

VERTEX PHARMACEUTICALS INC / MA  
Form 10-K  
February 22, 2012

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON, D.C. 20549

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**FORM 10-K**

ý **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE  
ACT OF 1934**

**For the Fiscal Year Ended December 31, 2011**

or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934**

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission file number 000-19319**

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**Vertex Pharmaceuticals Incorporated**

(Exact name of registrant as specified in its charter)

**Massachusetts**  
(State or other jurisdiction of  
incorporation or organization)

**04-3039129**  
(I.R.S. Employer  
Identification No.)

**130 Waverly Street, Cambridge, Massachusetts**  
(Address of principal executive offices)

**02139-4242**  
(Zip Code)

Registrant's telephone number, including area code **(617) 444-6100**

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Securities registered pursuant to Section 12(b) of the Exchange Act:

**Title of Each Class**  
Common Stock, \$0.01 Par Value Per Share

**Name of Each Exchange on Which Registered**  
The NASDAQ Global Select Market

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Securities registered pursuant to Section 12(g) of the Exchange Act: None

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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 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):

Large accelerated filer       Accelerated filer       Non-accelerated filer       Smaller reporting company   
(Do not check if a 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, 2011 (the last trading day of the registrant's second fiscal quarter of 2011) was \$10.7 billion. As of February 8, 2012, the registrant had 210,335,993 shares of common stock outstanding.

## DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive Proxy Statement for the 2012 Annual Meeting of Shareholders to be held on May 16, 2012 are incorporated by reference into Part III of this Annual Report on Form 10-K.

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## VERTEX PHARMACEUTICALS INCORPORATED

## ANNUAL REPORT ON FORM 10-K

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"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," "INCIVEK" and "KALYDECO" are registered trademarks of Vertex. Other brands, names and trademarks contained in this Annual Report on Form 10-K, including "INCIVO" and "TELAVIC," are the property of their respective owners.

Table of Contents**PART I****ITEM 1. BUSINESS****OVERVIEW**

We are in the business of discovering, developing, manufacturing and commercializing small molecule drugs for the treatment of serious diseases. Our two products are INCIVEK (telaprevir), which is approved for the treatment of patients with genotype 1 hepatitis C virus, or HCV, infection, and KALYDECO (ivacaftor), which is approved in the United States for the treatment of patients six years of age and older with cystic fibrosis, or CF, who have at least one copy of the G551D mutation in the cystic fibrosis transmembrane conductance regulator, or *CFTR*, gene. We have ongoing clinical programs involving drug candidates intended for the treatment of HCV infection, CF, rheumatoid arthritis, influenza and epilepsy. Our HCV clinical programs are focused on developing all-oral, interferon-free combinations of HCV drugs and drug candidates that have the potential to further improve treatment options available to patients with HCV infection. In our CF program, we are investigating the use of ivacaftor as a monotherapy in additional populations of patients with CF and combinations of ivacaftor and our other CF drug candidates, with the goal of expanding the group of patients with CF who can benefit from our medicines. We believe that our longer-term success will depend on our ability to continue to generate and develop innovative medicines for the treatment of serious diseases. As a result, we expect to continue investing in research programs directed toward the identification of new drug candidates and to develop and commercialize selected drug candidates that emerge from those programs, alone or with third-party collaborators.

**OUR PRODUCTS**

<b>Product</b>	<b>Indication</b>	<b>Mechanism</b>	<b>Marketed</b>	<b>Marketing Rights</b>
INCIVEK (telaprevir)	Genotype 1 HCV Infection	HCV Protease Inhibitor	United States and Canada	Vertex
KALYDECO (ivacaftor)	CF (G551D mutation)	CFTR Potentiator	United States	Vertex
INCIVO (telaprevir)	Genotype 1 HCV Infection	HCV Protease Inhibitor	United Kingdom, Germany, France, Sweden, Austria, Finland, Denmark, Switzerland and Norway	Janssen
TELAVIC (telaprevir)	Genotype 1 HCV Infection	HCV Protease Inhibitor	Japan	Mitsubishi Tanabe

INCIVEK (telaprevir) is an orally-administered HCV protease inhibitor for adults with genotype 1 HCV infection that is prescribed in combination with pegylated-interferon, or peg-IFN, and ribavirin, or RBV. INCIVEK was approved by the United States Food and Drug Administration, or FDA, in May 2011 and was approved by Health Canada in August 2011. In September 2011, our collaborators, Janssen Pharmaceutica, N.V., or Janssen, a Johnson & Johnson company, and Mitsubishi Tanabe Pharma Corporation, or Mitsubishi Tanabe, obtained marketing approval for telaprevir from the European Commission and the Japanese Ministry of Health, Labor and Welfare, respectively. Janssen markets telaprevir under the brand name INCIVO in Europe. Mitsubishi Tanabe markets telaprevir under the brand name TELAVIC in Japan.

KALYDECO (ivacaftor) is an orally-administered CFTR potentiator that is approved in the United States for the treatment of patients six years of age and older with CF who have at least one copy of the G551D mutation in the *CFTR* gene. KALYDECO, which was referred to during development as VX-770, was approved by the FDA in January 2012. In October 2011, we submitted a Marketing Authorization Application, or MAA, for ivacaftor (VX-770) to the European Medicines Agency, or EMA. Our MAA for ivacaftor has been validated by the EMA, and the EMA has granted our request for accelerated assessment, which applies to new medicines of major public health interest and shortens

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the EMA's review time. We also plan to seek approval for ivacaftor in a number of other countries, including Canada and Australia. We expect to obtain approval to market ivacaftor in the European Union later in 2012.

**OUR DRUG CANDIDATES**

<b>Drug Candidate</b>	<b>Indication</b>	<b>Mechanism</b>	<b>Development Stage</b>	<b>Marketing Rights</b>
<b><i>HCV Infection</i></b>				
VX-222	HCV Infection	Non-nucleoside HCV Polymerase Inhibitor	Phase 2	Vertex
ALS-2158	HCV Infection	HCV Nucleotide Analogue	Phase 1	Vertex
ALS-2200	HCV Infection	HCV Nucleotide Analogue	Phase 1	Vertex
<b><i>Cystic Fibrosis</i></b>				
VX-809	Cystic Fibrosis	CFTR Corrector	Phase 2	Vertex
VX-661	Cystic Fibrosis	CFTR Corrector	Phase 2	Vertex
<b><i>Immune-mediated Inflammatory Diseases</i></b>				
VX-509	Rheumatoid Arthritis	JAK3 Inhibitor	Phase 2	Vertex
<b><i>Epilepsy</i></b>				
VX-765	Epilepsy	ICE Inhibitor	Phase 2	Vertex
<b><i>Influenza</i></b>				
VX-787	Influenza A Infection	Influenza Virus Inhibitor	Phase 1	Vertex

**OUR STRATEGY**

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

*Commercialize our products and expand our international capabilities.* INCIVEK (telaprevir) achieved initial commercial acceptance following its approval in May 2011, allowing us to begin operating as a cashflow positive company in the second half of 2011. We also started marketing KALYDECO in the United States in January 2012, which will provide us an additional source of revenues. In addition to the establishment of our North American commercial organization, we have expanded our international operations in order to support the potential commercialization of KALYDECO in Europe if it is approved by the European Commission. We believe that we will be able to leverage the experience we gained in the late-stage development and the commercialization of INCIVEK and KALYDECO and our expanded international operations in connection with the development and potential commercialization of our drug candidates.

*Advance clinical development programs that have the potential to address significant unmet medical needs.* We plan to evaluate a number of drug candidates in mid-stage clinical trials in 2012, including potential all-oral, interferon-free treatment regimens for HCV infection, ivacaftor monotherapy and combination regimens that potentially could benefit a broader group of patients with CF, and VX-509 for the treatment of patients with rheumatoid arthritis and other immune-mediated inflammatory diseases. We believe these, and our other clinical development programs, have the potential to provide additional revenues to us in the future.

*Invest in research and early-stage drug candidates.* We believe that our long-term success depends on our ability to continue to generate and develop innovative compounds. We intend to continue to invest significant resources in research programs and early-stage drug candidates in an effort to identify and advance additional compounds that have the potential to address significant unmet medical needs.

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*Complement our internal efforts with external assets, technologies and capabilities.* Our business development activities have provided us with drug candidates and/or important financial and non-financial resources that have contributed to our products and a number of the drug candidates in our current development pipeline. We will continue to seek to license or acquire drugs, drug candidates and other technologies that have the potential to add to our pipeline or to provide us with new commercial opportunities. Furthermore, we may seek collaborators to support, develop and/or commercialize some of our drug candidates.

**HCV INFECTION**

*Background: Effects and Prevalence of HCV Infection*

Exposure to HCV often leads to chronic infection, although patients frequently do not have symptoms and are unaware that they have become infected with HCV. Over time, liver inflammation develops in many patients. This inflammation can progress to scarring of the liver, called fibrosis, or more advanced scarring of the liver, called cirrhosis. Patients with cirrhosis may go on to develop liver failure or other complications, including liver cancer. The World Health Organization, or WHO, 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 WHO has estimated that about 170 million people are chronically infected with HCV worldwide and that an additional 3 million to 4 million people are newly infected each year. The Centers for Disease Control and Prevention, or CDC, have estimated that approximately 3.2 million people in the United States are chronically infected with HCV. The Institute of Medicine has estimated the infected population in the United States to be between 2.7 million and 3.9 million people. We believe that approximately 2.6 million patients in the United States have genotype 1 HCV infection.

*Telaprevir (INCIVEK in the United States and Canada, INCIVO in the European Union and TELAVIC in Japan)*

Telaprevir is an orally-administered HCV protease inhibitor that is indicated for the treatment of treatment-naïve and treatment-failure adults with genotype 1 HCV infection. We market telaprevir in the United States and Canada under the brand name INCIVEK, Janssen markets telaprevir under the brand name INCIVO in the United Kingdom, Germany, France, Sweden, Austria, Finland, Denmark, Switzerland and Norway, and Mitsubishi Tanabe markets telaprevir under the brand name TELAVIC in Japan. Telaprevir was discovered in our collaboration, now ended, with Eli Lilly and Company, and we pay Eli Lilly and Company royalties on net sales of telaprevir.

Patients who are prescribed a telaprevir-based treatment regimen receive telaprevir, peg-IFN and RBV for 12 weeks. After the first 12 weeks, patients stop receiving telaprevir and continue treatment with peg-IFN and RBV alone for an additional 12 weeks or 36 weeks of treatment. Peg-IFN is a medicine that is administered weekly by injection. Telaprevir is indicated for three-times-daily dosing and is being evaluated in a fully-enrolled Phase 3b clinical trial designed to support a supplemental New Drug Application, or sNDA, for twice-daily dosing, and comparable applications in the European Union.

We are conducting Phase 3b clinical trials to evaluate telaprevir-based combination regimens as treatments for genotype 1 HCV infection in patients who also have HIV infection and in patients who experience recurrent genotype 1 HCV infection following a liver transplant. In addition, we are evaluating a 12-week telaprevir-based combination regimen in a Phase 3 clinical trial in patients with genotype 1 HCV who have a specific variant in the patient's *IL-28B* gene, which is referred to as the CC variant, and which is associated with increased efficacy of interferon-based therapy. In this clinical trial, patients who meet certain response criteria will stop all treatment and be evaluated for efficacy

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after receiving the initial 12 weeks of telaprevir in combination with peg-IFN and RBV. Approximately one-third of patients with genotype 1 HCV infection have the CC variant in the patient's *IL-28B* gene.

*HCV Drug Candidates*

Our goal is to further improve treatment options available to patients with HCV infection by developing all-oral, interferon-free treatment regimens for HCV infection. Our HCV drug candidates, VX-222, ALS-2200 and ALS-2158, are designed to inhibit the replication of HCV by inhibiting the HCV NS5b polymerase enzyme. We are evaluating VX-222 in combination with telaprevir and RBV and plan to evaluate multiple combination regimens that incorporate our other HCV drug candidates.

Non-nucleoside HCV polymerase inhibitors, such as our investigational drug candidate VX-222, bind to the NS5b polymerase enzyme, changing its shape and inhibiting its enzymatic activity. HCV nucleotide analogues, such as our investigational drug candidates ALS-2200 and ALS-2158, also act on the HCV NS5b polymerase enzyme, but through mechanisms of action distinct from non-nucleoside HCV polymerase inhibitors. The separate mechanisms of action utilized by each of our HCV drug candidates and telaprevir support the possibility of developing all-oral treatment regimens for HCV infection involving multiple drugs and drug candidates, including dual nucleotide (adenosine and uracil analogue) treatment regimens.

VX-222 is being evaluated in a Phase 2 clinical trial referred to as ZENITH. ZENITH is designed to evaluate combination treatment regimens of telaprevir, VX-222 and RBV, with and without peg-IFN. The primary endpoint of this trial is safety and tolerability, and secondary endpoints are on-treatment antiviral activity and the proportion of people in each treatment arm who achieve a sustained viral response, which is defined in ZENITH as undetectable HCV RNA levels 12 weeks after completion of treatment, or SVR12. We have completed dosing in two, all-oral three-drug treatment arms of ZENITH in which treatment-naïve patients with genotype 1a HCV infection and genotype 1b HCV infection received VX-222 in combination with telaprevir and RBV. We expect to announce interim data, including the percentage of patients with undetectable HCV RNA levels 4 weeks after completion of treatment, from these two all-oral drug treatment arms in the first quarter of 2012.

In ZENITH, we also evaluated two dose levels of VX-222 in combination with telaprevir, RBV and peg-IFN in two treatment arms that enrolled a total of 59 patients with genotype 1 HCV infection. In these two treatment arms, 90% and 83%, respectively, of patients achieved a sustained viral response. At the higher dose level, 50% of patients completed all treatment after 12 weeks, while the other patients continued receiving peg-IFN and RBV for 12 weeks after receiving the four-drug combination for the initial 12-week period. The most frequent adverse events observed in these treatment arms were fatigue, nausea, diarrhea, anemia, pruritis, insomnia and rash. Three patients in each study arm discontinued treatment before week 12 and one patient in each arm discontinued treatment between weeks 12 and 24 while they were receiving peg-IFN and RBV alone.

In December 2011, our collaborator, Alios BioPharma, Inc., or Alios, and we initiated Phase 1 clinical trials to evaluate the safety and tolerability of single ascending doses of each of ALS-2200 and ALS-2158 taken alone in healthy volunteers, and of multiple ascending doses of each of ALS-2200 and ALS-2158 taken alone in patients with genotype 1 HCV. A secondary objective of these clinical trials is to evaluate the viral kinetics of ALS-2200 and ALS-2158 taken alone during seven days of dosing in patients with genotype 1 HCV infection. We expect to obtain the first data from these clinical trials in patients with genotype 1 HCV infection in the second quarter of 2012. Following these clinical trials, we plan to conduct Phase 2a clinical trials evaluating multiple all-oral combination HCV treatment regimens in the second half of 2012. These potential all-oral combinations include combinations of ALS-2200 or ALS-2158 with telaprevir or VX-222, potential dual regimens of ALS-2200 and ALS-2158 together, and other all-oral, interferon-free combinations that include RBV.

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**CYSTIC FIBROSIS**

*Background: Effects and Prevalence of Cystic Fibrosis*

The underlying cause of CF is a genetically inherited deficiency in the production or activity of the CFTR protein, which is involved in controlling the movement of chloride ions into and/or out of cells in the lungs, sweat glands, pancreas and other organs. 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.

CF occurs when neither of the two copies of the *CFTR* gene, referred to as alleles, produce sufficient functional CFTR protein. There are a variety of mutations in the *CFTR* gene that result in CF, including two of the most prevalent mutations in the *CFTR* gene, 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. There are many additional mutations in the *CFTR* gene that result in CF, including other mutations that result in gating or trafficking defects.

KALYDECO and our CF drug candidates were selected because of their potential to improve the function of defective CFTR proteins in patients with CF. We discovered KALYDECO, VX-809 and VX-661 in our research collaboration with the Cystic Fibrosis Foundation Therapeutics Incorporated, or CFFT. We hold worldwide development and commercialization rights to KALYDECO, VX-809 and VX-661. We pay royalties to CFFT on net sales of KALYDECO and will pay royalties to CFFT on any net sales of VX-809 or VX-661, if they are approved.

It is estimated that CF affects about 30,000 people in the United States and 40,000 people in Europe. According to the 2010 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, approximately 48% of patients with CF have the F508del mutation on both alleles and an additional approximately 40% of patients with CF have the F508del mutation on one allele. In Europe, we believe approximately 2.5% of patients with CF have the G551D mutation on at least one allele and approximately 40% of patients with CF have the F508del mutation on both alleles.

*KALYDECO (ivacaftor/VX-770)*

KALYDECO (ivacaftor) is an orally-administered CFTR potentiator approved in January 2012 in the United States for the treatment of patients six years of age and older with CF who have the G551D mutation on at least one allele. In October 2011, we submitted an MAA for ivacaftor (VX-770) with the EMA. We are seeking approval from the European Commission to market ivacaftor for the treatment of patients with CF six years of age and older with the G551D mutation in the *CFTR* gene and with certain other mutations in the *CFTR* gene that result in gating defects. Our MAA for ivacaftor has been validated by the EMA. The EMA also has granted our request for accelerated assessment, which applies to new medicines of major public health interest and shortens the EMA's review time. We also plan to seek approval for ivacaftor in a number of other countries, including Canada and Australia. We believe that the European Commission could approve ivacaftor in the third quarter of 2012.

In mid-2012, we plan to initiate additional clinical trials to evaluate KALYDECO as a monotherapy for younger patients with CF who have gating mutations, including the G551D mutation on at least one allele, and in patients that have other mutations in the *CFTR* gene where there is the potential for KALYDECO to be administered as a monotherapy. In the first of these trials, KALYDECO will be evaluated in children ages two through five years with gating mutations in the



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*CFTR* gene, including the G551D mutation. In this clinical trial, we expect to evaluate the safety, tolerability and effect on sweat chloride levels as well as other measures of clinical activity using a pediatric formulation of KALYDECO. In the second of these clinical trials, KALYDECO will be evaluated in patients six years of age or older with CF with gating mutations other than the G551D mutation. These remaining gating mutations account for approximately 1% of patients with CF in the United States. In the third of these clinical trials, KALYDECO will be evaluated in patients six years of age or older with CF with the R117H mutation in the *CFTR* gene on at least one allele. The R117H mutation is a mutation that causes abnormal function of the CFTR protein on the cell surface and is present in approximately 3% of patients with CF in the United States.

KALYDECO (ivacaftor) was granted orphan drug status in the United States and the European Union. We are entitled to orphan drug exclusivity for KALYDECO in the United States, which means that the FDA may not approve other applications to market ivacaftor for the same indication for seven years except in very limited circumstances. We have a U.S. patent that covers the composition-of-matter of KALYDECO that expires in 2027 and that we expect will provide intellectual property protection in the United States through its expiration date. As a result of the seven-year orphan drug marketing exclusivity period, even if a competitor successfully challenges the KALYDECO patent it would not obtain approval from the FDA to market ivacaftor in the United States for at least seven years from the date of approval of KALYDECO. For more information regarding orphan drugs, see "*Orphan Drug Designation*" below.

*CF Drug Candidates*

We are investigating treatment regimens combining KALYDECO with our investigational correctors VX-809 and VX-661. We believe these regimens potentially could be used to treat patients with CF with mutations in the *CFTR* gene other than the G551D mutation, including patients with the F508del mutation, who represent the majority of patients with CF. VX-809 and VX-661 are oral CFTR corrector compounds that were selected because of their potential to increase the concentration of CFTR proteins on cell surfaces in patients with the F508del mutation in the *CFTR* gene. *In vitro*, studies of CFTR corrector and potentiator compounds have suggested that these compounds can partially restore function of defective F508del CFTR protein, with increased trafficking of F508del CFTR protein to the cell surface.

We are evaluating VX-809 in combination with ivacaftor in patients with CF who have the F508del mutation in the *CFTR* gene. In the second quarter of 2011, we obtained interim data from Part 1 of a Phase 2 clinical trial designed to evaluate multiple combination regimens of ivacaftor and VX-809, which enrolled 62 patients with CF with the F508del mutation on both alleles. Part 1 of the clinical trial evaluated a 200 mg dose of VX-809, or placebo, alone for 14 days and then in combination with two doses of ivacaftor, or placebo, for 7 days. The interim safety and efficacy data from Part 1 of this clinical trial supported the initiation of Part 2, in which we are evaluating multiple dose levels of VX-809, including doses higher than those evaluated in Part 1 of this clinical trial, in approximately 100 patients with CF who have the F508del mutation on one or both of their alleles. In Part 2, we are evaluating VX-809 alone for 28 days followed by VX-809 in combination with KALYDECO for 28 days compared to placebo. The primary goals of this clinical trial are to evaluate the safety and tolerability of the combination therapy and its effect on CFTR function as measured by sweat chloride levels. Lung function will be measured as a secondary endpoint.

We initiated a Phase 2 clinical trial of VX-661 in the first quarter of 2012. In this clinical trial, we are evaluating VX-661 as both a monotherapy and in combination with ivacaftor in patients with CF who have two copies of the F508del mutation in the *CFTR* gene.

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**IMMUNE-MEDIATED INFLAMMATORY DISEASES**

*Background: Effects and Prevalence of Rheumatoid Arthritis*

Immune-mediated inflammatory diseases, including rheumatoid arthritis, are characterized by inflammation that is believed to be the result of an incorrectly regulated immune response. Rheumatoid arthritis is a chronic disease that affects 0.5% to 1.0% of the world's population and, according to the CDC, approximately 1.5 million adults in the United States. Rheumatoid arthritis causes destruction of joint cartilage and erosion of adjacent bone, resulting in deformity, loss of function and substantial disability. Many patients with rheumatoid arthritis also eventually require joint replacements. While approved drugs, including oral and injectable disease-modifying antirheumatic drugs, or DMARDs, are effective in a portion of patients with rheumatoid arthritis, a significant portion of patients do not respond adequately to DMARDs or experience a decrease in the effectiveness of DMARDs over time. We are seeking to develop an oral therapy for the treatment of rheumatoid arthritis that could be used alone or in combination with existing DMARDs.

*VX-509*

VX-509 is an investigational oral drug candidate intended to inhibit Janus kinase 3, or JAK3, which is involved in the modulation of a type of white blood cell, referred to as a lymphocyte, that is central to auto-immune disease pathology. 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-mediated inflammatory diseases, including rheumatoid arthritis. Based on *in vitro* data, VX-509 appears to be a potent and selective inhibitor of JAK3. Pfizer is seeking approval to market its JAK inhibitor, tofacitinib, as treatment for rheumatoid arthritis based on a Phase 3 clinical program it completed in 2011.

