to the Purchaser pursuant to the purchase agreements require the Company to make estimates regarding, among other things, the assumptions market participants would make regarding the timing and probability of achieving the milestones and the appropriate discount rates. The fair value of the rights sold to the Purchaser pursuant to the purchase agreements will be evaluated each reporting period, with any changes in the fair value of the derivative instruments based on the probability of achieving the milestones, the timing of achieving the milestones or discount rates resulting in a corresponding gain or loss. Because the Company's estimate of the fair value of the rights to the future milestone payments includes the application of a discount rate to reflect the time-value of money, the Company expects to record interest costs related to this liability each quarter. In the fourth quarter of 2009, the Company recorded expense of \$2.0 million with respect to the sale of the future milestone payments and increased the liability on its consolidated balance sheet to \$38.2 million as of December 31, 2009.

#### S. Employee Benefits

The Company has a 401(k) retirement plan (the "Vertex 401(k) Plan") in which substantially all of its permanent United States employees are eligible to participate. Participants may contribute up to 60% of their annual compensation to the Vertex 401(k) Plan, subject to statutory limitations. The Company may declare discretionary matching contributions to the Vertex 401(k) Plan that are payable in Vertex common stock. The match is paid in the form of fully vested interests in a Vertex common stock fund. Employees have the ability to transfer funds from the Company stock fund as they choose. The Company declared matching contributions to the Vertex 401(k) Plan as follows:

	2009	2008	2007
	(in thousands)		
Discretionary matching contributions during the year ended December 31,	\$6,044	\$5,027	\$4,340
Shares issued during the year ended December 31,	198	195	133
Shares issuable as of the year ended December 31,	35	38	48

#### T. Contingencies

ı

The Company has certain contingent liabilities that arise in the ordinary course of its business activities. The Company accrues a reserve for contingent liabilities when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. There were no contingent liabilities accrued as of December 31, 2009 or 2008.

#### Notes to Consolidated Financial Statements (Continued)

#### **U.** Guarantees

As permitted under Massachusetts law, the Company's Articles of Organization and Bylaws provide that the Company will indemnify certain of its officers and directors for certain claims asserted against them in connection with their service as an officer or director. The maximum potential amount of future payments that the Company could be required to make under these indemnification provisions is unlimited. However, the Company has purchased directors' and officers' liability insurance policies that could reduce its monetary exposure and enable it to recover a portion of any future amounts paid. No indemnification claims are currently outstanding and the Company believes the estimated fair value of these indemnification arrangements is minimal.

The Company customarily agrees in the ordinary course of its business to indemnification provisions in agreements with clinical trials investigators and sites in its drug development programs, in sponsored research agreements with academic and not-for-profit institutions, in various comparable agreements involving parties performing services for the Company in the ordinary course of business, and in its real estate leases. The Company also customarily agrees to certain indemnification provisions in its drug discovery, development and commercialization collaboration agreements. With respect to the Company's clinical trials and sponsored research agreements, these indemnification provisions typically apply to any claim asserted against the investigator or the investigator's institution relating to personal injury or property damage, violations of law or certain breaches of the Company's contractual obligations arising out of the research or clinical testing of the Company's compounds or drug candidates. With respect to lease agreements, the indemnification provisions typically apply to claims asserted against the landlord relating to personal injury or property damage caused by the Company, to violations of law by the Company or to certain breaches of the Company's contractual obligations. The indemnification provisions appearing in the Company's collaboration agreements are similar, but in addition provide some limited indemnification for its collaborator in the event of third-party claims alleging infringement of intellectual property rights. In each of the cases above, the indemnification obligation generally survives the termination of the agreement for some extended period, although the obligation typically has the most relevance during the contract term and for a short period of time thereafter. The maximum potential amount of future payments that the Company could be required to make under these provisions is generally unlimited. The Company has purchased insurance policies covering personal injury, property damage and general liability that reduce its exposure for indemnification and would enable it in many cases to recover a portion of any future amounts paid. The Company has never paid any material amounts to defend lawsuits or settle claims related to these indemnification provisions. Accordingly, the Company believes the estimated fair value of these indemnification arrangements is minimal.