In 2011, we completed a Phase 2a clinical trial that evaluated VX-509 in patients with rheumatoid arthritis. This double-blind, randomized, placebo-controlled clinical trial enrolled 204 people with active moderate-to-severe rheumatoid arthritis. We evaluated four dose levels of VX-509, which was given twice daily for 12 weeks. Patients in this clinical trial did not receive methotrexate. We achieved the two primary endpoints in this Phase 2a clinical trial, defined as a statistically significant improvement in the proportion of patients who achieved at least a 20 percent improvement in the signs and symptoms of rheumatoid arthritis, also known as ACR20, and a statistically significant improvement from baseline in Disease Activity Score 28, or DAS28.

The most frequently reported class of adverse event in the VX-509 and placebo arms of this Phase 2a clinical trial was infection. The most common individual adverse events observed in this Phase 2a clinical trial, each of which occurred in approximately 5% or less of patients in the clinical trial, were nausea, headache and increased alanine transaminase, regardless of treatment arm. Five percent of patients discontinued treatment due to adverse events in the placebo group, compared to eight percent of patients in the VX-509 treatment arms.

Based on the safety and efficacy data from this Phase 2a clinical trial, we plan to evaluate VX-509 as part of a six-month Phase 2b clinical trial in patients with rheumatoid arthritis. In this Phase 2b clinical trial, we expect to evaluate once-daily and twice-daily doses of VX-509 in combination with methotrexate. We expect to initiate this clinical trial in the first quarter of 2012 and to enroll approximately 350 patients with active moderate-to-severe rheumatoid arthritis. In addition, we plan to evaluate VX-509 in patients with other immune-mediated inflammatory diseases.

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**EPILEPSY**

*Background: Effects and Prevalence of Epilepsy*

Epilepsy is a chronic neurological disorder that is defined by recurrent seizures resulting from overactive neurons in the brain. Recent studies suggest that inflammation and overproduction of the cytokine IL-1 $\beta$  may be associated with the initiation and maintenance of epileptic seizures. While there are a number of 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*

VX-765 is an interleukin-1 converting enzyme, or ICE, inhibitor. VX-765 is designed to inhibit an enzyme that controls the generation of two cytokines, IL-1 $\beta$  and IL-18, believed to mediate a wide range of immune and inflammatory responses in many cell types. In 2011, we completed a Phase 2a clinical trial of VX-765 that randomized approximately 60 patients with treatment-resistant epilepsy. This clinical trial was designed to evaluate the safety, tolerability and clinical activity of VX-765. The primary endpoints of the trial were safety and tolerability, and the clinical trial showed a similar safety profile for VX-765 as compared to placebo. The efficacy data from this clinical trial supported the initiation of a Phase 2b clinical trial in patients with treatment-resistant epilepsy. We have initiated a Phase 2b clinical trial of VX-765 to evaluate longer dosing of VX-765 in patients with treatment-resistant epilepsy.

**INFLUENZA**

*Background: Effects and Prevalence of Influenza*

The CDC has estimated that in the United States more than 200,000 patients with influenza infection are hospitalized annually with respiratory and cardiac-related complications. While the number of influenza related deaths varies significantly depending on the severity of the influenza season, the CDC has estimated the number of influenza related deaths in the United States averages approximately 25,000 per year. In addition to vaccinations designed to prevent the spread of infection, we believe that there is a significant market for antiviral agents that could potentially be used to treat influenza. Currently, neuraminidase inhibitors, oseltamivir (Tamiflu) and zanamivir (Relenza), are the antiviral agents that are used to treat influenza infection, but these drugs must be administered within 24 to 48 hours of initial infection in order to be effective and do not produce responses in a significant portion of patients.

*VX-787*

VX-787 is an investigational drug candidate intended for the treatment of influenza A, which is typically the predominate strain of influenza and includes H1 (pandemic) and H5 (avian) influenza strains. VX-787 aims to treat influenza A in a way that is distinct from neuraminidase inhibitors. We have begun Phase 1 clinical development of VX-787 and, if the clinical trials in healthy volunteers are successful, we could begin a Phase 2a clinical trial to evaluate VX-787 in healthy volunteers infected with the influenza A virus in the first half of 2012.

**COMMERCIAL ORGANIZATION**

We have established a commercial organization to support sales of INCIVEK (telaprevir) and KALYDECO (ivacaftor) in North America. Our sales force and managed markets organizations are responsible for promoting our products to health care providers and payors.

Our U.S. sales force includes approximately 150 employees, most of whom are focused on marketing INCIVEK and have experience in marketing drugs for the treatment of infectious diseases. Our HCV sales force focuses its efforts on those physicians in private practice and at major medical centers who write the majority of prescriptions for HCV therapies, as well as the health care professionals who support their practices. We also have a small sales force dedicated to marketing INCIVEK in Canada.

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Our United States field-based CF commercial team includes 14 therapeutic specialists who each have prior experience with CF, as well as case managers and a marketing and managed markets organization. We are focusing our CF marketing efforts on a relatively small number of physicians and health care professionals, less than 1,000, who write approximately 80% of the CF prescriptions in the United States. Many of these physicians and health care professionals are located at one of the approximately 110 accredited centers in the United States focused on the treatment of CF. In addition, we are establishing a small commercial organization in Europe to support the potential sale of ivacaftor in Europe if it is approved by the European Commission.

We market our products and educate physicians by calling on individual physicians, advertising, sending direct mail, public relations efforts and other activities. In addition, our government affairs and public policy group advocates for policies that promote life sciences innovation and increase awareness of the diseases on which we are focusing with state and federal legislatures, government agencies and public health officials and other policy-makers.

We also have established programs in the United States that provide our products to qualified uninsured or underinsured patients at no charge or at a reduced charge, based on specific eligibility criteria.

**RESEARCH**

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 platform integrates biology, pharmacology, drug metabolism and pharmacokinetics, toxicology, material sciences, biophysics, medicinal chemistry and process chemistry, automation and information technologies in a coordinated fashion throughout the discovery process. We believe that our approach has been validated through our success in moving novel drug candidates into clinical trials and obtaining marketing approvals for INCIVEK and KALYDECO. Currently, the therapeutic areas of highest priority to us from a research perspective are: infectious diseases, including viral infections, such as influenza and bacterial infections; immune-mediated inflammatory diseases and other inflammatory diseases; cancer; neurological diseases and disorders, including pain; and CF. Within each therapeutic area, we focus initially on specific medical or disease indications. Driven by the complexity of the therapeutic areas selected, we are attempting to identify multiple approaches 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 eventually to provide multiple drugs in each of these therapeutic areas. We select therapeutic areas by mapping our research strengths, including expertise in kinases, proteases and membrane proteins, onto therapeutic areas with high unmet medical need, with an emphasis on indications where based on scientific insights we believe we, independently or in collaboration with other third parties, will be able to discover, develop and commercialize important medicines for serious diseases.

Our past drug discovery efforts have produced a variety of drug candidates that have been commercialized or are in preclinical or clinical development. We believe our ongoing research programs will continue to create value for us by generating new drug candidates in areas of significant unmet medical need. We are engaged in nonclinical activities involving a number of investigational compounds, one or more of which may enter clinical development in 2012.

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 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.

**CORPORATE COLLABORATIONS**

We have entered into corporate collaborations with pharmaceutical and other companies and organizations that provide us financial and other resources, including capabilities in research, development, manufacturing, and sales and marketing, and licenses to intellectual property.

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***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 on the development and commercialization of telaprevir. Under the terms of the collaboration agreement, we have exclusive commercial rights to telaprevir in North America and lead the development program for INCIVEK (telaprevir) in North America and the Janssen territories. Janssen has exclusive rights to commercialize INCIVO (telaprevir) outside of North America and the Far East.

Janssen pays us a tiered royalty, averaging in the mid-20% range, subject to adjustment for generic competition, as a percentage of net sales of INCIVO in the Janssen territories. Janssen is responsible for certain third-party royalties in its territories. Pursuant to the collaboration agreement, we received an up-front payment of \$165.0 million and milestone payments of \$350.0 million related to the development and commercialization of INCIVO. We do not expect to receive any further milestone payments pursuant to this collaboration. Janssen was responsible for 50% of drug development costs under the development program for North America and the Janssen territories through approval, and continues to be responsible for 50% of drug development costs related to certain post-approval activities. Janssen is required to use diligent efforts to maximize net sales of telaprevir in its territories through its commercial marketing, pricing and contracting strategies. Each of the parties to the collaboration agreement is responsible for drug supply in their respective territories.

Janssen may terminate the agreement upon the later of (i) one year's advance notice and (ii) such period as may be required to assign and transfer to us specified filings and approvals. The agreement also may be terminated by either party for a material breach by the other, subject to notice and cure provisions. Unless earlier terminated, the agreement will continue in effect until the expiration of Janssen's royalty obligations, which expire on a country-by-country basis on the later of (a) the last-to-expire patent covering INCIVO and (b) ten years after the first commercial sale in the country. In the European Union, we have a patent covering the composition-of-matter of INCIVO that expires in 2021, and we expect to obtain extensions to the term of this patent through 2026.

***Mitsubishi Tanabe Pharma Corporation***

We have a collaboration agreement with Mitsubishi Tanabe pursuant to which Mitsubishi Tanabe has a fully-paid license to manufacture and commercialize TELAVIC (telaprevir) to treat HCV infection in Japan and other specified countries in the Far East. This agreement was entered into in 2004 and amended in 2009. Pursuant to this agreement, Mitsubishi Tanabe provided financial and other support for the development and commercialization of telaprevir, made a \$105.0 million payment to us in connection with the 2009 amendment of the collaboration agreement and made a \$65.0 million payment to us in the fourth quarter of 2011 related to the commercialization of TELAVIC in Japan. There are no further milestone payments due to us under this collaboration agreement. 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. The agreement also may be terminated by either party for a material breach by the other, subject to notice and cure provisions. Unless earlier terminated, the agreement will continue in effect until the expiration of the last-to-expire patent covering TELAVIC. In Japan, we have a patent covering the composition-of-matter of TELAVIC that expires in 2021.

***Cystic Fibrosis Foundation Therapeutics Incorporated***

We began working with CFFT in 1998. We entered into the current collaboration agreement with CFFT in 2004 and amended it several times to support research and development activities related to potentiator compounds and corrector compounds, including KALYDECO (ivacaftor), VX-809 and VX-661. Pursuant to an April 2011 amendment to the collaboration agreement, CFFT agreed to

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provide financial support for development activities for VX-661, a corrector compound discovered under the collaboration, and additional research and development activities directed at discovering new corrector compounds. We retain worldwide rights to develop and commercialize KALYDECO, VX-809, VX-661 and any other compounds discovered during the course of the research collaboration with CFFT and will pay to CFFT tiered royalties ranging from single digits to sub-teens, calculated as a percentage of net sales, on KALYDECO, as well as VX-809 and VX-661 and any other compounds discovered during the original research term or the research term that began in 2011. We also are obligated to make two one-time commercial milestone payments upon achievement of certain sales levels for a potentiator compound, including KALYDECO, and two one-time commercial milestone payments upon achievement of certain sales levels for corrector compounds, including VX-809 or VX-661.

For each compound commercialized under this collaboration, we will have royalty obligations to CFFT until the expiration of patents covering that compound. We have patents in the United States and European Union covering the composition-of-matter of KALYDECO that expire in 2027 and 2025, respectively, subject to potential patent life extensions. CFFT may terminate its funding obligations under the collaboration, as amended, in certain circumstances, in which case there will be a proportional reduction in the royalty rates and commercial milestone payments for certain corrector compounds. The collaboration also may be terminated by either party for a material breach by the other, subject to notice and cure provisions.

***Alios BioPharma, Inc.***

In June 2011, we entered into a license and collaboration agreement with Alios, a privately-held biotechnology company. Pursuant to the agreement, we will collaborate on the research, development and commercialization of two HCV nucleotide analogues discovered by Alios, ALS-2200 and ALS-2158. We are responsible for all costs related to development and commercialization of the compounds, and are providing funding for a research program directed to the discovery of additional HCV nucleotide analogues that act on the HCV polymerase.

Under the terms of the agreement, we received exclusive worldwide development and commercialization rights to ALS-2200 and ALS-2158, and have the option to select additional compounds discovered in the research program. We paid Alios a \$60.0 million up-front payment, and Alios is eligible to receive research and development milestone payments of up to \$715.0 million if two compounds resulting from the collaboration are approved and commercialized. As of December 31, 2011, Alios had earned \$35.0 million of these contingent research and development milestones. Alios also is eligible to receive commercial milestone payments of up to \$750.0 million, as well as tiered royalties on net sales of approved drugs.

We may terminate our agreement with Alios (i) upon 30 days' notice to Alios if we cease development after both ALS-2200 and ALS-2158 have experienced a technical failure and/or (ii) upon 60 days' notice to Alios at any time after we complete specified Phase 2a clinical trials. The agreement also may be terminated by either party for a material breach by the other, and by Alios for our inactivity or if we challenge certain Alios patents, in each case subject to notice and cure provisions. Unless earlier terminated, the agreement will continue in effect until the expiration of our royalty obligations, which expire on a country-by-country basis on the later of (a) the date the last-to-expire patent covering a licensed product expires or (b) ten years after the first commercial sale in the country.

**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

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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 our drugs and 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 drugs and drug candidates:

<b>Drug/Drug Candidate</b>	<b>Status of United States Patent (Anticipated Expiration, Subject to Potential Extensions)</b>	<b>Status of European Union Patent (Anticipated Expiration, Subject to Potential Extensions)</b>
INCIVEK/INCIVO (telaprevir)	Granted (2025)	Granted (2021)
KALYDECO (ivacaftor)	Granted (2027)	Application Pending (2025)
VX-222	Granted (2027)	Application Pending (2027)
VX-809	Application Pending (2026)	Application Pending (2026)
VX-661	Granted (2027)	Application Pending (2027)
VX-509	Granted (2026)	Application Pending (2025)
VX-765	Granted (2021)	Application Pending (2021)

The United States patent covering the composition-of-matter for INCIVEK (telaprevir) was granted in 2010 with a term that expires in 2025. We do not expect material extensions to the term of the patent covering the composition-of-matter of INCIVEK (telaprevir) in the United States. In the European Union, we expect to obtain extensions to the term of the patent covering the composition-of-matter of INCIVO (telaprevir) and that as a result of these extensions the patent will expire in 2026. We will need to apply separately for the extensions in the European Union on a country-by-country basis.

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 research and development programs. In addition to the composition-of-matter patents and patent applications listed above, our intellectual property holdings include:

United States and foreign patents and patent applications covering telaprevir, VX-222 and other HCV protease and polymerase inhibitors and the use of these compounds to treat HCV infection.

United States and foreign patent applications licensed from Alios covering ALS-2200 and ALS-2158 and the use of these compounds to treat HCV infection.

United States and foreign patent applications covering potentiator compounds and corrector compounds for the CFTR protein, including ivacaftor, VX-809 and VX-661 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, and the use of those inhibitors to treat rheumatoid arthritis.

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United States and foreign patents and patent applications covering ICE inhibitors, including VX-765, and the use of VX-765 to treat epilepsy.

United States and foreign patents and patent applications covering influenza virus inhibitors, including VX-787.

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 our two marketed products telaprevir and ivacaftor.

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 market and sell our approved products and advance our drug candidates through clinical development toward commercialization, we continue to build and maintain our supply chain and quality assurance resources. We rely on an international network of third parties, including sole source suppliers of certain components of our products and drug candidates, to manufacture and distribute our products for commercial sale and post-approval clinical trials and to manufacture and distribute our drug candidates for clinical trials. We expect that we will continue for the foreseeable future to rely on third parties to meet our commercial and clinical supply needs.

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 China, 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 for each of our drugs and drug candidates requires a significant financial commitment and the creation and maintenance of numerous third-party contractual relationships.

We have developed systems and processes to track, monitor and oversee our third-party manufacturers' activities, including a quality assurance program intended to ensure that our third-party manufacturers comply with current Good Manufacturing Practices, or cGMP. 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 other U.S. and foreign government authorities. A failure by any of our third-party manufacturers to pass an inspection could adversely affect our ability to distribute INCIVEK (telaprevir) or KALYDECO (ivacaftor) in a timely manner.

*Manufacture of INCIVEK (telaprevir)*

We require a supply of INCIVEK for our commercial sales in North America and our clinical trials. We provide a secondary commercial supply source for Janssen through our third-party manufacturers. We also are providing Mitsubishi Tanabe, until April 2012, specified supplies of telaprevir drug substance and drug product intermediate through these third-party manufacturers. We



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believe our efforts to establish and maintain relationships with third-party manufacturers and oversee their activities are important to support consistent supply of INCIVEK.

Janssen manufactures INCIVO (telaprevir) for sale in Janssen's territories and serves as a secondary supply source of drug substance and drug product intermediate 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 INCIVEK. It is also possible that supply of materials needed to manufacture INCIVEK that cannot be second-sourced can be managed with inventory planning. If we underestimate demand, our manufacturing capacity through third-party manufacturers may not be sufficient. Also, while we believe we can effectively forecast demand for INCIVEK, we have limited flexibility to adjust our supply in response to changes in demand, due to the significant lead times required to manufacture INCIVEK.

*Manufacture of KALYDECO (ivacaftor)*

We require a supply of KALYDECO for commercial sale in the United States and for our clinical trials. We also will require a supply of ivacaftor for international sales, if ivacaftor is approved for marketing in countries outside the United States. We obtain KALYDECO to meet our commercial and clinical supply needs through a third-party manufacturing network. Our supply chain for KALYDECO includes several sole source suppliers, and we are in the process of establishing secondary sources for our KALYDECO supply needs.

**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 and biotechnology companies, engaged in developing products for the indications our drugs are approved to treat and the therapeutic areas we are targeting with our research and development activities. Many of our competitors have substantially greater financial, technical and human resources than we do. We face competition based on the safety and efficacy of our products, 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 and maintain market acceptance and our ability to generate meaningful revenues from our products. Future competitive products may render our products, or future products, obsolete or noncompetitive. 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***

*Competitive Products*

In 2011, our collaborators and we obtained approval to market our HCV protease inhibitor telaprevir for the treatment of treatment-naïve and treatment-experienced adults with genotype 1 HCV infection in the United States, European Union and other international markets. In the United States, we believe over 25,000 patients were treated with INCIVEK in 2011. Merck & Co., Inc.'s HCV protease inhibitor boceprevir, which it markets under the brand name VICTRELIS<sup>®</sup>, also was approved in the United States, European Union and other international markets in 2011. Prior to the introduction of telaprevir and boceprevir, genotype 1 HCV infection was treated using a 48-week course of peg-IFN, which requires weekly injections, in combination with RBV, which is an oral drug. A

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majority of patients with genotype 1 HCV infection did not achieve a sustained viral response with peg-IFN and RBV alone. We believe that prior to the approval of telaprevir, sales of peg-IFN and RBV declined as physicians and patients became aware of promising clinical data regarding potential treatment regimens that include HCV protease inhibitors.

*Development-stage Product Candidates*

We are aware of a number of clinical trials investigating compounds and all-oral, interferon-free treatment regimens involving multiple drug candidates that target HCV infection through various 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 HCV protease inhibitors, HCV nucleotide analogues, non-nucleoside HCV polymerase inhibitors and HCV NS5A inhibitors, each of which is a direct-acting antiviral compound, in mid- and late-stage clinical development. If any of these drug candidates or combinations of drug candidates is approved as a treatment for HCV infection, we expect that it would compete with the INCIVEK (telaprevir)-based regimens containing peg-IFN and RBV, and any of our HCV drug candidates that are approved, on the basis of the factors described above.

We do not expect that additional competitive products for the treatment of HCV infection will enter the market until late 2013 at the soonest. We believe that the most advanced potentially competitive product for the treatment of HCV infection is TMC-435, an HCV protease inhibitor being developed by Tibotec, an affiliate of our collaborator Janssen, and Medivir AB, which entered Phase 3 clinical trials in the first quarter of 2011. Even prior to the introduction of competitive products, however, we believe that information regarding future potential treatments from clinical trials of HCV drug candidates could influence some physicians or patients to defer treatment until these drug candidates or other treatment options become available.

We believe that the most significant future competition in the HCV treatment market will result from all-oral, interferon-free treatment regimens. We are conducting a Phase 2a clinical trial in which we are evaluating an all-oral combination of VX-222, our non-nucleoside HCV polymerase inhibitor, with telaprevir and RBV, and we are evaluating ALS-2158 and ALS-2200, our HCV nucleotide analogues, in Phase 1 clinical trials. We are aware that many competitors, including Abbott Laboratories, Achillion Pharmaceuticals, Inc., Boehringer Ingelheim, Bristol-Myers Squibb Company, Gilead Sciences, Inc., Hoffman-La Roche, Idenix Pharmaceuticals, Inc. and Janssen also are seeking to develop all-oral, interferon-free treatment regimens to treat HCV infection. In particular, Gilead may initiate in 2012 a Phase 3 clinical trial to evaluate GS-7977, an HCV nucleotide analogue, in combination with RBV as a treatment for patients with genotype 1 HCV infection, depending on the data generated in its ongoing Phase 2b clinical trial in this genotype. While it is difficult to predict drug development and regulatory timelines, we believe that one or more all-oral treatment regimens could enter the market as early as 2014 or 2015.

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The following table provides information regarding selected drug candidates that are being evaluated for the treatment of HCV infection:

Drug Candidate	Company	Development Phase
<b>HCV Protease Inhibitors</b>		
TMC-435	Janssen/Medivir AB	Phase 3
BI 201335	Boehringer Ingelheim	Phase 3
MK-5172	Merck	Phase 2
GS-9451	Gilead	Phase 2
BMS-650032	Bristol-Myers Squibb	Phase 2
ACH-1625	Achillion	Phase 2
ABT-450	Abbott	Phase 2
Danoprevir / RG7227	Roche	Phase 2
ACH-2684	Achillion	Phase 1
<b>HCV Nucleotide Analogues</b>		
GS-7977	Gilead	Phase 3
INX-189	Bristol-Myers Squibb	Phase 2
IDX184	Idenix	Phase 2
Mercitabine (R7128)	Gilead/Roche	Phase 2
ALS-2200	Vertex/Alios	Phase 1
ALS-2158	Vertex/Alios	Phase 1
<b>Non-nucleoside HCV Polymerase Inhibitors</b>		
VX-222	Vertex	Phase 2
tegobuvir (GS-9190)	Gilead	Phase 2
ABT-333	Abbott	Phase 2
ABT-072	Abbott	Phase 2
Setrobuvir	Roche	Phase 2
BI 207127	Boehringer Ingelheim	Phase 2
<b>HCV NS5a Inhibitors</b>		
GS-5885	Gilead	Phase 2
daclatasvir (BMS-790052)	Bristol-Myers Squibb	Phase 2
ABT-267	Abbott	Phase 2
ACH-2928	Achillion	Phase 1
<b>Cystic Fibrosis</b>		

Several companies are engaged in researching and/or developing treatments for CF. PTC Therapeutics, Inc., in collaboration with Genzyme Corporation, a Sanofi company, is evaluating ataluren 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 mutations in the *CFTR* gene that halt the production of CFTR proteins before the protein is fully formed. We do not believe that there is significant overlap between patients with the G551D mutation in the *CFTR* gene and patients with nonsense mutations in the *CFTR* gene. In addition, several companies, including Genzyme, have research programs directed at identifying CFTR corrector compounds.

**GOVERNMENT REGULATION**

The research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record keeping, promotion, advertising, distribution and marketing of our products and drug candidates are subject to extensive regulation by United States and foreign governmental authorities.

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***United States Government Regulation***

*New Drug Application Approval Processes*

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act, or the FDCA, and implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the drug development process, approval process or after approval, may subject us to administrative or judicial sanctions, any of which could have a material adverse effect on us. These sanctions could include:

refusal to approve pending applications;

withdrawal of an approval;

imposition of a clinical hold;

warning letters;

product seizures;

total or partial suspension of production or distribution; or

injunctions, fines, disgorgement, or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

completion of preclinical laboratory tests, animal studies and formulation studies conducted according to Good Laboratory Practices, or GLP, and other applicable regulations;

submission to the FDA of an investigational new drug, or IND, application, which must become effective before clinical trials in the United States may begin;

performance of adequate and well-controlled clinical trials according to Good Clinical Practices, or GCP, to establish the safety and efficacy of the proposed drug for its intended use;

submission to the FDA of a New Drug Application, or NDA;

satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product will be produced to assess compliance with cGMP to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity; and

FDA review and approval of the NDA.

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Once a drug candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal pharmacology and toxicology studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. Preclinical or nonclinical testing typically continues even after the IND is submitted. In addition to including the results of the preclinical studies, the IND also will include a protocol detailing, among other things, the objectives of the initial clinical trial and the parameters to be used in monitoring safety. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the IND on clinical hold. If an IND is placed on clinical hold, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. A clinical hold may occur at any time during the life of an IND, and may affect one or more specific clinical trials or all clinical trials conducted under the IND.

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All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCP. They must be conducted under protocols detailing the objectives of the trial, dosing procedures, subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol and any amendments must be submitted to the FDA as part of the IND, and progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently in other situations, including the occurrence of serious adverse events. An institutional review board, or IRB, at each institution participating in the clinical trial must review and approve the protocol and any amendments before a clinical trial commences or continues at that institution, approve the information regarding the clinical trial and the consent form that must be provided to each trial subject or his or her legal representative, and monitor the clinical trial until completed and otherwise comply with IRB regulations.

Clinical trials typically are conducted in three sequential phases that may overlap or be combined:

*Phase 1.* The drug initially is introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and elimination. In the case of some drug candidates for severe or life-threatening diseases, such as cancer, especially when the drug candidate may be inherently too toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

*Phase 2.* Clinical trials are initiated in a limited patient population intended to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the drug candidate for specific targeted diseases and to determine dosage tolerance and optimal dosage.

*Phase 3.* Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk-benefit ratio of the drug candidate and provide an adequate basis for regulatory approval and product labeling.

Phase 1, Phase 2, and Phase 3 testing may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend a clinical trial at any time for a variety of reasons, including a finding that the healthy volunteers or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug candidate has been associated with unexpected serious harm to healthy volunteers or patients.

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:

<b>Phase</b>	<b>Estimated Duration</b>
Discovery	2 to 4 years
Preclinical	1 to 2 years
Phase 1	1 to 2 years
Phase 2	2 to 4 years
Phase 3	2 to 4 years
FDA approval	6 months to 2 years

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and FDA to reach agreement on the next phase of development. Sponsors typically use the end of Phase 2 meeting to discuss their Phase 2 clinical results and present their plans for the pivotal Phase 3 clinical trial that they believe will support approval of the drug candidate.

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Concurrently with clinical trials, companies usually complete additional animal safety studies and also must develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate, and the manufacturer must develop methods for testing the quality, purity and potency of the final products. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf-life.

The results of drug development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the drug candidate. The FDA reviews each NDA submitted to ensure that it is sufficiently complete for substantive review before it accepts it for filing. It may request additional information rather than accept an NDA for filing.

Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA may not approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. The FDA reviews an NDA to determine, among other things, whether a drug candidate is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the drug candidate's identity, strength, quality and purity. The FDA may refer the NDA to an advisory committee for review and recommendation as to whether the NDA should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will inspect the facility or facilities where the drug candidate is manufactured and tested.

The FDA may require, as a condition of approval, restricted distribution and use, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, pre-approval of promotional materials, restrictions on direct-to-consumer advertising or commitments to conduct additional research post-approval. The FDA will issue a complete response letter if the agency decides not to approve the NDA in its present form. The complete response letter usually describes all of the specific deficiencies in the NDA identified by the FDA. If a complete response letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application.

*Expedited Review and Approval*

The FDA has various programs, including Fast Track, priority review, and accelerated approval, that are intended to expedite or simplify the process for reviewing drug candidates, and/or provide for approval on the basis of surrogate endpoints. Even if a drug candidate qualifies for one or more of these programs, the FDA may later decide that the drug candidate no longer meets the conditions for qualification or that the time period for FDA review or approval will not be shortened. Generally, drug candidates that may be eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs, and those that offer meaningful benefits over existing treatments. For example, Fast Track is a process designed to facilitate the development, and expedite the review of drug candidates to treat serious diseases and fill an unmet medical need. Priority review is designed to give drug candidates that offer major advances in treatment or provide a treatment where no adequate therapy exists an initial review within six months as compared to a standard review time of ten months. Although Fast Track and priority review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track designated drug candidate and expedite review of the application for a drug candidate designated for priority review. Accelerated approval provides an earlier approval of drugs to treat

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serious diseases, and that fill an unmet medical need based on a surrogate endpoint, which is a laboratory measurement or physical sign used as an indirect or substitute measurement representing a clinically meaningful outcome. As a condition of approval, the FDA may require that a sponsor of a product receiving accelerated approval perform post-marketing clinical trials.

*Post-approval Requirements*

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or complete withdrawal of the product from the market. In addition, under the FDCA the sponsor of an approved drug in the United States may not promote that drug for unapproved, or off-label, uses, although a physician may prescribe a drug for an off-label use in accordance with the practice of medicine. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

Products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things:

record-keeping requirements;

reporting of adverse experiences with the product;

providing the FDA with updated safety and efficacy information;

drug sampling and distribution requirements;

notifying the FDA and gaining its approval of specified manufacturing or labeling changes;

complying with certain electronic records and signature requirements; and

complying with FDA promotion and advertising requirements.

Drug manufacturers and other entities involved in the manufacture and distribution of approved products are required to register with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and some state agencies for compliance with cGMP and other laws.

We rely, and expect to continue to rely, on third parties for the production of our products. Future FDA and state inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt manufacture or distribution of our products, or require substantial resources to correct.

From time to time, new legislation is enacted that changes the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition, FDA regulations and guidance often are revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed.

*Patent Term Restoration and Marketing Exclusivity*

Depending upon the timing, duration and specifics of FDA approval of the use of our drugs, some of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments.





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The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND, and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved product is eligible for the extension and the extension must be applied for prior to expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restorations of patent term for some of our currently owned or licensed patents to add patent life beyond their current expiration date, depending on the expected length of clinical trials and other factors involved in the submission of the relevant NDA.

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. For a new chemical entity that qualifies for Orphan Drug designation, the FDCA provides such marketing exclusivity for a period of seven years. A product is a new chemical entity if the FDA has not previously approved any other new product containing the same active moiety, which is the molecule responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such product where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages, or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent.

*Pediatric Exclusivity*

Section 505A of the FDCA, as amended by the FDA Amendments Act of 2007, permits certain drugs to obtain an additional six months of exclusivity, if the sponsor submits information requested in writing by the FDA, or a written request, relating to the use of the drug in children. The FDA may not issue a written request for clinical trials on unapproved or approved indications or where it determines that information relating to the use of a drug in a pediatric population, or part of the pediatric population, may not produce health benefits in that population.

***Foreign Regulation***

In addition to regulations in the United States, we are subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a drug candidate, we must obtain approval by the comparable regulatory authorities of foreign countries or economic areas, such as the European Union, before we can commence clinical trials or market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

Under European Union regulatory systems, a company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is

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compulsory for medicines produced by biotechnology or those medicines intended to treat AIDS, cancer, neurodegenerative disorders, or diabetes and optional for those medicines that are highly innovative, provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for approval by one or more "concerned" member states based on an assessment of an application performed by one member state, known as the "reference" member state. Under the decentralized approval procedure, an applicant submits an application, or dossier, and related materials 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 or not to approve the assessment report and related materials. If a member state does not recognize the marketing authorization, the disputed points are eventually referred to the European Commission, whose decision is binding on all member states.

***Orphan Drug Designation***

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drug candidates intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 people in the United States, or more than 200,000 people in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. KALYDECO and VX-809 have been granted designation as orphan drugs by the FDA.

If a drug candidate that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for seven years. Orphan drug exclusivity, however, also could block the approval of our drug candidates for seven years if a competitor obtains approval of the same product as defined by the FDA or if our drug candidate is determined to be contained within the competitor's product for the same indication or disease.

As in the United States, we may apply for designation of a drug candidate as an orphan drug for the treatment of a specific indication in the European Union before the application for marketing authorization is made. Orphan drugs in Europe enjoy economic and marketing benefits, including up to 10 years of market exclusivity for the approved indication unless another applicant can show that its product is safer, more effective or otherwise clinically superior to the orphan-designated product.

The FDA and foreign regulators expect holders of exclusivity for orphan drugs, such as KALYDECO, to assure the availability of sufficient quantities of their orphan drugs to meet the needs of patients. Failure to do so could result in the withdrawal of marketing exclusivity for the orphan drug.

***Reimbursement***

Sales of our products depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial insurance and managed health care organizations. These third-party payors increasingly are reducing reimbursements for medical products and services. Additionally, the containment of health care costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing

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cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could limit our revenues. Decreases in third-party reimbursement for a product or a decision by a third-party payor to not cover a product could reduce physician usage of the product.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities, which will provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan likely will be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by the Department of Health and Human Services, or HHS, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of our products. It is possible that comparative effectiveness research demonstrating benefits of a competitor's product could adversely affect the sales of our products. If third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, which is referred to as the ACA, enacted in March 2010, is expected to have a significant effect on the U.S. health care industry. The ACA is designed to expand coverage for the uninsured while at the same time containing overall health care costs. With regard to pharmaceutical products, among other things, the ACA is designed to expand and increase industry rebates for drugs covered under Medicaid programs, impose an annual fee on branded pharmaceutical manufacturers and make changes to the coverage requirements under the Medicare Part D program. We cannot predict the effect of the ACA on pharmaceutical companies as many of the ACA reforms require the promulgation of detailed regulations implementing the statutory provisions, which has not yet occurred. In addition, the current legal challenges to the ACA, as well as congressional efforts to repeal the ACA, add to the uncertainty of the legislative changes enacted as part of the ACA.

In some foreign countries, the proposed pricing for a drug must be approved before it may be marketed. 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 drugs for which their national health insurance systems provide reimbursement and to control the prices of drugs for human use. A member state may approve a specific price for the drug or it may instead adopt a system

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of direct or indirect controls on the profitability of the company placing the drug on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and the prices of these products generally tend to be lower.

**Other United States 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, and the reporting of payments to physicians and teaching hospitals.

*Anti-Kickback Laws*

U.S. federal laws prohibit fraud and abuse involving state and federal health care programs, such as Medicare and Medicaid. These laws are interpreted broadly and enforced aggressively by various state and federal agencies, including the Centers for Medicare & Medicaid Services, or CMS, the Department of Justice, the Office of Inspector General for the Department of Health and Human Services and various state agencies. These anti-kickback laws prohibit, among other things, knowingly and willfully offering, paying, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for or recommending of an item or service that is reimbursable, in whole or in part, by a federal health care program. Remuneration is broadly defined to include anything of value, such as, cash payments, gifts or gift certificates, discounts, or the furnishing of services, supplies or equipment. The anti-kickback laws are broad and prohibit many arrangements and practices that are lawful in businesses outside of the health care industry.

The penalties for violating the anti-kickback laws can be severe. The sanctions include criminal and civil penalties, and possible exclusion from the federal health care programs. Many states have adopted laws similar to the federal anti-kickback laws, and some apply to items and services reimbursable by any payor, including third-party payors.

*State and Federal Prohibitions on False Claims*

The federal False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government. Under the False Claims Act, a person acts knowingly if he has actual knowledge of the information or acts in deliberate ignorance or in reckless disregard of the truth or falsity of the information. Specific intent to defraud is not required. Provisions of the False Claims Act allow a private individual to bring an action on behalf of the federal government and to share in any amounts paid by the defendant to the government in connection with the action. The number of filings under these provisions has increased significantly in recent years. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each false claim. Conduct that violates the False Claims Act may also lead to exclusion from the federal health care programs. Given the number of claims likely to be at issue, potential damages under the False Claims Act for even a single inappropriate arrangement could be significant. In addition, various states have enacted similar laws modeled after the False Claims Act that apply to items and services reimbursed under Medicaid and other state health care programs, and, in several states, such laws apply to claims submitted to all payors.

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*Federal Prohibitions on Health Care Fraud and False Statements Related to Health Care Matters*

Under the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996, or HIPAA, and state laws there are numerous regulations for protecting the privacy and security of protected health information. Additional administrative simplification provisions created the following new federal crimes: health care fraud, false statements relating to health care matters, theft or embezzlement in connection with a health benefit program and obstruction of criminal investigation of health care offenses. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including a private insurer. The false statements statute prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for health care benefits, items, or services. The theft or embezzlement statute prohibits knowingly and willfully embezzling, stealing or otherwise converting or misapplying the money or property of a health care benefit program. The obstruction of criminal investigations of health care offenses statute prohibits willfully preventing, obstructing, misleading or delaying the communication of information and records relating to a violation of a federal health care offense to a criminal investigator. A violation of any of these laws is a felony and may result in fines, or exclusion from the federal health care programs.

*Physician Payment Sunshine Act*

The Physician Payment Sunshine Act, which was enacted as part of the ACA, requires pharmaceutical manufacturers to report annually to the Secretary of HHS payments or other transfers of value made by that entity to physicians and teaching hospitals during the course of the preceding calendar year. Because CMS was late in publishing the related proposed regulation, the start date for the collection of the data was postponed from January 1, 2012 to sometime after the publication of the final regulation later in 2012. Failure to comply with the reporting requirements would result in significant civil monetary penalties. We will be required to collect and report such payments.

In addition to the statutes and regulations described above, we also are subject to regulation in the United States 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, 2011, we had approximately 2,000 employees. The number of our employees increased by approximately 18% during 2011, from approximately 1,700 on December 31, 2010. We are likely to further increase our headcount in 2012. Of these employees, approximately 1,800 were based in the United States, 125 were based in Europe and 60 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. Employees in our commercial organization have extensive experience in selling and marketing pharmaceutical products as well as seeking reimbursement from government and third-party payors for pharmaceutical products. Our employees are not covered by a collective bargaining agreement, except for a small number of employees in France. Science magazine named Vertex number one on its 2011 list of top employers in the life sciences. We consider our relations with our employees to be good.

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**OTHER MATTERS**

**Financial Information Regarding Geographic Areas**

Financial information about our net product revenues and other revenues generated in the principal geographic regions in which we operate is set forth in Note W, "Geographic Information," to our consolidated financial statements included in this Annual Report on Form 10-K. A discussion of the risks attendant to our international operations is set forth in the "Risk Factors" section of this Annual Report on Form 10-K.

**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. We have established our European headquarters in Switzerland and are building out our European commercial organization in France, Germany, Ireland and the United Kingdom.

Table of Contents**EXECUTIVE OFFICERS AND DIRECTORS**

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

<b>Name</b>	<b>Age</b>	<b>Position</b>
Matthew W. Emmens	60	Executive Chairman and Chairman of the Board
Jeffrey M. Leiden, M.D., Ph.D.	56	Chief Executive Officer, President and Director
Peter Mueller, Ph.D.	55	Executive Vice President, Global Research and Development, and Chief Scientific Officer
Ian F. Smith	46	Executive Vice President and Chief Financial Officer
Nancy J. Wysenski, M.B.A	54	Executive Vice President and Chief Commercial Officer
David T. Howton, J.D.	40	Senior Vice President and Chief Legal Officer
Lisa Kelly-Crowell	45	Senior Vice President, Human Resources
Amit K. Sachdev, J.D.	44	Senior Vice President, Corporate Affairs and Public Policy, and Commercial Business Lead, Canada
Christiana Stamoulis, M.B.A.	41	Senior Vice President, Corporate Strategy and Business Development
Paul M. Silva	46	Senior Vice President and Corporate Controller
Joshua S. Boger, Ph.D.	60	Director
Terrence C. Kearney	57	Director
Margaret G. McGlynn	52	Director
Wayne J. Riley, M.D., M.B.A.	52	Director
Bruce I. Sachs	52	Director
Elaine S. Ullian	64	Director
Dennis L. Winger	64	Director

Mr. Emmens is our Executive Chairman, a position he was appointed to on February 1, 2012. Mr. Emmens plans to retire in May 2012. Mr. Emmens was our Chief Executive Officer from May 2009 through January 2012 and our President from February 2009 through January 2012. He has been a member of our Board of Directors since 2004 and became our Chairman in May 2009. Mr. Emmens is the Chairman of the Board of Directors of Shire plc, 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. 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 pharmaceutical business. Mr. Emmens held the position of President and Chief Executive Officer at EMD 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, a drug development company, from 2006 through February 2009. Mr. Emmens received a B.S. degree in business management from Farleigh Dickinson University.

Dr. Leiden is our Chief Executive Officer and President, a position he was appointed to on February 1, 2012 after joining us as CEO Designee on December 14, 2011. He has been a member of our Board of Directors since July 2009 and served as our lead independent director from October 2010 through December 2011. Dr. Leiden was a Managing Director at Clarus Ventures, a life sciences venture capital firm, from 2006 through January 2012. Dr. Leiden was President and Chief Operating Officer of Abbott Laboratories, Pharmaceuticals Products Group, and a member of the Board of



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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 a senior advisor to Clarus Ventures. Dr. Leiden was a director and the non-executive Vice Chairman of the board of Shire plc, a specialty biopharmaceutical company, from 2006 to January 2012, and was also a member of the Board of Directors of Millennium Pharmaceuticals, Inc. from October 2007 until it was acquired in June 2008. Dr. Leiden received his M.D., Ph.D. and B.A. degrees from the University of Chicago.

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 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., a drug development company, and Infinity Pharmaceuticals, Inc., a drug development company. 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 as a director for Reata Pharmaceuticals, Inc., a privately held company. She 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 M.B.A. from Baldwin Wallace College.

Mr. Howton is our Senior Vice President and Chief Legal Officer, a position he has held since September 2011. Mr. Howton was our Chief Compliance Officer from September 2009 through

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September 2011. Mr. Howton worked at Genentech, Inc. in a number of legal roles from 2003 through 2009 and served as Genentech's Healthcare Compliance Officer from May 2006 through August 2009. Prior to Genentech, Mr. Howton practiced law in the Healthcare Group at the law firm of Sidley Austin. Mr. Howton holds a B.A. in Political Science from Yale University and a J.D. from Northwestern University School of Law.

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, and Commercial Business Lead, Canada. As a Senior Vice President, he has led our government affairs, public policy and patient advocacy functions since he joined us in July 2007. In October 2010, he took on the added role of building and managing our Canadian business operations. 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 United States 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.

Ms. Stamoulis is our Senior Vice President, Corporate Strategy and Business Development, a position she has held since October 2009. Prior to joining us, she was a Managing Director in Citigroup's Healthcare Banking Group from April 2006 to February 2009. From 2000 to April 2006, Ms. Stamoulis was an investment banker in the Healthcare Investment Banking Group of Goldman, Sachs & Co., where she was a Vice President from January 2002 through April 2006. Ms. Stamoulis started her career as a strategy consultant at The Boston Consulting Group. Ms. Stamoulis is a member of the Board of Directors of Hologic, Inc., a company focused on diagnostics, medical imaging systems and surgical products for women. Ms. Stamoulis holds a B.S. in Economics and a B.S. in Architecture from the Massachusetts Institute of Technology and an M.B.A. from the MIT Sloan School of Management.

Mr. Silva is our Senior Vice President and Corporate Controller, a position he has held since April 2011. Mr. Silva joined us in August 2007 as Senior Director, Accounting Operations and was our Vice President and Corporate Controller from September 2008 through April 2011. 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. 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

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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.

Mr. Kearney has been a member of our Board of Directors since May 2011. Mr. Kearney served as the Chief Operating Officer of Hospira, Inc., a specialty pharmaceutical and medication delivery company, from April 2006 to January 2011. From April 2004 to April 2006, he served as Hospira's Senior Vice President, Finance, and Chief Financial Officer, and he served as Acting Chief Financial Officer through August 2006. Mr. Kearney served as Vice President and Treasurer of Abbott Laboratories from 2001 to April 2004. From 1996 to 2001, Mr. Kearney was Divisional Vice President and Controller for Abbott's International Division. He received his B.S. in biology from the University of Illinois and his M.B.A. from the University of Denver.

Ms. McGlynn has been a member of our Board of Directors since May 2011. Ms. McGlynn has served as the President and Chief Executive Officer of the International AIDS Vaccine Initiative, a global not-for-profit organization whose mission is to ensure the development of safe, effective and accessible HIV vaccines for use throughout the world, since July 2011. Ms. McGlynn served as President, Vaccines and Infectious Diseases of Merck & Co., Inc. from 2005 until 2009. Ms. McGlynn joined Merck in 1983 and served in a variety of marketing, sales and managed care roles. Currently, Ms. McGlynn serves as a member of the Board of Directors for Air Products and Chemicals, Inc., a company specializing in gases and chemicals for industrial uses, and Amicus Therapeutics, Inc., a biopharmaceutical company. She is also a member of the National Industrial Advisory Committee at the University at Buffalo School of Pharmacy and Pharmaceutical Sciences. Ms. McGlynn holds a B.S. in Pharmacy and an M.B.A. in Marketing from the State University of New York at Buffalo.