In March 2003, the Company sold certain assets of PanVera LLC to Invitrogen Corporation for approximately \$97 million. In December 2003, the Company sold certain instrumentation assets to Aurora Discovery, Inc. for approximately \$4.3 million. The agreements with the buyers each require the Company to indemnify the buyer against any loss it may suffer by reason of Vertex's breach of certain representations and warranties, or failure to perform certain covenants, contained in such agreement. The representations, warranties and covenants contained in the agreements are of a type customary in agreements of this sort. The Company's aggregate obligations under the indemnity contained in each agreement are, with a few exceptions which the Company believes are not material, capped at one-half of the applicable purchase price, and apply to claims under representations and warranties made within fifteen months after closing (which period has ended) although there is no corresponding time limit for claims made based on breaches of covenants. Neither Invitrogen nor Aurora has made any claims to

#### Notes to Consolidated Financial Statements (Continued)

#### **U. Guarantees (Continued)**

date under the applicable indemnities, and the Company believes that the estimated fair value of the remaining indemnification obligations is minimal.

On February 12, 2008, the Company entered into underwriting agreements with Merrill Lynch, Pierce, Fenner & Smith Incorporated: on September 18, 2008, the Company entered into an underwriting agreement with Goldman, Sachs & Co.; on February 18, 2009, the Company entered into an underwriting agreement with Merrill Lynch, Pierce, Fenner & Smith Incorporated; and on December 2, 2009, the Company entered into an underwriting agreement with Goldman, Sachs & Co. (collectively, the "Underwriting Agreements"), in each case as the representative of the several underwriters, if any, named in such agreements, relating to the public offering and sale of shares of the Company's common stock or convertible subordinated notes. The Underwriting Agreement relating to each offering requires the Company to indemnify the underwriters against any loss they may suffer by reason of the Company's breach of representations and warranties relating to that public offering, the Company's failure to perform certain covenants in those agreements, the inclusion of any untrue statement of material fact in the prospectus used in connection with that offering, the omission of any material fact needed to make those materials not misleading, and any actions taken by the Company or its representatives in connection with the offering. The representations, warranties and covenants in the Underwriting Agreements are of a type customary in agreements of this sort. The Company believes the estimated fair value of these indemnification arrangements is minimal.

#### V. Subsequent Event

In February 2010, the Company announced that it will redeem the remaining \$32.1 million in aggregate principal amount of 2013 Notes on March 19, 2010. If the holders of the 2013 Notes all elect to convert their 2013 Notes into common stock at the conversion price of approximately \$23.14 per share, the Company will issue approximately 1.4 million shares of the Company's common stock in full satisfaction of the 2013 Notes. If the holders of the 2013 Notes do not elect to convert their 2013 Notes into common stock, the Company will be required to redeem the 2013 Notes at a redemption price of \$1,032.99 per \$1,000 principal amount, which includes principal and unpaid interest that will accrue through the redemption date.