Dr. Riley has been a member of our Board of Directors since July 2010. Dr. Riley is President and Chief Executive Officer of Meharry Medical College, a position he has held since January 2007. In addition, he holds the academic rank of Professor of Internal Medicine at both Meharry and Vanderbilt University Schools of Medicine. From May 2004 to December 2006, Dr. Riley served as a corporate officer and member of the executive management team as Vice President and Vice Dean for Health Affairs and Governmental Relations and Associate Professor of Medicine at Baylor College of Medicine, and Assistant Chief of Medicine at Ben Taub General Hospital, Baylor's primary adult public hospital teaching affiliate. He served as Assistant Dean for Education at Baylor College of Medicine from 2000 to 2004. Dr. Riley is a member of the Board of Directors of Pinnacle Financial Partners, Inc., a financial services holding firm, and HCA Holdings, Inc., a leading operator of hospitals and health facilities. Dr. Riley earned a B.A. from Yale University, an M.P.H. in health systems management from the Tulane University School of Public Health and Tropical Medicine, an M.D. from the Morehouse School of Medicine and an M.B.A. from the Jones Graduate School of Business, Rice University.

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., a network-based platform company, from 2005 through June 2009. Mr. Sachs holds a B.S.E.E. in electrical engineering from Bucknell

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University, an M.E.E. in electrical engineering from Cornell University, and an M.B.A. 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. from 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 Accuray Incorporated and Nektar Therapeutics. In addition, Mr. Winger was a member of the Board of Directors of Cell Genesys, Inc. until its merger with BioSante Pharmaceuticals in October 2009 and a member of the Board of Cephalon Inc. until its acquisition by Teva Pharmaceutical Industries Ltd. in October 2011. He holds an M.B.A. from Columbia University Graduate School of Business and he earned his undergraduate degree from Siena College.

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**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 Commercialization of Our Products**

***We depend heavily on our revenues from sales of INCIVEK (telaprevir) in the United States, and our future revenues from INCIVEK are uncertain.***

We obtained approval to sell INCIVEK (telaprevir) in the United States in May 2011. Prior to the launch of INCIVEK we had not sold or marketed a therapeutic product. As a result, a majority of our total revenues in 2011 were attributable to sales of INCIVEK in the United States. INCIVEK competes with VICTRELIS (boceprevir), a protease inhibitor that also was approved in 2011 and is being marketed by Merck & Co., Inc. We expect that, starting in late 2013, one or more additional competitive products currently in late-stage development for the treatment of HCV infection may become available. Our future revenues from sales of INCIVEK depend on numerous factors, including:

The number of patients with genotype 1 HCV infection, including treatment-naïve patients and patients who did not achieve a sustained viral response with prior treatment, who seek treatment. Although the number of patients with genotype 1 HCV infection is significant, it is estimated that less than half of those patients are aware that they are infected, and many of the patients that are aware of their infection have not historically sought treatment.

Competition from VICTRELIS-based treatment regimens, which compete with INCIVEK-based treatment regimens on the basis of, among other things, efficacy, cost, breadth of approved use, side-effect profile and cost of co-therapies.

Competitive pressures from development-stage drug candidates, including potential all-oral, interferon-free combination therapies, which may influence some physicians and patients with HCV infection to defer treatment until these drug candidates or other treatment options become available.

Competition from any additional products for the treatment of HCV infection that are approved by the FDA in the future.

The safety profile of INCIVEK, including whether previously unknown side-effects or increased incidence or severity of side-effects as compared to those seen during development are identified with the increased use of INCIVEK after approval.

The effectiveness of our commercial strategy for marketing INCIVEK and our execution of that strategy, including our pricing strategy and the effectiveness of our efforts to obtain adequate third-party reimbursements.

The capacity of physicians and health care providers to provide treatment to patients with HCV infection.

Our ability to maintain and successfully monitor commercial manufacturing arrangements for INCIVEK with third-party manufacturers to ensure they meet our standards and those of regulatory authorities, including the FDA, which extensively regulate and monitor pharmaceutical manufacturing facilities.



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While INCIVEK has established a competitive commercial profile, we cannot accurately predict the amount of revenues INCIVEK will generate in future periods. If our revenues, market share and/or other indicators of market acceptance of INCIVEK do not meet the expectations of investors or public market analysts, the market price of our common stock would likely decline. In addition, if one or more of the factors above negatively affects INCIVEK sales, our business and financial condition could be materially harmed.

***Janssen began marketing INCIVO (telaprevir) at the end of the third quarter of 2011, and we cannot predict the royalty revenues we will receive based on INCIVO sales by Janssen in its territories.***

Janssen obtained approval to market INCIVO (telaprevir) from the European Commission in September 2011, and we earned \$16.5 million in royalty revenues on net sales of INCIVO by Janssen in the fourth quarter of 2011. In addition to the factors that contribute to the uncertainty of sales of INCIVEK (telaprevir) by us in the United States discussed above, which apply equally to Janssen's sales in its territory, sales in Janssen's territory are dependent upon Janssen's sales and marketing efforts, which we do not control and may not be able to effectively influence, and the actions and decisions of foreign regulatory authorities. While we expect our royalty revenues on net sales of INCIVO to increase in future periods as compared to the fourth quarter of 2011, we cannot predict the royalty revenues that we will recognize in future periods from sales of INCIVO by Janssen or the timing of such revenues.

***We cannot accurately predict future revenues from KALYDECO (ivacaftor), which will be dependent on, among other factors, our ability to obtain adequate reimbursement and whether or not we are able obtain additional regulatory approvals for KALYDECO.***

We have obtained approval to market KALYDECO (ivacaftor) in the United States for the treatment of patients with CF six years of age and older with the G551D mutation in the *CFTR* gene, but have not yet obtained approval for KALYDECO in any other population or jurisdiction. We believe that the total number of patients with CF who have this mutation in the United States is approximately 1,200. KALYDECO was approved for marketing in January 2012, and we do not yet know how many patients with CF will receive treatment with KALYDECO or the adequacy of the extent of coverage, pricing and level of reimbursement from governmental agencies and third-party payors that will be available for KALYDECO.

Over the next several years our revenues from KALYDECO also will depend on our ability to obtain regulatory approval in Europe, Canada and Australia. We are seeking approval from the European Commission to market KALYDECO for the treatment of patients with CF six years of age and older with the G551D mutation in the *CFTR* gene and with certain other mutations in the *CFTR* gene that result in gating defects. There can be no assurance that ivacaftor will be approved by the European Commission or that the European Commission will not limit any such approval to patients with CF who have the G551D mutation in the *CFTR* gene.

We are planning to conduct several additional clinical trials to evaluate KALYDECO as a monotherapy in additional patient populations, including patients younger than six years of age with gating mutations and patients with other mutations in the *CFTR* gene, which may result in additional revenues if successful. These clinical trials are subject to many of the same risks and uncertainties as the clinical trials for our drug candidates. Even if these clinical trials are successful, we do not expect that we would obtain approval for the use of KALYDECO in additional populations until 2013 or later.

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***If our competitors bring drugs with superior product profiles to market, our drugs may not be competitive and our revenues could decline.***

INCIVEK, KALYDECO and any drugs we develop in the future 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 order to compete successfully in these areas, we must demonstrate improved safety, efficacy and/or tolerability, and ease of manufacturing, and gain and maintain market acceptance over competing drugs that may receive regulatory approval before or after our products and drug candidates, and over those that currently are marketed. Many of our competitors, including major pharmaceutical companies such as Merck, Bristol-Myers Squibb, Gilead, Johnson & Johnson, Novartis, Pfizer, Abbott, Sanofi and Roche, possess substantially greater financial, technical and human resources than we possess.

In addition to the initial competition from Merck's VICTRELIS, we are aware of a number of companies that are developing new treatments for HCV infection including HCV protease inhibitors, HCV nucleotide analogues, non-nucleoside HCV polymerase inhibitors, HCV NS5A inhibitors and advanced interferons. Although drug development is a lengthy process and involves a high degree of risk, we expect that over the next several years one or more of these competitive HCV drug candidates may be approved for marketing in the United States and elsewhere in the world. As a result, the longer-term commercial prospects for INCIVEK and VX-222, ALS-2200 and ALS-2158, if approved, will depend on, among other factors:

the efficacy, safety, tolerability and other characteristics of INCIVEK and VX-222, ALS-2200 and ALS-2158, if approved, relative to existing and future treatments for HCV infection;

our ability to establish INCIVEK and/or VX-222, ALS-2200 and/or ALS-2158, if approved, as a significant component of any approved all-oral therapy or shorter-duration therapy for the treatment of HCV infection; and

the clinical data obtained and timing of marketing approvals for drug candidates being developed by our competitors, including any all-oral therapy or shorter-duration therapy for the treatment of HCV infection.

It is possible that one or more competing therapies for the treatment of HCV infection could be developed with a better efficacy, safety and/or tolerability profile than our telaprevir-based treatment regimens, which would negatively affect INCIVEK and INCIVO sales and could negatively affect our business and financial condition.

***If we discover safety issues with our products that were not known at the time of approval or if we fail to comply with continuing United States and applicable foreign regulations, commercialization efforts for our products could be negatively affected, approved products could lose their approval or sales could be suspended, and our business could be materially harmed.***

Our products are subject to continuing regulatory oversight, including the review of additional safety information. 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, or were not as prevalent or severe, during pre-approval clinical trials or nonclinical studies. The subsequent discovery of previously unknown problems with a product could negatively affect commercial sales of the product, result in restrictions on the product or lead to the withdrawal of the product from the market. The reporting of adverse safety events involving our products or public speculation about such events could cause our stock price to decline or experience periods of volatility.

If we or our collaborators fail to comply with applicable continuing regulatory requirements, we or our collaborators may be subject to fines, suspension or withdrawal of regulatory approvals for specific drugs, product recalls and seizures, operating restrictions and/or criminal prosecutions. In addition, the



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manufacturers we engage to make our products and the manufacturing facilities in which our products are made are subject to periodic review and inspection by the FDA and foreign regulatory authorities. If problems are identified during the review or inspection of these manufacturers or manufacturing facilities, it could result in our inability to use the facility to make our product or a determination that inventories are not safe for commercial sale.

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

Our drugs may not gain or maintain market acceptance among physicians and patients. Effectively marketing INCIVEK and KALYDECO, and any of our other drug candidates, if approved, requires 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 efficacy, safety and/or tolerability 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 in development that have significant perceived advantages over our applicable drug;

convenience and ease of administration;

other potential advantages of alternative treatment methods; and

ineffective marketing and/or distribution support.

If our drugs fail to achieve and maintain market acceptance, we will not be able to generate significant revenues in future periods.

*Government and other third-party payors seek to contain costs of health care through legislative and other means. If they fail to provide coverage and adequate reimbursement rates for our products, our revenues will be harmed.*

In both domestic and foreign markets, our sales of products depends 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 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. The recently enacted ACA will require discounts under the Medicare drug benefit program and increases the rebates paid by pharmaceutical companies on drugs covered by Medicaid. In addition, the ACA imposes an annual fee, which will increase annually, on sales by branded pharmaceutical manufacturers. The financial impact of these discounts, increased rebates and fees and the other provisions of the ACA on our business is unclear, and there can be no assurance that our business will not be materially harmed by future implementation of the ACA.

In addition, 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 drugs. As a result, they may not cover or provide adequate payment for our products. We might need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of our drugs or any other future drugs to such payors' satisfaction.



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Such studies might require us to commit a significant amount of management's time and financial and other resources. Our products 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 already are 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 products are reduced by mandatory discounts or rebates required by government health care programs and privately-negotiated discounts. While we have implemented policies in an effort to comply with mandated reimbursement rates, the United States federal government, state governments and private payors frequently pursue actions against pharmaceutical and biotechnology companies alleging that the companies have overstated prices in order to inflate reimbursement rates. Any such action could adversely affect the pricing of and the commercial success of our products.

Any legislation or regulatory changes or relaxation of laws that restrict imports of drugs from other countries also could reduce the net price we receive for our products.

***If we market any of our products in a manner that violates federal or state health care laws, including fraud and abuse laws, laws prohibiting off-label promotion, disclosure laws or other similar laws, we may be subject to civil or criminal penalties.***

We are subject to health care "fraud and abuse" laws, such as the federal False Claims Act and the anti-kickback provisions of the federal Social Security Act, laws prohibiting off-label product promotion and other similar state and federal laws and regulations. While we have a corporate compliance program designed to actively identify, prevent and mitigate risk through the implementation of compliance policies and systems and the promotion of a culture of compliance, if we are found not to be in full compliance with these laws our business could be materially harmed.

The federal anti-kickback law prohibits knowingly and willfully offering, paying, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the ordering, furnishing, arranging for or recommending of an item or service that is reimbursable, in whole or in part, by a federal health care program, such as Medicare or Medicaid. The federal statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, patients, purchasers and formulary managers on the other hand, and therefore constrains our marketing practices and our various service arrangements with physicians, including physicians who make clinical decisions to use our products. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing, or recommending may be subject to scrutiny or penalty if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, known as "off-label" uses, that caused claims to be submitted to Medicaid for non-covered off-label uses; and submitting inflated "best price" information to the Medicaid Rebate Program.

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Although physicians are permitted to, based on their medical judgment, prescribe products for indications other than those cleared or approved by the FDA, manufacturers are prohibited from promoting their products for such off-label uses. We market INCIVEK for adults with genotype 1 HCV infection and KALYDECO for patients six years of age or older with CF who have the G551D mutation in the *CFTR* gene, and provide promotional materials and training programs to physicians regarding the use of INCIVEK and KALYDECO in these patient populations. If the FDA determines that our promotional materials, training or other activities constitute off-label promotion, it could request that we modify our training or promotional materials or other activities or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. It also is possible that other federal, state or foreign enforcement authorities might take action if they believe that the alleged improper promotion led to the submission and payment of claims for an off-label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. Even if it is later determined we were not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our actions and have to divert significant management resources from other matters.

Also applicable to some of our practices is HIPAA and its implementing regulations, which created federal criminal laws that prohibit executing a scheme to defraud any health care benefit program or making false statements relating to health care matters and which also imposes certain regulatory and contractual requirements regarding the privacy, security and transmission of individually identifiable health information.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. In addition, certain states have laws governing the privacy of certain health information, which may differ from each other in significant ways and often are not preempted by HIPAA, complicating compliance efforts. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a pharmaceutical manufacturer's products from reimbursement under government programs and criminal fines. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business.

In recent years, several states and localities, including California, the District of Columbia, Maine, Minnesota, Nevada, New Mexico, Vermont and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, HCP payments and other activities. Similar legislation is being considered in other states. Additionally, as part of the ACA, the federal government has enacted the Physician Payment Sunshine provisions. The Physician Payment Sunshine provisions will require pharmaceutical manufacturers to publicly report gifts and payments made to physicians and teaching hospitals. On December 14, 2011, CMS published a proposed rule and postponed the statute's January 1, 2012 start date for pharmaceutical manufacturers to collect data to be used in fulfilling their reporting requirements. When the final rules are issued, many of these requirements will be new and uncertain, and the penalties for failure to comply with these requirements will be significant. If we are found not to be in full compliance with these laws, we could face enforcement action, fines and other penalties, and could receive adverse publicity.

The ACA also includes various provisions designed to strengthen significantly fraud and abuse enforcement, such as increased funding for enforcement efforts and the lowering of the intent requirement of the federal anti-kickback statute and criminal health care fraud statute such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it.

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If our past or present operations are found to be in violation of any such laws or any other governmental regulations that may apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from federal health care programs and/or the curtailment or restructuring of our operations. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are subject to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against them, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

The sales and marketing practices of our industry have been the subject of increased scrutiny from federal and state government agencies, and we believe that this trend will continue. We have in place policies to govern how we may retain health care professionals as consultants that reflect the current climate on this issue and are providing training on these policies. Any action against us for violation of these laws, even if we successfully defend against them, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

***Future health care reform measures could hinder or prevent commercial success of our drugs and drug candidates.***

The United States federal government and other governments have shown significant interest in pursuing health care reform. Any government-adopted reform measures could adversely affect the pricing of health care products, including our approved products and/or any future drug candidates approved for sale. The continuing efforts of governments, insurance companies, managed care organizations and other payors for health care products to contain or reduce health care costs may adversely affect our ability to set prices we believe are fair for our products or any drugs we may develop and commercialize.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, relating to health care availability, methods of delivery or payment for drugs, or sales, marketing or pricing, may limit our potential revenues, and we may need to revise our research and development or commercialization programs. The pricing and reimbursement environment may change in the future and become more challenging for any of several reasons, including policies advanced by the U.S. government, new health care legislation or fiscal challenges faced by government health administration authorities. Specifically, in the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals and initiatives to change the health care system in ways that could affect our ability to sell products. Some of these proposed and implemented reforms could result in reduced reimbursement rates for our current or future products, which would adversely affect our business, operations and financial results. As discussed above, the recently enacted ACA may have far reaching consequences for biopharmaceutical companies like us. As a result of this new legislation, substantial changes could be made to the current system for paying for health care in the United States, including changes made in order to extend medical benefits to those who currently lack health insurance coverage. Extending coverage to a large population could substantially change the structure of the health insurance system and the methodology for reimbursement. If reimbursement for our products is substantially less than we expect in the future, or rebate obligations associated with them are substantially increased, our business could be materially and adversely affected.

Further federal and state proposals and health care reforms in and outside of the United States could limit the prices that can be charged for our products and may further limit our commercial opportunity. Our results of operations could be materially adversely affected by the ACA, by the Medicare prescription drug coverage legislation, by the possible effect of such current or future legislation on amounts that private insurers will pay and by other health care reforms that may be enacted or adopted in the future.

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**Risks Related to Development, Clinical Testing and Regulation of our Products and Drug Candidates**

*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.*

In addition to the successful commercialization of INCIVEK and KALYDECO, our business depends upon the successful development and commercialization of additional drug candidates. 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 must allocate resources among our various development programs and must engage in expensive and lengthy testing of our drug candidates. Discovery and development efforts for new pharmaceutical products, including new combination therapies, 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.

We have ongoing or planned Phase 2 clinical trials for a number of our drug candidates. The strength of our company's pipeline of drug candidates, including drug candidates that could potentially be complementary to INCIVEK (telaprevir) and/or KALYDECO (ivacaftor), will depend in large part upon the outcomes of these Phase 2 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. 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 later-stage clinical trials even after achieving promising results in earlier-stage clinical trials. Accordingly, the results from the completed preclinical studies and 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 clinical trials or of the likelihood of approval of a drug candidate for commercial sale. In addition, from time to time we and our competitors report interim data from our clinical trials, including, with respect to our HCV drug candidates, data regarding patients' HCV RNA levels during treatment or at the completion of treatment. Interim data from a clinical trial, and in particular interim on-treatment data, may not be predictive of final results from the clinical trial.

*If we are unable to obtain 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 will be approved for marketing.

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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 also may encounter unanticipated delays or increased costs due to government regulation from future legislation or administrative action or changes in governmental policy during the period of drug development, clinical trials and governmental regulatory review.

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

We also are 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 and approval by a foreign regulatory authority does not ensure approval by the FDA. In addition, the FDA may not favorably consider data from clinical trials conducted in foreign jurisdictions. Foreign jurisdictions have different approval procedures than those required by the FDA and may impose additional testing requirements for our drug candidates.

***If clinical trials for a drug candidate are prolonged or delayed, our development timelines for the affected drug candidate could be extended, our costs to develop the drug candidate could increase and the competitive position of the drug candidate could be adversely affected.***

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 scientific results from clinical trials of our drug candidates;

serious and unexpected drug-related side-effects experienced by participants in our clinical trials;

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favorable results in testing of our competitors' drug candidates, or FDA or foreign regulatory authority approval of our competitors' drug candidates; 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 is 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, patients may drop out of our clinical trials or may be lost to follow-up medical evaluation after treatment ends, and this could 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, 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 healthy volunteers 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.

***We may not successfully develop VX-222 and/or either of the HCV nucleotide analogues we license from Alios and, as a result, we could be subject to significant impairment charges in future periods.***

In March 2009, we acquired ViroChem Pharma Inc., or 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 non-nucleoside 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 INCIVEK and/or our earlier-stage drug candidates. 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 third quarter of 2011, we determined that the fair value of VX-759 was zero dollars, which resulted in a \$105.8 million impairment charge in the third quarter of 2011. In 2011, we licensed two HCV nucleotide analogues, ALS-2200 and ALS-2158, from Alios and recorded \$250.6 million as an intangible asset on our consolidated balance sheet. As of December 31, 2011, our consolidated balance sheet included intangible assets of \$412.9 million related to VX-222 and \$250.6 million related to ALS-2200 and ALS-2158.

While we believe the data from the clinical trials and nonclinical studies to date support the continued development of VX-222, ALS-2200 and ALS-2158 for the treatment of HCV infection, there are numerous reasons why we may not be able to successfully develop a combination therapy for the treatment of HCV infection that includes VX-222, ALS-2200, ALS-2158 or a combination of any of them, including:

data from clinical trials involving compounds evaluated separately may not predict possible outcomes, such as unforeseen drug interactions, from compounds dosed in combination, which could negatively affect the efficacy and safety profile of the combination therapy;

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 with a better product profile.

There can be no assurance that we will be able to successfully develop VX-222, ALS-2200 or ALS-2158 alone or in combination, and if we do not successfully develop these drug candidates we will incur additional impairment charges in future periods related to VX-222 or the HCV nucleotide



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analogues licensed from Alios. If we incur a significant impairment charge, the value of our common stock could decrease.

*If our processes and systems are not compliant with regulatory requirements, we could be subject to restrictions on marketing our drugs or could be delayed in submitting regulatory filings seeking approvals for our drug candidates.*

We have a number of regulated processes and systems that are required to obtain and maintain regulatory approval for our drugs and drug candidates. These processes and systems are subject to continual review and periodic inspection by the FDA and other regulatory bodies. 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. 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, which could have a material adverse effect on our business.

**Risks Related to Collaborators, Manufacturing and Reliance on Third Parties**

*We depend on our collaborators to work with us to develop, manufacture and commercialize our products and some 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 are entitled to royalties from any sales of INCIVO (telaprevir) in Janssen's territories. The success of the commercialization of INCIVO in Janssen's territories is dependent upon Janssen's sales and marketing efforts, which we do not control and may not be able to effectively influence. If Janssen does not effectively commercialize INCIVO, our anticipated cash flows from royalties on net sales of INCIVO would be materially harmed. We also in-license ALS-2200 and ALS-2158 from Alios and any loss of this license could materially harm our efforts to develop an all-oral, interferon-free treatment regimen for HCV infection.