# Notes to Consolidated Financial Statements (Continued)

# W. Quarterly Financial Data (unaudited)

	Three Months Ended				
	March 31, 2009	June 30, 2009	Sept. 30, 2009	Dec. 31, 2009	
	(in thousands, except per share amounts)				
Revenues:	e (140	ф со1 <b>7</b>	<b>* 7</b> 00 4	¢ 0.400	
Royalty revenues	\$    6,140 17,839	\$    5,917 13,147	\$ 7,834 17,123	\$ 8,429 25,460	
Total revenues	23,979	19,064	24,957	33,889	
Royalty expenses	3,576	· 3,267	3,712	3,647	
Research and development expenses	143,581	139,331	132,132	135,230	
Sales, general and administrative expenses	28,520	32,526	36,572	32,574	
Restructuring expense	2,402	1,107	774	1,957	
Intangible asset impairment charges	7 702		$\rightarrow$	7,200	
Acquisition-related expenses	7,793				
Total costs and expenses	185,872	176,231	173,190	180,608	
Loss from operations	(161,893)	(157,167)	(148,233)	(146,719)	
Interest expense	2,599 (3,378)	1,489 (3,325)	595 (1,927)	327 (4,562)	
Loss on exchanges of convertible subordinated notes	(3,576)	(12,294)	(1,927)	(5,843)	
Loss on derivative instruments, net			·	(1,847)	
Net loss	\$(162,672)	\$(171,297)	\$(149,565)	\$(158,644)	
Basic and diluted net loss per common share	\$ (1.04)	\$ (0.99)	\$ (0.84)	\$ (0.86)	
Basic and diluted weighted-average number of common shares			<u> </u>		
outstanding	155,860	172,563	178,735	185,492	
	Three Months Ended				
	March 31, 2008	June 30, 2008	Sept. 30, 2008	Dec. 31, 2008	
	(in the	(in thousands, except per share amounts)			
Revenues:					
Royalty revenues	\$ 10,851 30,824	\$    9,741 59,668	\$    7,763 23,846	\$    9,128 23,683	
Total revenues	41,675	69,409	31,609	32,811	
Royalty expenses	3,576	3,701	4,194	4,215	
Research and development expenses	116,273	129,573	131,728	139,338	
Sales, general and administrative expenses	19,932	26,448	25,430	29,480	
Restructuring expense	630	1,168	885	1,641	
Total costs and expenses	140,411	160,890	162,237	174,674	
Loss from operations	(98,736)	(91,481)	(130,628)	(141,863)	
Interest income	4,496	3,993	4,396	3,443	
Interest expense	(1,914)	(3,833)	(3,812)	(3,912)	
Net loss	\$(96,154)	<u>\$(91,321)</u>	\$(130,044)	\$(142,332)	
Basic and diluted net loss per common share	\$ (0.72)	\$ (0.66)	\$ (0.93)	\$ (0.96)	
Basic and diluted weighted-average number of common shares					
outstanding	134,471	138,725	140,109	148,783	

# AYEAROF DEFINING MOMENTS VERTEX

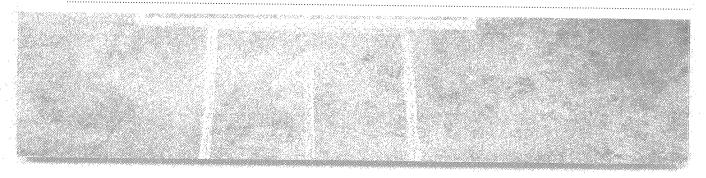


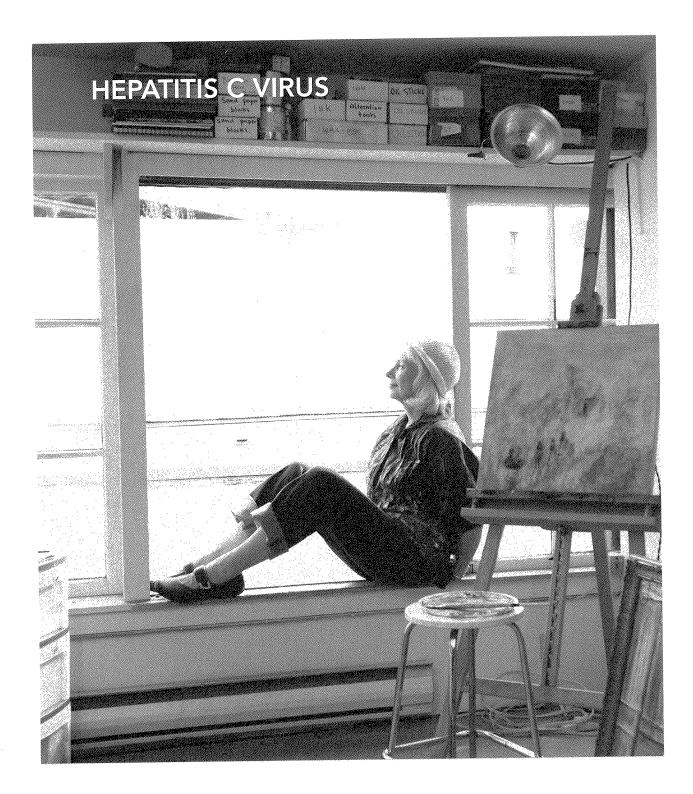
# FROM OUR CHAIRMAN, PRESIDENT AND CEO

2010 will be a year of defining moments as Vertex evolves toward becoming a fully capable biopharmaceutical company.

In HCV, clinical data presented throughout 2009 provided further support for the potential future role of telaprevir, our lead hepatitis C virus (HCV) protease inhibitor, to improve patient care in HCV - a disease that is estimated to affect more than three million people in the U.S. We remain on track to submit a New Drug Application (NDA) for telaprevir in the second half of 2010 for both treatment-naïve and treatment-failure HCV patients. Importantly, we also recognize the need for continued innovation in the treatment of HCV, and an ongoing clinical trial combining telaprevir with VX-222, our lead HCV polymerase inhibitor, will help define the potential role that this combination regimen may play in the future treatment of this disease.

Beyond our development progress in HCV, Vertex also continues to build its commercial capabilities to support the potential launch of telaprevir and other drug candidates. The submission of the telaprevir NDA is but one of many critical steps toward ensuring the long-term success of our business. We have in place a highly experienced team charged with leading key pre-launch and commercialization activities, and we continue to make significant strides in our efforts to fully understand the disease areas where we expect to





# HEPATITIS C VIRUS



More than three million people in the U.S. are infected with the hepatitis C virus (HCV), a potentially deadly infection that can cause severe liver disease, liver cancer and death. Three-quarters of those infected with HCV are unaware of their infection. HCV is four times as prevalent as HIV, but a widespread lack of awareness around HCV and its consequences hinders effective screening, diagnosis and optimal care for those infected.

"I believe that telaprevir represents a significant opportunity to improve the treatment of patients with HCV. But the development of new and more effective therapies is only part of the fight to eradicate this disease. Just as important are Vertex's ongoing efforts to increase awareness of HCV and to support activities to improve screening and diagnosis of this disease so that millions of patients may avoid potentially lifethreatening future health consequences."

-Nancy Wysenski, EVP and Chief Commercial Officer

The majority of patients infected with HCV were born between 1946 and 1964, accounting for two of every three chronic HCV cases in the U.S. With the aging of the baby boomer generation, the medical impact and financial burden of HCV has only begun to emerge. Today, deaths as a result of HCV-related liver disease number some 12,000 annually and are expected to grow dramatically in the coming decade. Further, total HCV-related medical costs are estimated to increase from \$30 billion today to approximately \$85 billion by 2024.

HCV is one of our nation's largest health epidemics. But unlike many other chronic viral diseases, HCV is curable. Currently approved treatment consisting of pegylatedinterferon and ribavirin results in a sustained viral response (SVR), or viral cure, in 40% to 50% of treatment-naïve genotype 1 patients who undergo a 48-week regimen. But for many patients, 48 weeks of treatment with a less than 50% chance of any benefit is not an appealing option.

#### COMMITMENT TO IMPROVE HCV PATIENT CARE

With its lead investigational HCV protease inhibitor, telaprevir, Vertex hopes to transform HCV care by providing patients and the health care community with a better treatment option for this growing,epidemic.

In Phase 2 clinical trials in both treatment-naïve and treatment-failure genotype 1 HCV patients, telaprevir increased SVR rates when dosed in combination with currently available therapies, as compared to currently available therapies alone. For the treatment-naïve population, specifically, the majority of patients received 24 weeks of telaprevir-based therapy, as compared to 48 weeks of currently available therapies alone.

A broad Phase 3 clinical development program for telaprevir is nearing completion, with the first SVR data expected in the spring of 2010. Vertex plans to submit a New Drug Application for telaprevir as part of combination therapy in treatment-naïve and treatment-failure HCV patients in the second half of 2010, marking what Vertex believes will be a milestone in the company's more than decade-long commitment to HCV.

As part of this commitment to improve HCV patient care, Vertex is also evaluating novel combination regimens of telaprevir and VX-222, the company's lead investigational HCV polymerase inhibitor. And beyond its clinical development efforts, Vertex is also actively engaged with the HCV community to fully understand the impact of this disease, the needs of patients and health care providers, and how the health care system may integrate potential new therapies in the future care of this disease.

Please visit investors.vrtx.com for additional clinical data on Vertex's Phase 2 trials with telaprevir, including safety information. These materials include forward-looking statements; please refer to the Safe Harbor statement on the accompanying annual report.