The risks that we face in connection with these existing and any future collaborations include the following:

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 products and drug candidates to reach their potential could be limited if collaborators decrease or fail to increase development or commercialization efforts related to those products or drug candidates.

Any future 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.

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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. For example, Janssen is evaluating a potentially competitive HCV protease inhibitor in Phase 3 clinical trials, which could increase the likelihood that Janssen would terminate our collaboration or apply fewer resources to the commercialization of INCIVO.

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 disrupt the commercial sale of INCIVO in Janssen's territories.

***We depend on third-party manufacturers, including sole source suppliers, to manufacture our products and the materials we require for our clinical trials. We may not be able to maintain these relationships and could experience supply disruptions outside of our control.***

We rely on a worldwide network of third-party manufacturers to manufacture and distribute INCIVEK (telaprevir) and KALYDECO (ivacaftor) for commercial sale and post-approval clinical trials, and our drug candidates for clinical trials. As a result of our reliance on these third-party manufacturers and suppliers, including sole source suppliers of certain components of our products and drug candidates, we could 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 China, 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.

We require a supply of INCIVEK for sale in North America. We believe there are multiple third parties capable of providing most of the materials and services we need in order to manufacture and distribute INCIVEK. It is also possible that supply of materials that can not be second-sourced can be managed with inventory planning. If we underestimate demand, our manufacturing capacity through third-party manufacturers may not be sufficient. Also, while we believe we can effectively forecast demand for INCIVEK, we have limited flexibility to adjust our supply in response to changes in demand, due to the significant lead times required to manufacture INCIVEK.

We require a supply of KALYDECO in the United States, and we will require a supply of ivacaftor for sale in international markets if we obtain marketing approvals outside of the United States. We are in the process of establishing secondary sources for our KALYDECO supply needs. Holders of market exclusivity for orphan drugs such as KALYDECO are expected to assure the availability of sufficient quantities of their orphan drugs to meet the needs of patients.

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 disrupt sales of our products and/or the timing of our clinical trials. Furthermore, we may be required to modify our production methods to permit us to economically manufacture our drugs for sale and our drug candidates for clinical trials. 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.

In the course of providing its services, a contract manufacturer may develop process technology related to the manufacture of our products or drug candidates that the manufacturer owns, either independently or jointly with us. This would increase our reliance on that manufacturer or require us to

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obtain a license from that manufacturer in order to have our products or drug candidates manufactured by other suppliers utilizing the same process.

***We may not be able to attract collaborators for the development and commercialization of our drug candidates.***

As part of our ongoing strategy, we may seek additional collaborative arrangements. We have a number of research programs and early-stage and mid-stage clinical development programs. At any time, we may determine that in order to continue development of a drug candidate or program or successfully commercialize a drug 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.

***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 or regulatory requirements.***

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.

**Risks Related to Intellectual Property**

***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 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 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 have patents or patent applications with composition-of-matter claims for each of our products and clinical drug candidates, only a portion of these patents have been granted. 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.

Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the scope of claims made under these patents, our ability to

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maintain, obtain and enforce patents is uncertain and involves complex legal and factual questions. U.S. and foreign patent applications typically are maintained in confidence for a period of time after they initially are filed with the applicable patent office. Similarly, publication of discoveries in the scientific literature often lag behind actual discoveries. Consequently, we cannot be certain that we or our licensors were the first to invent, or the first to file patent applications on, our products or drug candidates or their use. If a third party also has filed a U.S. patent application relating to our products or drug candidates or a similar invention, we may have to participate in interference proceedings to determine priority of invention and could lose our patent position. Furthermore, we may not have identified all U.S. and foreign patents or published applications that affect our business by blocking our ability to commercialize our drugs or drug candidates.

Our patents may be challenged by third parties, resulting in the patent being deemed invalid, unenforceable or narrowed in scope, or the third party may circumvent any such issued patents. Also, our pending patent applications may not issue, and we may not receive any additional patents. Our patents might not contain claims that are sufficiently broad to prevent others from utilizing our technologies. For instance, the issued patents relating to our products or drug candidates may be limited to a particular molecule or molecules and may not cover similar molecules that have similar clinical properties. Consequently, our competitors may independently develop competing products that do not infringe our patents or other intellectual property.

The laws of many foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business could be substantially harmed.

Because of the extensive time required for development, testing and regulatory review of a drug candidate, it is possible that, before any of our drug candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization of our drug candidates, thereby reducing any advantages of the patent. To the extent our drug candidates are not commercialized significantly ahead of the expiration date of any applicable patent, or to the extent we have no other patent protection on such drug candidates, those drug candidates would not be protected by patents, and we would then rely solely on other forms of exclusivity, such as regulatory exclusivity provided by the FDCA.

### **Risks Related To Our Operations**

***Our business has a substantial risk of product liability claims. If we are unable to obtain appropriate levels of insurance, product liability claims 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 have product liability insurance and clinical trial insurance in amounts that we believe are adequate to cover this risk. However, our insurance may not provide adequate coverage against potential liabilities. If a claim is brought against us, we might be required to pay legal and other expenses to defend the claim, as well as pay uncovered damages awards resulting from a claim brought successfully against us and these damages could be significant and have a material adverse effect on our financial condition. 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.

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***Risks associated with operating in foreign countries could materially adversely affect our business.***

We have expanded our operations in Canada in order to market INCIVEK (telaprevir) and ivacaftor, if approved, in that country, and in Europe in order to market ivacaftor internationally, if approved. A significant portion of our commercial supply chain, including sourcing of raw materials and manufacturing, is located in China, Japan 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 and regulation of approved drugs 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 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.

In addition, our international operations are subject to regulation under United States law. For example, the Foreign Corrupt Practices Act prohibits United States companies and their representatives from offering, promising, authorizing or making payments to foreign officials for the purpose of obtaining or retaining business abroad. In many countries, the health care professionals we regularly interact with may meet the definition of a foreign government official for purposes of the Foreign Corrupt Practices Act. We also are subject to import/export control laws. Failure to comply with domestic or foreign laws could result in various adverse consequences, including the possible delay in approval or refusal to approve a product, recalls, seizures, withdrawal of an approved product from the market, the imposition of civil or criminal sanctions, the prosecution of executives overseeing our international operations and corresponding bad publicity and negative perception of our company in foreign countries.

***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 license or acquire technologies, resources, drugs or drug candidates. We might never realize the anticipated benefits of such a transaction or we may later incur impairment charges related to assets acquired in any such transaction. In particular, due to the risks inherent in drug development, we may not successfully develop or obtain marketing approval for the drug candidates we acquire. For example, we incurred a \$105.8 million impairment charge in the third quarter of 2011 in connection with VX-759, which we obtained through our 2009 acquisition of ViroChem. Future licenses or acquisitions could result in potentially dilutive issuances of



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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 fail to manage our growth effectively, our business may suffer.***

The number of our employees increased by approximately 18% in each of 2011 and 2010, and we expect to experience additional growth in 2012. 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, we need to attract and retain employees with experience in marketing and commercialization of medicines. We are planning to move from Cambridge, Massachusetts to Boston, Massachusetts, and this move must be managed successfully to avoid disruption to our business. While we do not expect the move to result in significant turnover, we cannot be sure that we will be able to retain all our key scientific, commercial and management employees. We face intense competition for our personnel from our competitors 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 products, and achieve our research and development objectives, depends on our ability to respond effectively to these demands and expand our internal organization to accommodate 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 affect 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. A loss of key personnel or a failure to properly integrate new personnel could be disruptive. We have entered into employment agreements with some executives 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 executive on relatively short notice. The value to employees of stock-related benefits that vest over time such as options and restricted stock is significantly affected by movements in our stock price, 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 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, federal and foreign regulations, the risk of accidental contamination or injury from these materials can not be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We also are 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. We maintain insurance to cover

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pollution conditions or other extraordinary or unanticipated events relating to our use and disposal of hazardous materials that we believe is appropriate based on the small amount of hazardous materials we generate. 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.

**Risks Related to Holding Our Common Stock and Potential Financing Activities**

***Our stock price may fluctuate.***

Market prices for securities of companies such as ours are highly volatile. From January 1, 2010 to December 31, 2011, our common stock traded between \$26.50 and \$58.87 per share. The market for our stock, like that of other companies in the pharmaceuticals industry, has from time to time experienced significant price and volume fluctuations. The future market price of our securities could be significantly and adversely affected by factors such as:

the information contained in our quarterly earnings releases, including our net product revenues, royalty revenues and operating expenses for completed periods and guidance regarding future periods;

prescription data and other information disclosed by third-parties regarding our business or products;

announcements of FDA actions with respect to our drugs or our competitors' drugs, or regulatory filings for our drug candidates or those of our competitors or of results of clinical trials or nonclinical studies relating to our drugs, drug candidates or those of our competitors;

technological innovations or the introduction of new drugs by our competitors;

government regulatory action;

public concern as to the safety of drugs developed by us or our competitors;

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;

business development, capital structuring or financing activities; and

general worldwide or national economic, political and capital market conditions.

***Our quarterly operating results are subject to significant fluctuation.***



## Edgar Filing: VERTEX PHARMACEUTICALS INC / MA - Form 10-K

Our operating results have fluctuated from quarter to quarter in the past, and we expect that they will continue to do so in the future. Factors that have caused quarterly fluctuations in the past include variable amounts of product revenues and collaboration revenues, impairment charges and changes in the fair value of derivative instruments. We cannot accurately predict our future revenues from our products and our revenues from our products could vary on a quarterly basis. Our revenues from our products, and in particular INCIVEK (telaprevir), may be affected by, among other factors, seasonality and the timing of orders from our significant distributors. Our quarterly results also could be significantly affected by any future impairment charges we take with respect to intangible assets and changes in the fair value of contingent milestone and royalty payments pursuant to our collaboration agreement with Alios. Most of our operating expenses relate to our research and development activities, do not vary directly with the amount of revenues and are difficult to adjust in the short term. As a result, if revenues in a particular quarter are below expectations, we are unlikely to proportionately reduce operating expenses for that quarter.

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These examples are only illustrative and other risks, including those discussed in these "Risk Factors," could also cause fluctuations in our reported financial results. Our operating results during any one period do not necessarily suggest the results of future periods.

***We expect that results from our clinical development activities and the clinical development activities of our competitors will continue to be released periodically, and may result in significant volatility in the price of our common stock.***

Any new information regarding our products and drug candidates or competitive products or potentially competitive drug candidates, and in particular any new information regarding INCIVEK and competitive HCV products or 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 or our competitors and/or information about our or our competitors' expectations regarding regulatory filings and submissions as well as future clinical development of our products or drug candidates, competitive products or potentially competitive 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 the timing of receipt of data from our clinical trials and by the general preference among pharmaceutical companies to disclose clinical data during medical conferences. In addition, the information that we and our competitors disclose about these trials may be based on interim rather than final data that may involve interpretation difficulties and may in any event not accurately predict final results.

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

Although we do not have any plans to do so in the near term, we may in the future need to raise additional capital. Any potential public offering or private placement 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.

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

We are obligated to repay an aggregate of \$400.0 million for our convertible senior subordinated notes due 2015, or 2015 Notes, no later than October 1, 2015. We also are obligated to make semi-annual interest payments on the outstanding principal amount of the 2015 Notes. We 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;

shortening the duration of available revolving credit because lenders may seek to avoid conflicting maturity dates;

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constraining our ability to react quickly in an unfavorable economic climate or to changes in our business or the pharmaceutical industry; or

potentially requiring the dedication of substantial amounts to service the repayment of outstanding debt, including periodic interest payments, thereby reducing the amount of cash available for other purposes.

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

As of December 31, 2011, we had 209.3 million shares of common stock issued and outstanding. As of December 31, 2011, we also had outstanding options to purchase 20.9 million shares of common stock with a weighted-average exercise price of \$34.23 per share and 8.2 million shares of common stock issuable upon conversion of our 2015 Notes, at a conversion price of approximately \$48.83 per share. Outstanding vested options are likely to be exercised if the market price of our common stock exceeds the applicable exercise price, and, in the future, we expect to issue additional options and restricted stock to employees. In addition, we may issue additional common stock or restricted securities in the future as part of 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.

***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 and Massachusetts state laws 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 shareholders, and certain provisions of our by-laws may be amended only with an 80% shareholder vote. We may issue shares of any class or series of preferred stock in the future without shareholder 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 shareholder who acquires 20% or more of our voting stock without shareholder approval. As a result, shareholders or other parties may find it more difficult to remove or replace our current management.

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***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:

expectations regarding the amount of, timing of and trends with respect to our revenues, costs and expenses and other gains and losses, including those related to product revenues from sales of INCIVEK and KALYDECO and royalty revenues from net sales of INCIVO and to the intangible assets associated with the ViroChem acquisition and the Alios collaboration;

our expectations regarding clinical trials, development timelines and regulatory authority filings and submissions for VX-222, ALS-2200, ALS-2158, VX-809, VX-661, VX-509, VX-765, VX-787 and our other drug candidates;

our ability to successfully market INCIVEK and/or KALYDECO or any of our other drug candidates if we obtain regulatory approval;

our expectations regarding the timing and structure of clinical trials of our drugs and drug candidates, including INCIVEK, KALYDECO, VX-222, ALS-2200, ALS-2158, VX-809, VX-661, VX-509, VX-765 and VX-787, and the expected timing of our receipt of data from our and our collaborators' ongoing and planned clinical trials;

the data that will be generated by ongoing and planned clinical trials and the ability to use that data to support regulatory filings;

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;

the focus of our drug development efforts and our financial and management resources and our plan to continue investing in our research and development programs and to develop and commercialize selected drug candidates that emerge from those programs, alone or with third-party collaborators;

the establishment, development and maintenance of collaborative relationships;

potential business development activities;

our ability to use our research programs to identify and develop new drug candidates to address serious diseases and significant unmet medical needs;

our estimates regarding obligations associated with a lease of a facility in Kendall Square, Cambridge, Massachusetts; and

our liquidity and our expectations regarding the possibility of raising 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 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.

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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, 2011 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 1.1 million square feet of laboratory and office space in facilities located in Massachusetts, California, Washington, DC, Iowa, Canada, Switzerland and the United Kingdom. We believe our facilities are adequate for our current needs.

*Massachusetts*

We lease an aggregate of 870,000 square feet of space in eleven 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 for 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, and an option to terminate the lease in December 2013, subject to certain advance notice provisions. We sublease approximately 145,000 square feet at 88 Sidney Street, Cambridge, Massachusetts, as subtenant to Alkermes, Inc. who is the prime tenant in the building; this lease expires in June 2012. Vertex has entered into a master lease with the landlord for 88 Sidney Street that commences in June 2012 and expires in June 2014. We also lease approximately 56,000 square feet of office space at One Marina Park Drive, Boston, Massachusetts. This is a five year lease with one option to extend for either five or ten years.

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 we lease in the facility for our research operations. The subleases are for terms ending in 2015, with one sublease having an extension option to 2018.

We are planning to consolidate our headquarters operations in Massachusetts into one campus in Boston, Massachusetts. In May 2011, we entered into two leases pursuant to which we agreed to lease approximately 1.1 million square feet of office and laboratory space in two buildings being built in Boston, Massachusetts. We expect that the leases will commence upon completion of the buildings, scheduled for late 2013, and will extend for 15 years from the commencement date. We have an option to extend the term of the leases for an additional ten years.

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*California*

We lease approximately 81,000 square feet of laboratory and office space in San Diego, California. The lease for this space will expire in September 2013.

*Canada*

We lease approximately 63,000 square feet of laboratory and office space in Montreal, Canada. The lease for this space will expire in April 2016.

*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 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. MINE SAFETY DISCLOSURES**

Not applicable.

Table of Contents**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 Stock Market LLC:

<b>Year Ended December 31, 2011:</b>	<b>High</b>	<b>Low</b>
First quarter	\$ 52.13	\$ 35.19
Second quarter	58.87	44.57
Third quarter	54.38	39.06
Fourth quarter	45.26	26.50

<b>Year Ended December 31, 2010:</b>		
First quarter	\$ 44.24	\$ 36.15
Second quarter	41.62	32.41
Third quarter	37.95	31.25
Fourth quarter	38.70	32.08

**Stockholders**

As of February 8, 2012, there were 2,157 holders of record of our common stock.

**Performance Graph****CUMULATIVE TOTAL RETURN**

Based on Initial Investment of \$100 on December 31, 2006  
with dividends reinvested (fiscal years ended December 31)





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We have never declared or paid any cash dividends on our common stock, and we currently expect that any future earnings will be retained for use in our business. Additionally, the credit agreement we entered into in January 2011 restricts our ability to declare or pay dividends in certain circumstances.

**Issuer Repurchases of Equity Securities**

The table set forth below shows all repurchases of securities by us during the three months ended December 31, 2011:

<b>Period</b>	<b>Total Number of Shares Purchased</b>	<b>Average Price Paid per Share</b>	<b>Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs</b>	<b>Maximum Number of Shares that May Yet be Purchased Under the Plans or Programs</b>
Oct. 1, 2011 to Oct. 31, 2011	26,543	\$ 0.01		
Nov. 1, 2011 to Nov. 30, 2011	39,476	\$ 0.01		
Dec. 1, 2011 to Dec. 31, 2011	11,337	\$ 0.01		

The repurchases were made under the terms of our Amended and Restated 2006 Stock and Option Plan. Under this plan, we award shares of restricted stock to our employees that typically are subject to a lapsing right of repurchase by us. We may exercise this right of repurchase if 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 returned to the Amended and Restated 2006 Stock and Option Plan are available for future awards under the terms of that plan.

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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.

	Year Ended December 31,				
	2011	2010	2009	2008	2007
(in thousands, except per share amounts)					
<b>Consolidated Statements of Operations Data:</b>					
Revenues:					
Product revenues, net	\$ 950,889	\$ 30,244	\$ 28,320	\$ 37,483	\$ 47,973
Royalty revenues	50,015	113,126	73,569	138,021	151,039
Collaborative revenues	409,722				
Total revenues	1,410,626	143,370	101,889	175,504	199,012
Costs and expenses:					
Cost of product revenues	63,625				
Royalty expenses	16,880	12,730	14,202	15,686	13,904
Research and development expenses	707,706	637,416	550,274	516,912	519,227
Sales, general and administrative expenses	400,721	187,800	130,192	101,290	78,554
Restructuring expense	2,074	1,501	6,240	4,324	7,119
Intangible asset impairment charge(1)	105,800		7,200		
Acquisition-related expenses(1)			7,793		
Total costs and expenses	1,296,806	839,447	715,901	638,212	618,804
Income (loss) from operations	113,820	(696,077)	(614,012)	(462,708)	(419,792)
Interest income (expense), net	(36,574)	(17,320)	(8,182)	2,857	28,513
Change in fair value of derivative instruments(2)	(16,801)	(41,229)	(1,847)		
Loss on exchanges of convertible senior subordinated notes (due 2013)			(18,137)		
Income (loss) before provision for income taxes	60,445	(754,626)	(642,178)	(459,851)	(391,279)
Provision for income taxes	19,266				
Net income (loss)	41,179	(754,626)	(642,178)	(459,851)	(391,279)
Net income attributable to noncontrolling interest (Alios)(3)	11,605				
Net income (loss) attributable to Vertex	\$ 29,574	\$ (754,626)	\$ (642,178)	\$ (459,851)	\$ (391,279)
Net income (loss) per share attributable to Vertex common shareholders:					
Basic	\$ 0.14	\$ (3.77)	\$ (3.71)	\$ (3.27)	\$ (3.03)
Diluted	\$ 0.14	\$ (3.77)	\$ (3.71)	\$ (3.27)	\$ (3.03)
Shares used in per share calculations:					
Basic	204,891	200,402	173,259	140,556	128,986
Diluted	208,807	200,402	173,259	140,556	128,986

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	As of December 31,				
	2011	2010	2009	2008	2007
	(in thousands)				
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and marketable securities	\$ 968,922	\$ 1,031,411	\$ 1,284,913	\$ 832,101	\$ 467,796
Accounts receivable, net	183,135	12,529	9,601	23,489	31,320
Inventories	112,430				
Intangible assets(1)(3)	663,500	518,700	518,700		
Goodwill(1)(3)	30,992	26,102	26,102		
Total assets	\$ 2,204,280	\$ 1,725,446	\$ 1,955,488	\$ 980,479	\$ 601,477
Total current liabilities	\$ 392,348	\$ 474,783	\$ 284,883	\$ 216,564	\$ 199,279
Convertible senior subordinated notes (due 2013), net of current portion				287,500	
Convertible senior subordinated notes (due 2015)	400,000	400,000			
Secured notes (due 2012) and liability related to sale of milestone payments, net of current portion(2)			159,972		
Deferred tax liability(1)(3)	243,707	160,278	160,278		
Other liabilities, net of current portion	202,713	186,412	254,009	237,541	130,903
Noncontrolling interest (Alios)(3)	178,669				
Vertex shareholders' equity	786,843	503,973	1,096,346	238,874	271,295
Total liabilities and shareholders' equity	\$ 2,204,280	\$ 1,725,446	\$ 1,955,488	\$ 980,479	\$ 601,477

- (1) The intangible asset impairment charge, acquisition-related expenses, and a portion of the intangible assets, goodwill and deferred tax liability reflected in the selected financial data relate to our acquisition of ViroChem in 2009. See Note C to our consolidated financial statements included in this Annual Report on Form 10-K.
- (2) The change in fair value of derivative instruments, secured notes (due 2012) and liability related to sale of milestone payments reflected in the selected financial data relate to two financial transactions that we entered into in September 2009. As of December 31, 2010, the secured notes (due 2012) and the liability related to sale of milestone payments were included in total current liabilities. See Note N to our consolidated financial statements included in this Annual Report on Form 10-K.
- (3) Net income attributable to noncontrolling interest (Alios), noncontrolling interest (Alios) and a portion of the intangible assets, goodwill and deferred tax liability reflected in the selected financial data relate to our collaboration with Alios, which was entered into in 2011. See Note B to our consolidated financial statements included in this Annual Report on Form 10-K.

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

**Overview**

We are in the business of discovering, developing, manufacturing and commercializing small molecule drugs for the treatment of serious diseases. Our two products are INCIVEK (telaprevir), which is approved in the United States and Canada for the treatment of adults with genotype 1 hepatitis C virus, or HCV, infection, and KALYDECO (ivacaftor), which is approved in the United States for the treatment of patients six years of age or older with cystic fibrosis, or CF, who have a specific genetic mutation that is referred to as the G551D mutation. We began marketing INCIVEK in the United States in May 2011. Our collaborator, Janssen Pharmaceutica, N.V., or Janssen, began marketing telaprevir in its territories under the brand name INCIVO in September 2011. Our collaborator, Mitsubishi Tanabe Pharma Corporation, or Mitsubishi Tanabe, obtained marketing approval for telaprevir from the Japanese Ministry of Health, Labor and Welfare in September 2011. We began marketing KALYDECO in the United States in January 2012, and we expect to obtain approval to market ivacaftor in the European Union later in 2012.