# PIPELINE

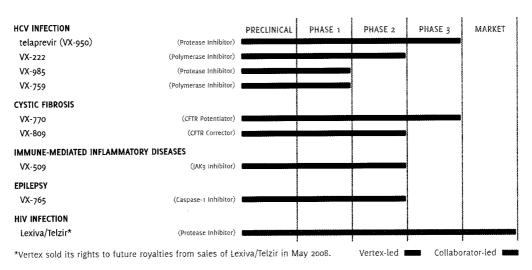
#### A BROAD DEVELOPMENT PIPELINE

At Vertex, we seek profound change in the treatment of serious diseases. Our team of dedicated scientists is driven by innovation and the opportunity to transform patients' lives through new scientific approaches to highly challenging medical problems.

Today, our primary focus is on the completion of the Phase 3 program with telaprevir for the treatment of hepatitis C virus (HCV) infection. We believe telaprevir has the potential to be a dramatic advance in the treatment of this disease and represents the type of innovation that Vertex seeks across its pipeline. In addition to telaprevir, Vertex is also advancing its development efforts for VX-770 and VX-809 in cystic fibrosis (CF), an orphan disease that is emerging as an important element of our business. And as part of our long-term commitment to improving patient care in HCV and CF, we are exploring the potential role of novel combination regimens with the hope of improving the future treatment of these diseases. Beyond HCV and CF, Vertex has a broad pipeline of additional clinical drug candidates and preclinical projects aimed at fueling our long-term growth.

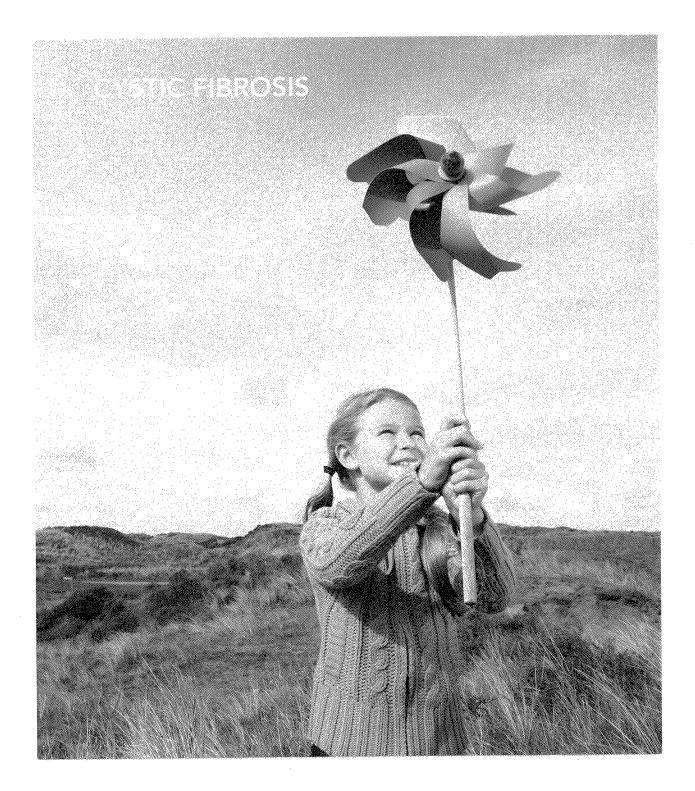
Vertex is currently conducting proof-of-concept clinical trials of VX-509, an oral, highly specific Janus kinase 3 (JAK3) inhibitor for the treatment of rheumatoid arthritis, and VX-765, an oral, Caspase-1 inhibitor that aims to inhibit key inflammatory processes leading to epileptic seizures. We also have more than a dozen ongoing preclinical programs aimed at some of the world's most serious diseases, including cancer, multiple sclerosis, pandemic influenza, Huntington's disease and tuberculosis. Similar to our approach in HCV and CF, our preclinical efforts are highly ambitious and seek to change the way diseases are treated.

At Vertex, innovation is not a corporate maxim; it's our lifeblood.



These materials include forward-looking statements; please refer to the Safe Harbor statement on the accompanying annual report.





# CYSTIC FIBROSIS



Today, patients with cystic fibrosis (CF) lead longer, healthier lives than ever before. But a "longer, healthier" life for a CF patient still means living, on average, only into their midthirties while enduring hours of daily therapy.