We generated earnings as a cashflow positive company in the second half of 2011 after experiencing significant losses in 2009, 2010 and the first half of 2011. In the second half of 2011, we had net income attributable to us of \$379.7 million and our cash, cash equivalents and marketable securities increased by \$375.4 million. We recognized net product revenues on sales of INCIVEK of \$419.6 million and \$456.8 million, respectively, in the third and fourth quarters of 2011. We began recognizing royalty revenues from commercial sales of INCIVO by Janssen in September 2011, and we will begin to recognize revenues from sales of KALYDECO in the first quarter of 2012. In order to maintain profitability and continue our strategic investment in research and development activities, we will need to continue to generate significant revenues in future periods.

We have ongoing clinical programs involving drug candidates intended for the treatment of HCV infection, CF, rheumatoid arthritis, epilepsy and influenza. Our HCV clinical programs are focused on developing all-oral, interferon-free combinations of HCV drugs and drug candidates that have the potential to further improve treatment options available to patients with HCV infection. In our CF program, we are investigating the use of ivacaftor as a monotherapy in additional populations of patients with CF and combinations of ivacaftor and our other CF drug candidates, with the goal of expanding the group of patients with CF who can benefit from our medicines. We believe that our longer-term success will depend on our ability to continue to generate and develop innovative compounds for the treatment of serious diseases. As a result, we expect to continue investing in research programs directed toward the identification of new drug candidates and to develop and commercialize selected drug candidates that emerge from those programs, alone or with third-party collaborators.

*Commercialization and Competition*

We believe that by focusing on serious diseases and innovative drugs that have the potential to provide significant advantages over existing therapies, we can increase the likelihood that our drug candidates, if approved, will be commercially successful. Our marketing efforts for INCIVEK in the United States have focused on establishing an effective sales force and managed markets organization to promote INCIVEK to health care providers and payors; implementing appropriate marketing, distribution and pricing strategies; and maintaining appropriate and sustained levels of INCIVEK inventory.

We believe that initial sales of INCIVEK have confirmed its commercially competitive profile, and to date a significant group of patients with genotype 1 HCV infection have sought treatment with an INCIVEK-based treatment regimen. We and Janssen are competing with Merck & Co., Inc.'s VICTRELIS (boceprevir), another HCV protease inhibitor that was approved for sale in the United

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States and Europe in 2011. In the United States, we believe over 25,000 patients were treated with INCIVEK in 2011. We believe that sales of INCIVEK will be subject to some seasonal fluctuations as, for example, historically fewer patients have started treatment for HCV infection during late November and December than during other periods of the year. However, the sales of drugs that obtain initial market acceptance may decline for a variety of reasons, including increased competition from currently approved competitive drugs, the introduction of new competitive drugs, adverse information regarding the safety characteristics or efficacy of the drug or significant new information regarding potential future treatment regimens that are being evaluated in clinical trials.

We, along with a number of competitors, are pursuing development programs involving all-oral combinations of HCV drugs and drug candidates with the goal of developing improved treatment regimens for HCV infection that could render the current treatments, which include the administration of pegylated-interferon, or peg-IFN, by injection, noncompetitive. In particular, each of Bristol-Myers Squibb Company and Gilead Sciences, Inc. is actively pursuing all-oral treatment regimens for HCV infection that would include an HCV nucleotide analogue and Bristol-Myers Squibb and Medivir AB are evaluating a combination of an HCV protease inhibitor and an HCV NS5A inhibitor. To date, potential all-oral treatment regimens have been evaluated in Phase 2 clinical trials involving relatively small numbers of patients. However, we expect that one or more companies may begin registration programs evaluating potential all-oral combination regimens for the treatment of genotype 1 HCV infection in 2012. While the development and regulatory timelines for these drug candidates are highly subjective and subject to change, we believe that substantial additional clinical data regarding these drug candidates and potential all-oral treatment regimens will become available in 2012 and 2013 and that one or more all-oral treatment regimens could enter the market as early as 2014 or 2015.

KALYDECO (ivacaftor) is a treatment for patients with CF six years of age or older who have a specific genetic mutation that is referred to as the G551D mutation. As with other marketed therapies for orphan diseases such as CF, we believe that we will be able to obtain adequate reimbursement for KALYDECO in the United States. In addition, we are focused on obtaining approval and adequate reimbursement for ivacaftor in Europe and plan to seek approval for ivacaftor in a number of other countries, including Canada and Australia. We believe that the number of patients with CF who have the G551D mutation in the *CFTR* gene is approximately 1,200 in the United States and 1,000 in Europe. We are planning to conduct three additional clinical trials to evaluate KALYDECO as a monotherapy in additional patient populations, including patients younger than six years of age and patients with other mutations in the *CFTR* gene. These clinical trials are subject to many of the same risks and uncertainties as the clinical trials for our drug candidates. Even if these clinical trials are successful, we do not expect we would obtain approval for the use of KALYDECO in additional populations until 2013 or later.

In addition to the factors described above, approved drugs continue to be subject to, among other things, numerous regulatory risks, post-approval safety monitoring and risks related to supply chain disruptions. As a result, it is difficult to predict future revenues that will be generated from sales by us of INCIVEK and KALYDECO and by Janssen of INCIVO.

*Drug 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. Potential drug candidates are subjected to rigorous evaluations, 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 development, and most drug candidates that do advance into development never receive marketing approval. Because our investments in drug candidates are subject to considerable

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risks, we closely monitor the results of our discovery research, clinical trials and nonclinical studies, and frequently evaluate our drug development programs 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 understanding of our ongoing programs and potential new programs as well as those of our competitors.

If we believe the data from a completed registration program support approval of a drug candidate, we submit a New Drug Application to the United States Food and Drug Administration, or FDA, requesting approval to market the drug candidate in the United States. We also may seek analogous approvals from comparable regulatory authorities in foreign jurisdictions, such as a Marketing Authorization Application in the European Union. To obtain approval, we must, among other things, demonstrate with evidence gathered in nonclinical studies and well-controlled clinical trials that the drug candidate is safe and effective for the disease it is intended to treat and that the manufacturing facilities, processes and controls for the manufacture of the drug candidate are adequate. The FDA and foreign regulatory authorities have substantial discretion in deciding whether or not a drug candidate should be granted approval based on the benefits and risks of the drug candidate in the treatment of a particular disease, and could delay, limit or deny regulatory approval. If regulatory delays are significant or regulatory approval is limited or denied altogether, our financial results and the commercial prospects for the drug candidate involved will be harmed.

*Drug Supply*

We require a supply of INCIVEK and KALYDECO for sale in North America and will require a supply of ivacaftor for international sales if we are successful in obtaining marketing approval outside the United States. We rely on an international network of third parties to manufacture and distribute our products and for supplies of compounds for clinical trials, and we expect that we will continue to rely on third parties to provide these manufacturing services for the foreseeable future. Third-party contract manufacturers, including some in China, 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 believe we effectively manage the business relationships with companies in our supply chain, we do not have complete control over their activities. Also, while we believe we can effectively forecast demand for INCIVEK, we have limited flexibility to adjust our supply in response to changes in demand, due to the significant lead times required to manufacture INCIVEK.

*Regulatory Compliance*

Our marketing of pharmaceutical products, which began in May 2011, is subject to extensive and complex laws and regulations. We have a corporate compliance program designed to actively identify, prevent and mitigate risk through the implementation of compliance policies and systems and the promotion of a culture of compliance. Among other laws, regulations and standards, we are subject to various federal and state laws pertaining to health care fraud and abuse, including anti-kickback and false claims statutes, and laws prohibiting the promotion of drugs for unapproved, or off-label, uses. Anti-kickback laws make it illegal for a prescription drug manufacturer 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 presenting for payment to third-party payors, including Medicare and Medicaid, 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. We expect to continue to devote substantial resources to maintain, administer and expand these compliance programs globally.

Table of Contents**RESULTS OF OPERATIONS**

	2011	2010	2009	2011/2010 Comparison		2010/2009 Comparison	
				Increase	Increase	Increase	Increase
	(in thousands)			(in thousands, except percentages)			
Revenues	\$ 1,410,626	\$ 143,370	\$ 101,889	\$ 1,267,256	884%	\$ 41,481	41%
Operating costs and expenses	1,296,806	839,447	715,901	457,359	54%	123,546	17%
Other loss, net	(84,246)	(58,549)	(28,166)	25,697	44%	30,383	108%
Net income (loss) attributable to Vertex	\$ 29,574	\$ (754,626)	\$ (642,178)	n/a	n/a	\$ 112,448	18%

***Net Income (Loss) Attributable to Vertex***

In 2011, we had net income attributable to Vertex of \$29.6 million. Our increased revenues in 2011 as compared to 2010 were the result of \$950.9 million of INCIVEK net product revenues and \$318.5 million in collaborative milestone revenues for which there were no comparable revenues in 2010. Our increased revenues were partially offset by increased operating costs and expenses in 2011 as compared to 2010. The \$457.4 million increase in operating costs and expenses in 2011 as compared to 2010 was principally attributable to a \$212.9 million increase in sales, general and administrative expenses, a \$63.6 million increase in cost of product revenues and a \$105.8 million impairment charge that we incurred in the third quarter of 2011 for VX-759, a back-up non-nucleoside HCV polymerase inhibitor.

The increased net loss in 2010 as compared to 2009 was the result of significant increases in our costs and expenses, partially offset by an increase in our revenues. The increase in our operating costs and expenses during 2010 as compared to 2009 was primarily due to increased expenses for our commercial organization and increased investment in commercial supplies of telaprevir.

Our operating costs and expenses in 2011, 2010 and 2009 included \$118.2 million, \$91.1 million and \$86.7 million, respectively, of stock-based compensation expense.

***Net Income (Loss) Attributable to Vertex per Diluted Share***

Our net income attributable to Vertex was \$0.14 per diluted share in 2011 as compared to a net loss attributable to Vertex of (\$3.77) per diluted share in 2010 and (\$3.71) per diluted share in 2009.

***Revenues***

	2011	2010	2009	2011/2010 Comparison		2010/2009 Comparison	
				Increase	Increase	Increase	Increase
	(in thousands)			(in thousands, except percentages)			
Product revenues, net	\$ 950,889	\$ 30,244	\$ 28,320	\$ 950,889	n/a	\$ 1,924	n/a
Royalty revenues	50,015	30,244	28,320	19,771	65%	1,924	7%
Collaborative revenues	409,722	113,126	73,569	296,596	262%	39,557	54%
Total revenues	\$ 1,410,626	\$ 143,370	\$ 101,889	\$ 1,267,256	884%	\$ 41,481	41%

**Product Revenues, Net**

We began recognizing net product revenues from sales of INCIVEK in the United States in the second quarter of 2011 and will begin recognizing net product revenues from sales of KALYDECO in the United States in the first quarter of 2012. We expect that our net product revenues will increase in 2012 in comparison to 2011 as we recognize INCIVEK net product revenues for a full fiscal year and begin to recognize KALYDECO net product revenues.



Table of Contents**Royalty Revenues**

Our royalty revenues increased by \$19.8 million in 2011 as compared to 2010 due to \$20.3 million of revenues recognized in 2011 from sales of INCIVO by Janssen for which there were no comparable revenues in 2010. We expect that our royalty revenues related to INCIVO will increase in 2012 as compared to 2011.

We recognized royalty revenues related to sales by GlaxoSmithKline of an HIV protease inhibitor that was discovered and developed pursuant to our collaboration with GlaxoSmithKline of \$29.7 million, \$30.2 million and \$28.3 million in 2011, 2010 and 2009, respectively. We sold our rights to these HIV royalties in 2008 for a one-time cash payment of \$160.0 million.

**Collaborative Revenues**

Our collaborative revenues have fluctuated significantly on an annual basis. This variability has been due to, among other things: the achievement of significant milestone revenues in 2011; the 2009 amendment of our collaboration agreement with Mitsubishi Tanabe, which provided for an up-front payment that is being recognized over the expected period of performance under that contract; the 2011 amendment to our collaboration agreement with the Cystic Fibrosis Foundation Therapeutics Incorporated, or CFFT, which began providing us additional research and development support in 2011; and variable revenues we have received from services we provided to Janssen and Mitsubishi Tanabe through our third-party manufacturing network.

The table presented below is a summary of revenues from collaborative arrangements for 2011, 2010 and 2009:

	2011	2010	2009
	(in thousands)		
Collaborative revenues:			
Janssen	\$ 274,393	\$ 30,750	\$ 54,640
Mitsubishi Tanabe	121,675	81,868	18,711
Other	13,654	508	218
Total collaborative revenues	\$ 409,722	\$ 113,126	\$ 73,569

The significant increase in our collaborative revenues from Janssen in 2011 as compared to 2010 was related to \$250.0 million in milestone payments that we recognized in 2011 for which there were no comparable revenues in 2010. The increase in revenues from Mitsubishi Tanabe in 2011 compared to 2010 was due to a \$65.0 million commercial milestone payment we recognized in 2011 partially offset by a decrease in revenues related to manufacturing services provided to Mitsubishi Tanabe through our third-party manufacturing network. Our collaborative revenues increased in 2010 as compared to 2009 because of an increase in our revenues from Mitsubishi Tanabe partially offset by a decrease in our revenues from Janssen. We expect that our collaborative revenues will decrease significantly in 2012 as compared to 2011 because there are no future milestone payments that we expect to earn pursuant to our collaboration agreements with Janssen or Mitsubishi Tanabe.

Table of Contents**Operating Costs and Expenses**

	2011	2010	2009	2011/2010 Comparison		2010/2009 Comparison	
				Increase/ (Decrease)	Increase/ (Decrease)	Increase/ (Decrease)	Increase/ (Decrease)
	(in thousands)			(in thousands, except percentages)			
Cost of product revenues	\$ 63,625	\$	\$	\$ 63,625	n/a	\$	n/a
Royalty expenses	16,880	12,730	14,202	4,150	33%	(1,472)	(10)%
Research and development expenses	707,706	637,416	550,274	70,290	11%	87,142	16%
Sales, general and administrative expenses	400,721	187,800	130,192	212,921	113%	57,608	44%
Restructuring expense	2,074	1,501	6,240	573	38%	(4,739)	(76)%
Intangible asset impairment charge	105,800		7,200	105,800	n/a	(7,200)	(100)%
Acquisition-related expenses			7,793		n/a	(7,793)	(100)%
Total costs and expenses	\$ 1,296,806	\$ 839,447	\$ 715,901	\$ 457,359	54%	\$ 123,546	17%

**Cost of Product Revenues**

Our cost of product revenues consists of the costs of producing inventories that correspond to product revenues for the reporting period, plus the third-party royalties payable on our net sales. We expensed most of the manufacturing costs of INCIVEK sold in 2011 as research and development expenses in periods prior to January 1, 2011. We expect our cost of INCIVEK product revenues to increase as a percentage of net sales of INCIVEK in future periods.

**Royalty Expenses**

Royalty expenses include third-party royalties payable upon net sales of telaprevir by our collaborators and royalty expenses related to a subroyalty payable to a third party on net sales of an HIV protease inhibitor sold by GlaxoSmithKline. Royalty expenses in 2011 increased compared to 2010 because of the third-party royalties payable on net sales of INCIVO by Janssen. We expect our royalty expenses to increase in 2012 as compared to 2011 as our collaborators continue to market telaprevir in their territories.

Royalty expenses in 2010 and 2009 primarily related to a subroyalty payable to a third party on net sales of an HIV protease inhibitor sold by GlaxoSmithKline. The subroyalty expense offsets a corresponding amount of HIV royalty revenues. We expect to continue to recognize this subroyalty as an expense in future periods.

**Research and Development Expenses**

	2011	2010	2009	2011/2010 Comparison		2010/2009 Comparison	
				Increase	Increase	Increase	Increase
	(in thousands)			(in thousands, except percentages)			
Research expenses	\$ 216,903	\$ 189,273	\$ 174,267	\$ 27,630	15%	\$ 15,006	9%
Development expenses	490,803	448,143	376,007	42,660	10%	72,136	19%
Total research and development expenses	\$ 707,706	\$ 637,416	\$ 550,274	\$ 70,290	11%	\$ 87,142	16%

Our research and development expenses include internal and external costs incurred for research and development of our drugs and drug candidates. We do not assign our internal costs, such as salary and benefits, stock-based compensation expense, laboratory supplies and infrastructure costs, to individual drugs or 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



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research organizations and other outsourced research, which we do allocate by individual program. All research and development costs for our drugs and drug candidates are expensed as incurred.

To date, we have incurred in excess of \$4.7 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 activities. 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, 2011, costs related to telaprevir have represented the largest portion of our development costs. We expect to continue to incur development costs related to the conduct of additional clinical trials to support potential supplemental applications for telaprevir and ivacaftor. Our drug candidates are still in early and mid-stage clinical development and, as a result, any estimates regarding development and regulatory timelines for these drug candidates are highly subjective and subject to change. We cannot make a meaningful estimate when, if ever, these drug candidates, including VX-222 and those we in-licensed from Alios BioPharma, Inc., or Alios, will generate revenues and cash flows.

*Research Expenses*

	2011	2010	2009	2011/2010 Comparison		2010/2009 Comparison	
				Increase/ (Decrease)	Increase/ (Decrease)	Increase/ (Decrease)	Increase/ (Decrease)
	(in thousands)			(in thousands, except percentages)			
Research Expenses:							
Salary and benefits	\$ 76,355	\$ 67,508	\$ 63,422	\$ 8,847	13%	\$ 4,086	6%
Stock-based compensation expense	25,305	23,496	23,802	1,809	8%	(306)	(1)%
Laboratory supplies and other direct expenses	35,641	29,145	28,136	6,496	22%	1,009	4%
Contractual services	13,213	9,881	5,406	3,332	34%	4,475	83%
Infrastructure costs	66,389	59,243	53,501	7,146	12%	5,742	11%
<b>Total research expenses</b>	<b>\$ 216,903</b>	<b>\$ 189,273</b>	<b>\$ 174,267</b>	<b>\$ 27,630</b>	<b>15%</b>	<b>\$ 15,006</b>	<b>9%</b>

Over the past three years we have maintained a substantial investment in research activities resulting in a 15% increase in research expenses in 2011 as compared to 2010 and a 9% increase in research expenses in 2010 as compared to 2009. We expect to continue to invest in our research programs in an effort to identify additional drug candidates.

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	2011	2010	2009	2011/2010 Comparison		2010/2009 Comparison		
				Increase/ (Decrease)	Increase/ (Decrease)	Increase/ (Decrease)	Increase/ (Decrease)	
	(in thousands)			(in thousands, except percentages)				
<b>Development Expenses:</b>								
Salary and benefits	\$ 126,441	\$ 108,617	\$ 98,830	\$ 17,824	16%	\$ 9,787	10%	
Stock-based compensation expense	50,269	41,702	40,326	8,567	21%	1,376	3%	
Laboratory supplies and other direct expenses	33,588	33,231	27,682	357	1%	5,549	20%	
Contractual services	149,033	113,031	111,579	36,002	32%	1,452	1%	
Drug supply costs	34,133	65,902	21,591	(31,769)	(48)%	44,311	205%	
Infrastructure costs	97,339	85,660	75,999	11,679	14%	9,661	13%	
Total development expenses	\$ 490,803	\$ 448,143	\$ 376,007	\$ 42,660	10%	\$ 72,136	19%	

Our total development expenses have been affected by the variable level of drug supply costs, which include costs of raw materials and work in process that are incurred before we begin capitalizing inventories for a drug candidate and costs of manufacturing services that we provided our collaborators through our third-party manufacturing network. With the approval of INCIVEK and KALYDECO, we expect drug supply costs to decrease significantly in 2012 because we began capitalizing telaprevir drug supply costs in 2011 and expect to capitalize ivacaftor drug supply costs in 2012.

Our development expenses, excluding our drug supply costs, increased by \$74.4 million, or 19%, in 2011 as compared to 2010 and by \$27.8 million, or 8%, in 2010 compared to 2009, principally due to increases in headcount and the expansion of our development efforts as we completed the registration program for telaprevir and ivacaftor, prepared the regulatory filings needed to obtain approval for these products and continued the development of our other drug candidates. We expect our development expenses to increase in 2012 as compared to 2011 because of additional clinical trials we expect to conduct to evaluate all-oral treatment regimens for HCV infection, KALYDECO, both as monotherapy and in combination with VX-809 and VX-661, VX-509, VX-765 and VX-787, and post-marketing commitment clinical trials of INCIVEK.

**Sales, General and Administrative Expenses**

	2011	2010	2009	2011/2010 Comparison		2010/2009 Comparison	
				Increase	Increase	Increase	Increase
	(in thousands)			(in thousands, except percentages)			
Sales, general and administrative expenses	\$ 400,721	\$ 187,800	\$ 130,192	\$ 212,921	113%	\$ 57,608	44%

Sales, general and administrative expenses increased substantially in each of 2011 and 2010 as compared to the preceding year as a result of increases in workforce expenses as we prepared for and commercially launched INCIVEK in 2011. Advertising expenses incurred to support the launch of INCIVEK totaled \$30.8 million in 2011, for which there were no comparable expenses in 2010 or 2009. We expect that our sales, general and administrative expenses in 2012 will be consistent with our sales, general and administrative expenses for 2011.

**Restructuring Expense**

As of December 31, 2011, our lease restructuring liability was \$26.3 million. In 2011, 2010 and 2009, we recorded restructuring expense of \$2.1 million, \$1.5 million and \$6.2 million, respectively. In 2011, 2010 and 2009, we made cash payments of \$14.9 million, \$14.8 million and \$14.9 million, respectively, against the accrued expense and received \$9.5 million, \$8.8 million and \$8.6 million,

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respectively, in sublease rental payments. During 2012, we expect to make additional cash payments of \$14.9 million against the accrued expense and to receive \$10.0 million in sublease rental payments.

**Intangible Asset Impairment Charge**

In 2011, we recorded a \$105.8 million impairment charge related to VX-759, a non-nucleoside HCV polymerase inhibitor that we acquired through our acquisition of ViroChem Pharma Inc., or ViroChem, in 2009. VX-759 was a back-up drug candidate for our non-nucleoside HCV polymerase inhibitor VX-222. Based on, among other factors, the advancement of VX-222 in 2011 and our consideration of potentially competitive drug candidates, we determined that the fair value of VX-759 had become impaired. In connection with this impairment charge, we recorded a credit of \$32.7 million in our provision for income taxes resulting in a net effect on our income related to this impairment charge of \$73.1 million in 2011. In 2009, we recorded a \$7.2 million impairment charge related to another drug candidate we acquired through our acquisition of ViroChem.