Approximately 30,000 people in the U.S. are afflicted with CF, an orphan, genetic disease where patients have defective or missing cystic fibrosis transmembrane conductance regulator (CFTR) proteins. When these CFTR proteins cannot properly move chloride ions across the cell membrane, mucus builds in the lungs, causing an environment prone to infection, inflammation and a gradual loss of lung function.

Current CF therapies aim to treat only the complications arising from CF, such as lung infections, and while these therapies have improved the lives of CF patients, the median predicted lifespan for those afflicted with CF remains only 37 years.

#### A BOLD ENDEAVOR TO TREAT CF AT ITS ROOT

In 1998, Vertex and the Cystic Fibrosis Foundation began a bold endeavor to discover and develop novel CF therapies aimed at treating the underlying defect of CF. Twelve years later, Vertex is advancing two novel CF compounds through clinical development: VX-770, known as a CFTR potentiator, and VX-809, known as a CFTR corrector.

VX-770 aims to increase the activity of defective CFTR proteins at the cell surface. In a Phase 2 trial in 39 patients with the G551D mutation in the CFTR gene completed in 2008, treatment with VX-770 for 14 or 28 days resulted in improvement in lung function as measured by forced expiratory volume (FEV,), as well as improvement in additional biomarkers of CFTR activity. Based on these results, a Phase 3 registration program is ongoing focused on patients with the G551D mutation, which accounts for approximately 4% of the U.S. CF patient population. Should these studies be successful, Vertex plans to submit a New Drug Application for VX-770 in the second half of 2011.

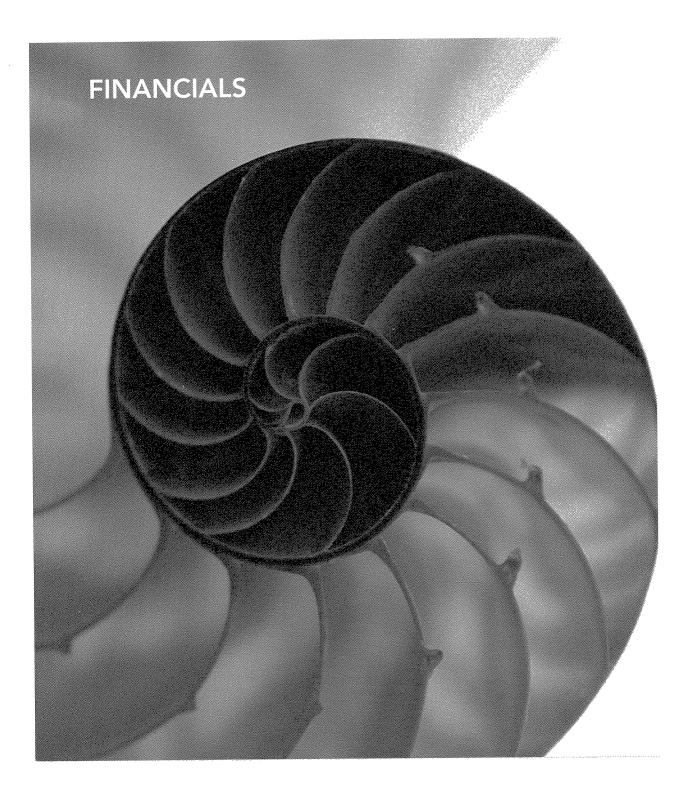
"Cystic fibrosis represents an important emerging disease area for Vertex – one where we believe that our innovative approach to treat the underlying cause of this orphan disease has the potential to dramatically improve the lives of CF patients."

> - Peter Mueller, Ph.D., EVP, Global Research and Development and Chief Scientific Officer

VX-809 aims to increase the concentration of CFTR proteins at the cell surface. In a Phase 2 trial completed in 2009 in 89 patients with the most common mutation in the *CFTR* gene, known as F508del, treatment with VX-809 for 28 days resulted in improvement in measures of sweat chloride, a key biomarker of CFTR activity.

Based on these results, Vertex is evaluating the potential development path for a combination regimen of VX-770 and VX-809 in patients with the F508del mutation, which is present in approximately 90% of the CF patient population in the U.S.

Please visit investors.vtx.com for additional clinical data on Vertex's Phase 2 trials with VX-770 and VX-809, including safety information. These materials include forward-looking statements; please refer to the Safe Harbor statement on the accompanying annual report.



# FINANCIALS



#### BALANCED INVESTMENT TO ADVANCE OUR BUSINESS

Vertex aspires to become a fully capable biopharmaceutical company – one capable of discovering, developing and marketing multiple breakthrough products that may improve the lives of patients and deliver value to our shareholders.

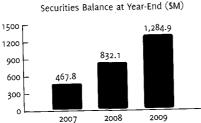
Today, Vertex has a unique set of product opportunities in various diseases to help define our future success. The planned submission of the New Drug Application for telaprevir in the second half of 2010 is our top priority. As the Phase 3 registration program for telaprevir nears completion, our 2010 investment in telaprevir will be focused on critical pre-launch activities, including the expansion of our commercial supply and the implementation of key elements of the infrastructure needed to support Vertex's first sales force. We are balancing investments across our business to ensure telaprevir's commercial success.

Beyond HCV, we are also strengthening our focus on novel approaches to other specialty disease areas, such as cystic fibrosis, and we continue to support our innovative research capabilities. We believe that cutting-edge science leads to future breakthrough products, and thus we will invest in the necessary areas of our business to support continued advancement toward becoming a fully capable biopharmaceutical company.

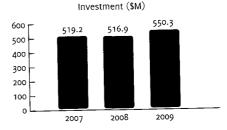
Vertex began 2010 with a cash position of approximately \$1.3 billion and, as of early 2010, had no outstanding convertible debt - a strong capital structure that creates flexibility as our business continues to grow in today's uncertain economic and industry environment.

"Vertex is committed to improving patient care in hepatitis C virus infection, cystic fibrosis and other serious diseases, and while our work is highly challenging, we believe the potential return – both for patients and for the company's shareholders – may be significant. As we progress our business over the coming year, we expect to increase our investment in pre-launch activities for telaprevir and to advance our development efforts in specialty disease areas such as cystic fibrosis."

- Ian Smith, EVP and Chief Financial Officer



Cash, Cash Equivalents & Marketable



Research & Development

These data are derived from our consolidated financial statements. Our audited consolidated financial statements, including the related footnotes and "Management's Discussion and Analysis of Financial Condition and Result of Operations," are included in our 2009 Annual Report on Form 10-K. These materials include forward-looking statements; please refer to the Safe Harbor statement on the accompanying annual report.



# CULTURE



At Vertex, we dream big. Each day, more than 1,400 employees walk through the doors of Vertex focused on one mission: Innovate to redefine health and transform lives with new medicines. A relentless commitment to scientific excellence and medical innovation drives our people and our culture and is reflected in a broad development pipeline with significant potential to improve patient care in a number of serious diseases.

"This is an exciting time to be part of Vertex. Today, we are building entirely new functions and capabilities in advance of the potential launch of telaprevir. As we continue to hire new, highly talented employees and expand the company's capabilities, our commitment to patients with serious diseases and to maintaining our unique, science-focused culture will remain unchanged."

- Lisa Kelly-Croswell, SVP, Human Resources

With two ongoing Phase 3 registration programs in hepatitis C virus (HCV) infection and cystic fibrosis (CF), 2010 brings a new set of challenges and opportunities for Vertex.

Today, we are building new functions within the company to support not only the potential launch of telaprevir, but also other potential future products to fuel the company's growth. We are also hiring and integrating new employees into our business to lead critical pre-launch activities for telaprevir, and we have begun to establish the internal infrastructure necessary to support the company's first sales force. This commercial team will help advance Vertex toward its mission in the coming years - linking the innovation created by our scientists to patients with serious diseases.

With the rapid growth of our company, it would be easy to lose sight of the culture and mission that brought Vertex to where it is today. But we remain focused on retaining a culture of innovation so that improving the lives of patients remains the company's top priority.

We support our employees with a variety of unique learning and development opportunities designed to foster collaboration and teamwork, create a network of minds and fuel our future success. Outside of the office, Vertex's innovative spirit is evidenced across our many activities in the local communities where we operate. In 2009, more than 800 Vertex employees participated in the Joshua Boger Day of Service, an annual event where Vertex employees volunteer at local charities and community organizations. In addition, our employees regularly conduct fund-raising events for the Cystic Fibrosis Foundation and American Liver Foundation, and we invite students from local schools to learn about the drug development process through hands-on activities led by Vertex scientists.