**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. We did not incur corresponding acquisition-related expenses in 2011 or 2010.

**Non-operating Items**

**Interest Income**

Interest income decreased by \$0.1 million, or 4%, to \$1.9 million in 2011 from \$2.0 million in 2010. Interest income decreased by \$3.1 million, or 61%, to \$2.0 million in 2010 from \$5.0 million in 2009. Our cash, cash equivalents and marketable securities yielded less than 1% on an annual basis in 2011.

**Interest Expense**

Interest expense increased by \$19.2 million, or 99%, to \$38.5 million in 2011 from \$19.3 million in 2010. Interest expense increased by \$6.1 million, or 46%, to \$19.3 million in 2010 from \$13.2 million in 2009. These increases were primarily the result of the 3.35% convertible senior subordinated notes due 2015, or 2015 Notes, we issued in September 2010. In 2012, we expect to incur approximately \$13.4 million in interest expense related to the 2015 Notes.

**Change in Fair Value of Derivative Instruments**

In 2011, 2010 and 2009, we recorded losses of \$16.8 million, \$41.2 million and \$1.8 million, respectively, in connection with the embedded and free-standing derivatives associated with two financial transactions that we entered into in September 2009 related to \$250.0 million in contingent milestone payments that were earned by us from Janssen in 2011. The losses were principally due to adjustments we made in estimates regarding the timing and probability of achieving the milestones pursuant to our collaboration agreement with Janssen. In 2011, the contingent milestone payments that were the subject of the 2009 financial transactions were earned in full, and we will not incur any further charges related to the September 2009 financial transactions in future periods.

**Loss on Exchanges of Convertible Senior Subordinated Notes**

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 our 4.75% convertible senior subordinated notes due 2013, or 2013 Notes, for 11.6 million newly-issued shares of our common stock. The charges were based

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on the value of 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 2011 or 2010.

**Provision for Income Taxes**

In 2011, we recorded a provision for income taxes of \$19.3 million. This provision for income taxes was due to a provision of \$48.8 million for income taxes payable by Alios and a provision of \$3.7 million for state taxes, partially offset by a benefit from income taxes of \$32.7 million due to a tax benefit resulting from the impairment of VX-759. The provision of \$48.8 million for income taxes payable by Alios reduces net income attributable to noncontrolling interest (Alios) by a corresponding amount and as a result has no effect on the net income attributable to Vertex.

**Noncontrolling Interest (Alios)**

The net income attributable to noncontrolling interest (Alios) recorded on our consolidated statements of operations reflects Alios' net income for the reporting period, excluding revenues related to the up-front payment and milestone payments earned by Alios and adjusted for any changes during the reporting period in the fair value of the contingent milestone and royalty payments payable by us to Alios.

A summary of net income attributable to noncontrolling interest (Alios) in 2011 is as follows:

	<b>2011</b>
	<b>(in thousands)</b>
Loss before provision for income taxes	\$ (9,536)
Provision for income taxes	(48,809)
Change in fair value of contingent milestone and royalty payments	69,950
Net income attributable to noncontrolling interest (Alios)	\$ 11,605

The \$70.0 million change in fair value of contingent milestone and royalty payments in 2011 results in a corresponding reduction in net income attributable to Vertex for 2011. The provision for income taxes of \$48.8 million in 2011 attributable to noncontrolling interest (Alios) corresponds to a provision for income taxes payable by Alios on revenues from us included as part of the provision for income taxes on our consolidated statements of operations and has no net effect on net income attributable to Vertex.

If we are able to successfully advance one or more of the HCV nucleotide analogues we licensed from Alios into mid-stage and late-stage clinical development, we believe the fair value of the contingent milestone and royalty payments will continue to increase, which will reduce net income attributable to Vertex.

**LIQUIDITY AND CAPITAL RESOURCES**

We began operating as a cashflow positive company in the second half of 2011. As of December 31, 2011, we had cash, cash equivalents and marketable securities, excluding Alios' cash and cash equivalents, of \$968.9 million, which was an increase of \$375.4 million from \$593.5 million as of June 30, 2011. This increase was primarily due to cash receipts from INCIVEK sales partially offset by cash expenditures we made in the second half of 2011 related to, among other things, research and development expenses and sales, general and administrative expenses. In order to continue to operate as a cashflow positive company and to continue our strategic investment in research and development activities, we will need to continue to generate significant revenues in future periods.

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Our cash, cash equivalents and marketable securities, excluding Alios' cash and cash equivalents, decreased by \$62.5 million during 2011, because of net cash expenditures in the first half of 2011 partially offset by net cash receipts in the second half of 2011. Our cash expenditures in 2011 were due to, among other things, research and development expenses, sales, general and administrative expenses, the \$60.0 million up-front payment we made to Alios and capital expenditures for property and equipment of \$34.6 million. In 2011, we received \$124.9 million in cash from issuances of common stock pursuant to employee benefit plans.

*Sources of Liquidity*

Prior to 2011, we financed our operations principally through public and private offerings of our equity and debt securities, strategic collaborative agreements that included 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. In future periods, we intend to rely on cash flows from product sales as our primary source of liquidity and cash flows from royalties as a secondary source of liquidity.

We may seek to borrow funds to finance our working capital needs if such financing is available to us. Our existing \$100.0 million credit facility, which terminates on July 6, 2012, is initially unsecured, but is subject to a number of affirmative and negative covenants, including a liquidity covenant that requires us to maintain cash, cash equivalents and marketable securities of more than \$400.0 million in domestic accounts. If we breach any of these covenants and it results in an event of default, upon the event of default the lender would obtain a security interest in cash, cash equivalents and marketable securities having a margined value of \$100.0 million, which would be transferred to an account controlled by the lender. To date, we have not utilized any funds available to us pursuant to this credit facility.

*Future Capital Requirements*

We are incurring substantial expenses to commercialize INCIVEK and KALYDECO, while at the same time continuing diversified research and development efforts for our drug candidates. In addition to funding our operating expenses, we have outstanding \$400.0 million in aggregate principal amount of 2015 Notes. The 2015 Notes bear interest at the rate of 3.35% per annum, and we are required to make semi-annual interest payments on the outstanding principal balance of the 2015 Notes on April 1 and October 1 of each year. The 2015 Notes will mature on October 1, 2015. The 2015 Notes are convertible, at the option of the holder, into our common stock at a price equal to approximately \$48.83 per share, subject to adjustment. In addition, we have substantial lease obligations that will continue through 2028.

In the second half of 2011, our cash flows from sales of INCIVEK exceeded our operating expenses, and we expect our cash flows from INCIVEK/INCIVO and KALYDECO together with our current cash, cash equivalents and marketable securities will be sufficient to fund our operations for at least the next twelve months. The adequacy of our available funds to meet our future operating and capital requirements will depend on many factors, including the amounts of future revenues generated by INCIVEK/INCIVO and KALYDECO, and the number, breadth, cost and prospects of our discovery and development programs.

*Financing Strategy*

Although we do not have any plans to do so in the near term, we may raise additional capital through public offerings or private placements of our securities, securing new collaborative agreements or other methods of financing. As part of our strategy for managing our capital structure, we have from time to time adjusted the amount and maturity of our debt obligations through new issues, privately negotiated transactions and market purchases, depending on market conditions and our perceived



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needs at the time. We expect to continue pursuing a general financial strategy that may lead us to undertake one or more additional transactions with respect to our outstanding debt obligations, and the amounts involved in any such transactions, individually or in the aggregate, may be material. We will continue to manage our capital structure and to consider all financing opportunities, whenever they may occur, that could strengthen our long-term liquidity profile. Any capital transaction related to our outstanding debt obligations may or may not be similar to transactions in which we have engaged in the past. There can be no assurance that any such financing opportunities will be available on acceptable terms, if at all.

**CONTRACTUAL COMMITMENTS AND OBLIGATIONS**

The first part of the following table sets forth commitments and obligations that were recorded on our consolidated balance sheet at December 31, 2011. Certain other obligations and commitments, while not required to be included on the consolidated balance sheet, may have a material effect on our 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.

	2012	2013-2014	2015-2016	2017 and later	Total
	(in thousands)				
<b>Commitments and Obligations Recorded on the Consolidated Balance Sheet at December 31, 2011:</b>					
Convertible senior subordinated notes (due October 2015) principal payment	\$	\$	\$ 400,000	\$	\$ 400,000
Convertible senior subordinated notes (due October 2015) interest payment	3,350				3,350
Construction financing obligation		55,950			55,950
<b>Additional Commitments and Obligations at December 31, 2011:</b>					
Convertible senior subordinated notes (due October 2015) interest payments	10,050	26,800	13,400		50,250
Facility operating leases, excluding Fan Pier Leases	54,715	103,487	63,809	34,364	256,375
Fan Pier Leases		11,256	134,412	887,211	1,032,879
Research, development and drug supply costs	12,985	1,575			14,560
Alios milestones payable	25,000				25,000
Other	3,683	2,141			5,824
Total contractual commitments and obligations	\$ 109,783	\$ 201,209	\$ 611,621	\$ 921,575	\$ 1,844,188

*Commitments and Obligations Recorded on the Consolidated Balance Sheet at December 31, 2011*

In September 2010, we issued \$400.0 million in aggregate principal amount of 2015 Notes. The principal and interest accrued as of December 31, 2011 under these notes is included on our consolidated balance sheet as of December 31, 2011. The interest that is due for periods after December 31, 2011 is not required under GAAP to be reflected on our consolidated balance sheet and is set forth separately on the table above.

Our construction financing obligation relates to two buildings under construction on Fan Pier in Boston, Massachusetts, which are scheduled to be completed in late 2013. Although we will lease the space in these buildings, we are deemed for accounting purposes to be the owner of these buildings during the construction period and have recorded a long-term liability under the caption "Construction financing obligation" on our consolidated balance sheet.

*Additional Commitments and Obligations Not Required to be Recorded on Consolidated Balance Sheet at December 31, 2011*

Our future minimum commitments and contractual obligations include facility operating leases, our leases for the Fan Pier buildings, and contractual commitments related to our research, development

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and drug supply, and interest that will accrue on the 2015 Notes after December 31, 2011. These items are not required to be recorded on our consolidated balance sheet.

Our future minimum commitments under our Kendall Square lease for the period commencing on January 1, 2012 are \$18.3 million for 2012, \$36.5 million for 2013 and 2014, \$36.5 million for 2015 and 2016, and \$24.3 million from 2017 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 future minimum committed income from the subleases is \$7.9 million for 2012, \$16.8 million for 2013 and 2014 and \$3.9 million for 2015. These amounts are not offset against our obligations set forth in the table above. See Note R, "Restructuring Expense," to our consolidated financial statements included in this Annual Report on Form 10-K.

"Fan Pier Leases" sets forth the future minimum rental payments that we are obligated to pay after taking occupancy of approximately 1.1 million square feet of office and laboratory space in two buildings under construction in Boston, Massachusetts less the amounts reflected on the consolidated balance sheet under the caption "Construction financing obligation." We expect to commence these rental payments upon completion of these buildings, scheduled for late 2013. The rental payments will extend for 15 years from the commencement date.

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

Pursuant to our collaboration with Alios, Alios is eligible to receive research and development milestone payments from us of up to \$715.0 million if ALS-2200 and ALS-2158 are approved and commercialized. As of December 31, 2011, Alios had earned \$35.0 million of these milestone payments, of which \$10.0 million had been paid as of December 31, 2011. Alios also is eligible to receive commercial milestone payments from us of up to \$750.0 million, as well as tiered royalties on net sales of approved drugs. In addition, we are obligated to make two one-time commercial milestone payments to CFFT upon achievement of certain sales levels for a potentiator compound such as KALYDECO. Contingent payments under these agreements become due and payable only upon achievement of certain milestones and are not included in the contractual obligations table above.

We exclude liabilities pertaining to uncertain tax positions from our summary of contractual obligations as we cannot make a reliable estimate of the period of cash settlement with the respective taxing authorities. As of December 31, 2011, we have approximately \$4.4 million of liabilities associated with uncertain tax positions. Approximately \$2.5 million are directly attributable to Alios and Vertex has no legal obligation associated with Alios' potential tax liabilities. As of December 31, 2011, we cannot reasonably estimate the amount we expect to pay within the next twelve months in connection with such settlements.

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

**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.

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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, including in certain circumstances future projections, that we believe to be reasonable under the circumstances. Actual results may differ from our estimates.

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:

revenue recognition;

business transactions;

research and development expenses;

commercial supplies;

derivative instruments and embedded derivatives;

stock-based compensation expense; and

income taxes.

Our accounting policies, including the ones discussed below, are more fully described in the Notes to our consolidated financial statements, including Note A "Nature of Business and Accounting Policies," included in this Annual Report on Form 10-K.

*Revenue Recognition*

**Product Revenues, Net**

In 2011, we began generating revenues in the United States from sales of INCIVEK. We sell INCIVEK principally to a limited number of major wholesalers, as well as selected regional wholesalers and specialty pharmacy providers, collectively our distributors, who subsequently resell INCIVEK to patients and health care providers. Separately, we have arrangements with numerous third-party payors that provide for government-mandated and privately-negotiated rebates, chargebacks and discounts.

We recognize net product revenues from sales of INCIVEK upon delivery to our distributors as long as:

there is persuasive evidence that an arrangement exists between us and our distributor;

collectability is reasonably assured; and

the price is fixed or determinable.

We have written contracts with our distributors and delivery occurs when a distributor receives INCIVEK. We evaluate the creditworthiness of each of our distributors and have determined that all of our material distributors are creditworthy. In order to conclude that the price is fixed or determinable, we must be able to calculate our gross product revenues from our distributors and reasonably estimate our net product revenues. Our gross product revenues are based on the fixed wholesale acquisition cost for INCIVEK that we charge our distributors. We estimate our net product revenues by deducting from our gross product revenues (i) trade allowances, such as invoice discounts for prompt

payment and distributor fees, (ii) estimated government and private payor rebates, chargebacks and discounts, such as Medicaid reimbursements, (iii) reserves for expected product returns and (iv) estimated costs of incentives offered to certain indirect customers including patients. These estimates, and in particular the estimates for rebates, chargebacks and discounts and expected product returns, require us to make significant judgments that materially affect our recognition of net product revenues on sales of INCIVEK.

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The value of the rebates, chargebacks and discounts provided to third-party payors per course of treatment vary significantly and are based on government-mandated discounts and our arrangements with other third-party payors. Typically, government-mandated discounts are significantly larger than discounts provided to other third-party payors. In order to estimate our total rebates, chargebacks and discounts, we estimate the percentage of prescriptions that will be covered by each third-party payor, which is referred to as the payor mix. We track available information regarding changes, if any, to the payor mix for INCIVEK, to our contractual terms with third-party payors and to applicable governmental programs and regulations and levels of INCIVEK in the distribution channel. If necessary, we will adjust our estimated rebates, chargebacks and discounts based on new information, including information regarding actual rebates, chargebacks and discounts for INCIVEK, as it becomes available. If we increased our estimate of the percentage of patients receiving INCIVEK covered by third-party payors entitled to government-mandated discounts by two percentage points, our net product revenues would decrease by less than 1% for the three months ended December 31, 2011.

Our distributors have the right to return unopened INCIVEK that has not been prescribed beginning six months prior to the labeled expiration date and ending twelve months after the labeled expiration date. The expiration date for INCIVEK is two years after it has been converted into tablet form, which is the last step in the manufacturing process for INCIVEK and generally occurs within a few months before INCIVEK is delivered to distributors. As of December 31, 2011, we have not received any material product returns. Based on our specialty distribution model with sales to a limited number of distributors, data provided to us by our distributors, including weekly reporting of distributor sales and inventory levels, and by other third parties, historical industry information regarding return rates for similar specialty pharmaceutical products, the estimated remaining shelf life of INCIVEK previously shipped and currently being shipped, and contractual agreements with our distributors, which include provisions designed to limit the amount of inventory they maintain, we have estimated that product returns for INCIVEK sold to distributors in 2011 will be less than 1% of net sales. We track actual returns by individual production lots and will continue to monitor inventory levels in the distribution channel. If necessary, we will adjust our estimated product returns based on new information as it becomes available.

**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 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 or manufacturing services are expected to be provided. When the period of performance is based on the period over which research and/or development is expected to occur, we are required to make estimates regarding drug development and commercialization timelines. Because of the many risks and uncertainties associated with the development of drug candidates, these 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, 2009 and 2010, as a result of changes in the global development plan for telaprevir. These adjustments were made on a prospective basis beginning in the periods in which the changes were identified and resulted in decreases in the amount of revenues we recognized on a quarterly basis from the Janssen collaboration.

**Milestone Payments**

At the inception of each agreement that includes contingent milestone payments payable to us, 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

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milestone event to be substantive, the revenues from the related milestone payment will be recognized over the period of performance. Where a substantive milestone event is achieved in a collaboration arrangement and the corresponding payment is reasonably assured, we recognize the payment as earned. 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. The milestone events that we achieved under our Janssen collaboration agreement in 2011 that resulted in \$250.0 million in revenues were considered substantive and the revenues related to each milestone event were recognized in the quarter in which the corresponding payment became reasonably assured.

**Royalty Revenues**

Royalty revenues for INCIVO are recognized based on net sales of INCIVO as reported to us by Janssen and are recognized in the period the sales occur. Because net sales as reported by Janssen could include certain estimates, we could experience future adjustments to royalty revenues and the adjustments could be significant.

*Business Transactions*

**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 the 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 deferred tax liability. The intangible assets acquired were in-process research and development assets relating to two drug candidates being developed by ViroChem, VX-222 and VX-759. VX-222 and VX-759 had estimated fair values on the acquisition date of \$412.9 million and \$105.8 million, respectively.

We have tested the fair value of VX-222 on an annual basis since the acquisition date and no impairment has been identified. In connection with preparing our quarterly report for the period ended September 30, 2011, we identified certain factors that were considered impairment indicators related to VX-759. We determined that the fair value of VX-759 was zero dollars, based on the advancement of VX-222 in the third quarter of 2011, our consideration of potentially competitive drug candidates and the other factors described in Note C, "Acquisition of Viro Chem Pharma, Inc.," in the accompanying notes to the consolidated financial statements. This determination resulted in a \$105.8 million impairment charge in the third quarter of 2011. In connection with this impairment charge, we also recorded an adjustment of \$32.7 million to our deferred tax liability. As of December 31, 2011, our consolidated balance sheet included the following related to the ViroChem acquisition: \$412.9 million of intangible assets related to VX-222 and a \$127.6 million deferred tax liability.

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 require us to make significant assumptions regarding the estimates that market participants would make in evaluating a drug candidate, including

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the probability of successfully completing clinical trials and obtaining regulatory approval to market the drug candidate, the timing of and the expected costs to complete in-process research and development projects, future cash flows from potential drug sales, which are based on estimates of the sales price of the drug, the number of patients that will be diagnosed and treated and our competitive position in the marketplace, and appropriate discount rates. The estimated fair value ascribed to VX-222 and VX-759 on the acquisition date was based on the estimated fair value that would be ascribed to each of these drug candidates by a market participant that acquired both drug candidates in a single transaction. The assumed probability of advancing VX-222 and VX-759 through various phases of development reflected 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 program was significantly more promising than the clinical and nonclinical data from the VX-759 program. In addition, the fair value estimate incorporated 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%.

ViroChem's in-process research and development assets were recorded at fair value and accounted for as indefinite-lived intangible assets. We maintain 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 as part of cost of product revenues over the remaining estimated life of the asset. If we determine that an asset has become impaired or we abandon a project, we write down the carrying value of the related intangible asset to its fair value and 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. In 2012, we expect to obtain data from an ongoing clinical trial evaluating telaprevir/VX-222-based combination therapy. In addition, while the development and regulatory timelines for VX-222 and drug candidates being developed by our competitors are highly subjective and subject to change, we believe that substantial additional clinical data regarding these drug candidates and potential all-oral treatment regimens will become available in 2012 and 2013 and that one or more all-oral treatment regimens could enter the market as early as 2014 or 2015. If the fair value of 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 VX-222, we could incur significant charges in the period in which the impairment occurs.

We test the ViroChem intangible assets for impairment on an annual basis as of October 1, and more frequently if indicators are present or changes in circumstance suggest that impairment may exist. Events that could indicate impairment and trigger an interim impairment assessment include the receipt of additional clinical or nonclinical data regarding our drug candidate or a potentially competitive drug candidate, changes in the clinical development program for a drug candidate or new information

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regarding potential sales prices for the drug. In connection with each annual impairment assessment and any interim impairment assessment, we compare the fair value of the asset as of the date of the assessment with the carrying value of the asset on our consolidated balance sheet. The fair value of the ViroChem intangible assets were estimated using the probability-weighted present-value models described above, utilizing updated assumptions and estimates regarding the status of the development programs for the drug candidates, the potential future cash flows from sales of drugs, and appropriate discount rates.

**Variable Interest Entity and Collaborative Arrangements Alios BioPharma, Inc.**

In June 2011, we entered into an agreement with Alios pursuant to which we agreed to collaborate on the research, development and commercialization of ALS-2200 and ALS-2158, two HCV nucleotide analogues discovered by Alios. We are responsible for all expenses related to the development and commercialization of the compounds and provide research funding to Alios. We paid Alios a \$60.0 million up-front payment, and Alios is eligible to receive research and development milestone payments, commercial milestone payments and tiered royalties on net sales of any approved drugs licensed by us under the collaboration agreement. Our interests in Alios are limited to those accorded to us pursuant to our collaboration agreement with Alios, and we have no equity interest, or right to acquire any equity interest, in Alios. In addition to Alios' activities related to HCV nucleotide analogues, Alios is engaged in separate programs directed at developing novel drugs.

Our collaboration with Alios requires us to apply accounting policies that involve significant judgments and that have a material effect on our consolidated financial statements. Under applicable accounting guidance, as a result of the relationship established through the collaboration agreement, Alios is deemed to be a variable interest entity, or VIE. Because we acquired an exclusive license to certain intellectual property belonging to the VIE, and based on the significance of the two licensed compounds to Alios taken as a whole, the collaboration is treated for accounting purposes as if we have acquired an interest in the entire VIE. In the Alios collaboration, where (a) through the joint steering committee, we have the power to direct the development and commercialization of the two licensed compounds, which are the activities that most significantly affect the economic performance of Alios, (b) we are required to fund research and development activities related to the licensed assets and (c) we are entitled to receive a majority of the potential revenues from sales of drugs developed pursuant to the collaboration, we are deemed under accounting guidance to be the primary beneficiary of a VIE that is a business. As a result, we are required to consolidate Alios' financial statements into our financial statements.