#### A CULTURE DEFINED BY ITS PEOPLE

2010 will be a defining year for Vertex. Our focus on science and a commitment to the needs of patients with serious diseases is unchanged. At Vertex, our employees will help define our future success.

Do you dream big? We do.

These materials include forward-looking statements; please refer to the Safe Harbor statement on the accompanying annual report.

operate. We are well-positioned to advance our commercial infrastructure over the coming months, and I look forward to this function playing a prominent role within our growing business in 2010.

And while telaprevir may represent a potentially significant advance in the treatment of HCV, Vertex will not become the fully capable company that we envision based solely on the success of a single product.

We are also focused on advancing two novel compounds - VX-770 and VX-809 - for the treatment of cystic fibrosis (CF), a devastating genetic disease that robs patients of a normal lifespan. Unlike currently approved therapies, our

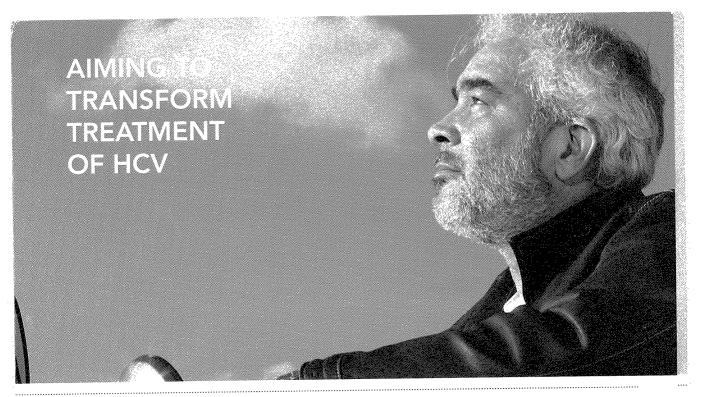
.....

approach to CF aims to directly treat the underlying defect of this orphan disease. A Phase 3 registration program is advancing rapidly for our lead CF compound VX-770, and we expect to submit an NDA in the second half of 2011 for CF patients with the G551D mutation. We are also evaluating the potential development path for a combination regimen with VX-770 and VX-809 in patients with the most common mutation of CF, known as F508del, potentially broadening the opportunity for our CF compounds to address the majority of CF patients.

To support our long-term growth, Vertex is also conducting clinical trials of VX-509, a novel, oral compound aimed at treating a key inflammatory pathway in rheumatoid arthri-

.....





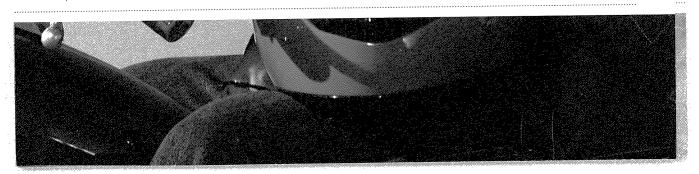
tis, and VX-765, an innovative, oral approach to the treatment of epilepsy. These proof-of-concept trials will provide important information in 2010 to help us begin to define the potential value of these compounds to patients and to Vertex.

What truly excites me about Vertex is that our clinical development programs represent only a fraction of our broad interests across multiple disease areas. Vertex has some of the world's leading scientists, and as a result, we currently have more than a dozen innovative preclinical programs ongoing in areas such as cancer, multiple sclerosis, pandemic influenza, Huntington's disease and tuberculosis. These and other early-stage programs may lead to additional clinical development candidates emerging in 2010. Today, Vertex is operating at a scale never before seen within our company. Our commitment to cutting-edge science and breakthrough products for patients with serious diseases is unwavering, and we continue to progress toward our goal of becoming a fully capable biopharmaceutical company.

I look forward to updating you as the year progresses. Thank you for your continued support of Vertex.

les

Matthew Emmens Chairman, President and CEO Vertex Pharmaceuticals







page parameters

The product and the summary of a series of the series of the and the state of the state of the series of the serie



Vertex Pharmaceuticals Incorporated | Cambridge, MA | www.vrtx.com