We believe that the following effects of the consolidation on our consolidated financial statements are the most significant:

In each period, we record net income (loss) attributable to the Alios noncontrolling interest. This net income (loss) reflects Alios' net income (loss) for the period as adjusted for gains and losses in the fair value of the contingent milestone and royalty payments payable by us to Alios. Determining the fair value of the contingent milestone and royalty payments payable by us to Alios requires us to make significant estimates regarding the probability and potential timing of achieving each of the milestones pursuant to the agreement; future potential net sales of HCV nucleotide analogues licensed from Alios and appropriate discount rates. We expect that the net income (loss) attributed to noncontrolling interest (Alios) will continue to be affected by changes in the fair value of the contingent milestone and royalty payments. For example, in 2011 we advanced both of Alios' HCV nucleotide analogues into clinical development and the fair value of the contingent milestone and royalty payments increased by \$70.0 million due to increases in the likelihood of achieving milestones and obtaining regulatory approvals, together with decreases in the time period over which we are discounting potential milestone and royalty



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payments. Increases in the fair value of the contingent milestone and royalty payments in 2011 resulted in a significant decrease in net income attributable to Vertex in 2011.

We recorded \$250.6 million of intangible assets on our consolidated balance sheet based on our estimate of the fair value of Alios' in-process research and development assets as of the transaction date and made significant estimates regarding: the probability of obtaining regulatory approval of an HCV nucleotide analogue; the timing and expected costs of clinical trials and other development activities; future potential cash flows from sales of drugs and the appropriate discount rates. If we are successful in developing one or more HCV nucleotide analogues, we will amortize the carrying value of the intangible asset as part of cost of product revenues. We test these in-process research and development assets for impairment on an annual basis as of October 1, and more frequently if indicators are present or changes in circumstances suggest that impairment may exist. If the fair value of Alios HCV nucleotide analogue program becomes impaired as the result of safety or efficacy data from any ongoing or future clinical trial conducted by us or our competitors or because of any other information regarding the prospects of successfully developing or commercializing the HCV nucleotide analogues we license from Alios, we could incur significant charges in the period in which the impairment occurs. We determined the fair value of these in-process research and development assets using probability-weighted present-value models.

Since the effective date of the collaboration we have consolidated all of Alios' expenses and revenues into our consolidated statements of operations, eliminating all intercompany balances and transactions. In 2011, Alios' operating expenses were immaterial to our consolidated statements of operations. In future periods, if Alios increases its headcount and/or expands its activities related to its other programs, its operating expenses could increase substantially. To the extent that Alios pursues other programs, we expect that expenses of Alios related to those activities would be reflected in our research and development expenses and our sales, general and administrative expenses as a result of the financial statement consolidation. We would not be entitled to any benefits from those activities.

We reflect all of Alios' cash and cash equivalents as restricted cash and cash equivalents (Alios) when we consolidate Alios' balance sheet. We do not have any rights to Alios' cash or cash equivalents; these resources are not available to fund research and development programs pursuant to the collaboration and these amounts do not provide us with any additional liquidity. As a result of payments we made to Alios in 2011, Alios had significant liquid assets as of December 31, 2011. Alios has control over the restricted cash and cash equivalents (Alios), including the ability to distribute the restricted cash and cash equivalents to Alios' equityholders, and as a result this asset, although carried on our consolidated balance sheet, is not included in the discussion of our liquidity and should be disregarded when evaluating our financial condition.

*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 drug supplies that are not being capitalized; 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 costs and costs for drug supply, incurred in a

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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.

*Commercial Supplies*

We capitalize inventories produced in preparation for potentially initiating sales of a drug candidate when the drug candidate is considered to have a high probability of regulatory approval and the costs to manufacture the drug candidate are expected to be recoverable through sales of the drug. In determining whether or not to capitalize such inventories, we evaluate, among other factors, information regarding the drug candidate's safety and efficacy, the status of regulatory submissions and communications with regulatory authorities and the outlook for commercial sales, including the existence of current or anticipated competitive drugs and the availability of reimbursement. In addition, we evaluate risks associated with manufacturing the drug candidate and the remaining shelf life of the inventories. After we begin capitalizing inventories, we continue to monitor these factors and, if there are significant negative developments regarding the drug candidate, we could be required to impair previously capitalized costs.

We began capitalizing the costs of our INCIVEK inventories on January 1, 2011. Because we expensed most of the manufacturing costs related to initial quantities of INCIVEK as research and development expenses in prior periods, our initial cost of product revenues for INCIVEK was low and will increase in future periods.

*Derivative Instruments and Embedded Derivatives September 2009 Financial Transactions*

Expenses related to two financial transactions that we entered into in September 2009 resulted in \$16.8 million, \$41.2 million and \$1.8 million, respectively, in expenses in 2011, 2010 and 2009. The two financial transactions related to \$250.0 million of milestone payments that were earned by us from Janssen in 2011 in connection with the regulatory filing, approval and launch of INCIVO in the European Union. In the first financial transaction, we issued secured notes due 2012, or 2012 Notes, which had a face value of \$155.0 million and did not carry an explicit interest rate, for \$122.2 million in cash. The 2012 Notes were payable in October 2012, subject to earlier redemption and were secured by \$155.0 million of contingent milestone payments. The 2012 Notes were redeemed in full in 2011 upon the receipt of the corresponding Janssen milestone payments. In the second transaction, we sold \$95.0 million in contingent milestone payments for a cash payment of \$32.8 million.

The 2012 Notes contained an embedded derivative related to their potential early repayment or redemption. The separate sale of the \$95.0 million in contingent milestone payments was accounted for as a free-standing derivative instrument. In order to account for the 2012 Notes and the sale of the rights to the \$95.0 million in milestone payments, we estimated the fair value of the derivative embedded in the 2012 Notes and of the free-standing derivative. The models we used to estimate these fair values required, among other things, estimates regarding the timing and probability of achieving the milestone events and the appropriate discount rates. As these milestones were achieved and we and Janssen obtained additional data from the telaprevir registration program, we updated these assumptions to reflect the increasing probability of achieving these milestone events and the expected timing of such events and recorded corresponding expenses or gains in each quarterly period. While the total amount of the expenses related to these two financial transactions was fixed at \$95.0 million, plus the initial transaction expenses, provided that the milestones were achieved prior to October 2012, the timing of these expenses in 2011, 2010 and 2009 was dependent on the estimates and assumptions incorporated in the models used to estimate the fair values of the embedded and free-standing derivatives at the end of each fiscal quarter.

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*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 that affect the period over which the expense is recognized. We calculate the fair value of stock options and shares purchased pursuant to our 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.

*Income Taxes*

Despite beginning to operate as a profitable and cashflow positive company in the second half of 2011, we continue to maintain a valuation allowance on our net operating losses and other deferred tax assets because we have an extended history of annual losses. Our U.S. federal net operating loss carryforwards totaled approximately \$2.7 billion as of December 31, 2011.

On a quarterly basis, we reassess the valuation allowance for deferred income tax assets. We would consider reversing a significant portion of the valuation reserve upon assessment of certain factors, including: (i) a demonstration of sustained profitability; and (ii) the support of internal financial forecasts demonstrating the utilization of the net operating loss carryforwards prior to their expiration. If we determine that the reversal of all or a portion of the valuation reserves is appropriate, a significant benefit could be recognized against our income tax provision in the period of the reversal.

**Recent Accounting Pronouncements**

Refer to Note A, "Nature of Business and 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.

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*Foreign Exchange Market Risk*

As a result of our foreign operations, we face exposure to movements in foreign currency exchange rates, primarily the Euro, Swiss Franc, British Pound and Canadian Dollar against the U.S. dollar. The current exposures arise primarily from cash, accounts receivable, intercompany receivables and payables, and calculations of royalties receivable from net sales denominated in foreign currencies. Both positive and negative impacts to our international product sales from movements in foreign currency exchange rates are partially mitigated by the natural, opposite impact that foreign currency exchange rates have on our international operating expenses.

We are considering a foreign currency management program with the objective of reducing the volatility of exchange rate fluctuations on our operating results and to increase the visibility of the foreign exchange impact on forecasted revenues.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The information required by this Item 8 is contained on pages F-1 through F-54 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

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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, 2011. 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, 2011, 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, 2011, 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.

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**(4) Report of Independent Registered Public Accounting Firm**

The Board of Directors and Shareholders of  
Vertex Pharmaceuticals Incorporated

We have audited Vertex Pharmaceuticals Incorporated's internal control over financial reporting as of December 31, 2011, 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, 2011, 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, 2011 and 2010, and the related consolidated statements of operations, shareholders' equity, comprehensive income (loss) and noncontrolling interest, and cash flows for each of the three years in the period ended December 31, 2011 of Vertex Pharmaceuticals Incorporated and our report dated February 22, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts  
February 22, 2012

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**ITEM 9B. OTHER INFORMATION**

Not applicable.

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**PART III**

Portions of our definitive Proxy Statement for the 2012 Annual Meeting of Shareholders, or 2012 Proxy Statement, during which, we expect to, among other things, (i) elect our Class II Directors, (ii) conduct the non-binding advisory vote on our executive compensation program and (iii) ratify the appointment of our independent registered accounting firm, are incorporated by reference into this Part III of our Annual Report on Form 10-K. After taking into consideration the results of the "say-on-pay-frequency vote" at the 2011 Annual Meeting of Shareholders held in May 2011, our Board of Directors adopted the recommendation of our shareholders to conduct the vote on our executive compensation program on an annual basis until the next "say-on-pay-frequency vote" by shareholders.

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The information regarding directors required by this Item 10 will be included in our 2012 Proxy Statement under "Proposal 1 Election of Directors," "Information Regarding Our Board," "Shareholder Proposals for the 2012 Annual Meeting and Nominations for Director" and is incorporated herein by reference. Other information required by this Item 10 will be included in the 2012 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 2012 Proxy Statement under "Compensation Committee Interlocks and Insider Participation," "Executive Compensation" and/or "Information Regarding Our Board" 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 2012 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 2012 Proxy Statement under "Proposal 1 Election of Directors" and "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 2012 Proxy Statement under "Independent Registered Public Accounting Firm" and is incorporated herein by reference.



Table of Contents**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:

	<b>Page Number in this Form 10-K</b>
<u>Report of Independent Registered Public Accounting Firm</u>	<u>F-1</u>
<u>Consolidated Statements of Operations for the years ended December 31, 2011, 2010 and 2009</u>	<u>F-2</u>
<u>Consolidated Balance Sheets as of December 31, 2011 and 2010</u>	<u>F-3</u>
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(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.

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Filed with this report</b>	<b>Incorporated by Reference herein from Form or Schedule</b>	<b>Filing Date/ Period Covered</b>	<b>SEC File/ Reg. Number</b>
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	Subordinated Indenture, dated as of September 28, 2010, by and between Vertex Pharmaceuticals Incorporated and U.S. Bank National Association, as trustee.		8-K (Exhibit 4.1)	September 29, 2010	000-19319
4.3	First Supplemental Indenture, dated as of September 28, 2010, by and between Vertex Pharmaceuticals Incorporated and U.S. Bank National Association, as trustee.		8-K (Exhibit 4.2)	September 29, 2010	000-19319
4.4	Form of 3.35% Convertible Senior Subordinated Note due 2015.		8-K (Exhibit 4.3)	September 29, 2010	000-19319
<b>Collaboration Agreements</b>					
10.1	License, Development, Manufacturing and Commercialization Agreement, dated June 30, 2006, by and between Vertex Pharmaceuticals Incorporated and Janssen Pharmaceutica, N.V.	X			
10.2	License, Development and Commercialization Agreement, dated as of June 11, 2004, between Vertex Pharmaceuticals Incorporated and Mitsubishi Pharma Corporation.		10-Q (Exhibit 10.1)	November 9, 2009	000-19319

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<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Filed with this report</b>	<b>Incorporated by Reference herein from Form or Schedule</b>	<b>Filing Date/ Period Covered</b>	<b>SEC File/ Reg. Number</b>
10.3	Second Amendment to License, Development and Commercialization Agreement, dated July 30, 2009, between Mitsubishi Tanabe Pharma Corporation and Vertex Pharmaceuticals Incorporated.		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.		10-Q/A (Exhibit 10.2)	August 19, 2011	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.		10-Q/A (Exhibit 10.6)	August 19, 2011	000-19319
10.8	Amendment No. 5 to Research, Development and Commercialization Agreement, effective as of April 1, 2011, between Vertex Pharmaceuticals Incorporated and Cystic Fibrosis Foundation Therapeutics Incorporated.		10-Q (Exhibit 10.3)	August 9, 2011	000-19319
10.9	Research and Development Agreement between the Company and Eli Lilly and Company effective June 11, 1997*		10-Q (Exhibit 10.1)	August 14, 1997	000-19319
10.10	License and Collaboration Agreement, dated June 13, 2011, by and between Alios BioPharma, Inc. and Vertex Pharmaceuticals Incorporated and Vertex Pharmaceuticals (Switzerland) LLC.		10-Q (Exhibit 10.1)	August 9, 2011	000-19319
<b>Financial Transactions</b>					
10.11	Credit Agreement, dated January 7, 2011 among Vertex Pharmaceuticals Incorporated, the Lenders and Bank of America, N.A.		10-Q (Exhibit 10.1)	May 6, 2011	000-19319
10.12	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
<b>Leases</b>					
10.13	Lease, dated May 5, 2011, between Fifty Northern Avenue LLC and Vertex Pharmaceuticals Incorporated.		10-Q (Exhibit 10.4)	August 9, 2011	000-19319
10.14	Lease, dated May 5, 2011, between Eleven Fan Pier Boulevard LLC and Vertex Pharmaceuticals Incorporated.		10-Q (Exhibit 10.5)	August 9, 2011	000-19319
10.15	Lease, dated as of March 3, 1995, between Fort Washington Realty Trust and Vertex.		10-K (Exhibit 10.15)	Year Ended December 31, 1994	000-19319

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<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Filed with this report</b>	<b>Incorporated by Reference herein from Form or Schedule</b>	<b>Filing Date/ Period Covered</b>	<b>SEC File/ Reg. Number</b>
10.16	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
10.17	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
10.18	Third, Fourth and Fifth Amendments to Lease between Fort Washington Realty Trust and Vertex Pharmaceuticals Incorporated.		10-K (Exhibit 10.14)	March 26, 2001	000-19319
10.19	Lease, dated as of September 17, 1999, between Trustees of Fort Washington Realty Trust and Vertex Pharmaceuticals Incorporated.		10-Q (Exhibit 10.27)	November 15, 1999	000-19319
10.21	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	Lease, dated as of January 18, 2001, between Kendall Square, LLC and Vertex Pharmaceuticals Incorporated.		10-K (Exhibit 10.16)	March 26, 2001	000-19319
10.22	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
10.23	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
<b>Equity Plans</b>					
10.24	1996 Stock and Option Plan, as amended and restated as of March 14, 2005.*		10-K (Exhibit 10.3)	March 16, 2005	000-19319
10.25	Form of Stock Option Grant under 1996 Stock and Option Plan.*		8-K (Exhibit 10.1)	February 9, 2005	000-19319
10.26	Form of Restricted Stock Award under 1996 Stock and Option Plan Annual Vesting.*		8-K (Exhibit 10.2)	February 9, 2005	000-19319
10.27	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
10.28	Amended and Restated 2006 Stock and Option Plan.*		10-Q (Exhibit 10.1)	August 3, 2010	000-19319
10.29	Form of Stock Option Grant under 2006 Stock and Option Plan.*		8-K (Exhibit 10.2)	May 15, 2006	000-19319
10.30	Form of Restricted Stock Award under Stock and Option Plan.*		8-K (Exhibit 10.3)	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	Form of Stock Option Grant-Performance Accelerated 2009 Stock-Options.*		10-K (Exhibit 10.33)	February 19, 2010	000-19319
10.33	Vertex Pharmaceuticals Incorporated Employee Stock Purchase Plan, as amended and restated.*		10-Q (Exhibit 10.8)	August 11, 2008	000-19319

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<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Filed with this report</b>	<b>Incorporated by Reference herein from Form or Schedule</b>	<b>Filing Date/ Period Covered</b>	<b>SEC File/ Reg. Number</b>
<b>Agreements with Executive Officers and Directors</b>					
10.34	Agreement between Jeffrey M. Leiden and Vertex, dated December 14, 2011.*	X			
10.35	Employee Non-disclosure, Non-competition and Inventions Agreement between Jeffrey M. Leiden and Vertex, dated December 14, 2011.*	X			
10.36	Agreement between Matthew W. Emmens and Vertex, dated February 5, 2009.*		8-K (Exhibit 10.1)	February 10, 2009	000-19319
10.38	Transition Agreement between Matthew W. Emmens and Vertex, dated December 14, 2011.*	X			
10.39	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
10.40	Amended and Restated Employment Agreement, dated February 5, 2010, between Peter Mueller and Vertex.*		10-Q (Exhibit 10.1)	May 3, 2010	000-19319
10.41	Amended and Restated Change of Control Agreement, dated February 5, 2010, between Vertex and Peter Mueller.*		10-Q (Exhibit 10.2)	May 3, 2010	000-19319
10.42	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
10.43	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
10.44	Employment Agreement, dated as of December 9, 2009 between Vertex and Nancy Wysenski.*		10-K (Exhibit 10.42)	February 19, 2010	000-19319
10.45	Change of Control Agreement, dated as of December 9, 2009 between Vertex and Nancy Wysenski.*		10-K (Exhibit 10.43)	February 19, 2010	000-19319
10.46	Amended and Restated Employment Agreement, dated February 5, 2010, between Lisa Kelly-Croswell and Vertex.*		10-Q (Exhibit 10.5)	May 3, 2010	000-19319
10.47	Amended and Restated Change of Control Agreement, dated February 5, 2010, between Vertex and Lisa Kelly-Croswell.*		10-Q (Exhibit 10.6)	May 3, 2010	000-19319
10.48	Amended and Restated Employment Agreement, dated February 5, 2010, between Amit Sachdev and Vertex.*		10-Q (Exhibit 10.3)	May 3, 2010	000-19319
10.49	Amended and Restated Change of Control Agreement, dated February 5, 2010, between Amit Sachdev and Vertex.*		10-Q (Exhibit 10.4)	May 3, 2010	000-19319
10.50	Employment Agreement, dated as of January 26, 2012 between Vertex and David T. Howton.*	X			
10.51	Change of Control Agreement, dated as of January 26, 2012 between Vertex and David T. Howton.*	X			
10.52	Employment Agreement, dated as of January 31, 2012 between Vertex and Christiana Stamoulis.*	X			
10.53	Change of Control Agreement, dated as of January 31, 2012 between Vertex and Christiana Stamoulis.*	X			

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Exhibit Number	Exhibit Description	Filed with this report	Incorporated by Reference herein from Form or Schedule	Filing Date/ Period Covered	SEC File/ Reg. Number
10.54	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	Vertex Employee Compensation Plan.*	X			
10.57	Vertex Pharmaceuticals Non-Employee Board Compensation.*	X			
21.1	Subsidiaries of Vertex Pharmaceuticals Incorporated.	X			
23.1	Consent of Independent Registered Public Accounting Firm Ernst & Young LLP.	X			
31.1	Certification of the Chief Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002.	X			
31.2	Certification of the Chief Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32.1	Certification of the Chief Executive Officer and the Chief Financial Officer under Section 906 of the Sarbanes- Oxley Act of 2002.	X			
101.INS	XBRL Instance**				
101.SCH	XBRL Taxonomy Extension Schema**				
101.CAL	XBRL Taxonomy Extension Calculation**				
101.LAB	XBRL Taxonomy Extension Labels**				
101.PRE	XBRL Taxonomy Extension Presentation**				
101.DEF	XBRL Taxonomy Extension Definition**				

\* Management contract, compensatory plan or agreement.

\*\* Pursuant to applicable securities laws and regulations, we will be deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and will not be subject to liability under any anti-fraud provisions of the federal securities laws with respect to such interactive data files as long as we have made a good faith attempt to comply with the submission requirements and promptly amend the interactive data files after becoming aware that the interactive data files fail to comply with the submission requirements. Users of this data are advised that, pursuant to Rule 406T of Regulation S-T, these interactive data files are deemed not filed and otherwise are not subject to liability, except as provided by applicable securities laws and regulations.

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

Table of Contents**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 22, 2012

By:           /s/ JEFFREY M. LEIDEN          

Jeffrey M. Leiden

*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
<u>          /s/ MATTHEW W. EMMENS          </u> Matthew W. Emmens	Executive Chairman and Chairman of the Board	February 22, 2012
<u>          /s/ JEFFREY M. LEIDEN          </u> Jeffrey M. Leiden	Chief Executive Officer, President and Director (Principal Executive Officer)	February 22, 2012
<u>          /s/ IAN F. SMITH          </u> Ian F. Smith	Executive Vice President and Chief Financial Officer (Principal Financial Officer)	February 22, 2012
<u>          /s/ PAUL M. SILVA          </u> Paul M. Silva	Senior Vice President and Corporate Controller (Principal Accounting Officer)	February 22, 2012
<u>          /s/ JOSHUA S. BOGER          </u> Joshua S. Boger	Director	February 22, 2012
<u>          /s/ TERRENCE C. KEARNEY          </u> Terrence C. Kearney	Director	February 22, 2012
<u>          /s/ MARGARET G. MCGLYNN          </u> Margaret G. McGlynn	Director	February 22, 2012
<u>          /s/ WAYNE J. RILEY          </u> Wayne J. Riley	Director	February 22, 2012
<u>          /s/ BRUCE I. SACHS          </u>	Director	February 22, 2012

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Bruce I. Sachs

/s/ ELAINE S. ULLIAN

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Director

February 22, 2012

Elaine S. Ullian

/s/ DENNIS L. WINGER

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Director

February 22, 2012

Dennis L. Winger

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**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Shareholders of  
Vertex Pharmaceuticals Incorporated

We have audited the accompanying consolidated balance sheets of Vertex Pharmaceuticals Incorporated as of December 31, 2011 and 2010, and the related consolidated statements of operations, shareholders' equity, comprehensive income (loss) and noncontrolling interest, and cash flows for each of the three years in the period ended December 31, 2011. 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, 2011 and 2010, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2011, 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, 2011, based on the criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commissions and our report dated February 22, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts  
February 22, 2012



Table of Contents**VERTEX PHARMACEUTICALS INCORPORATED****Consolidated Statements of Operations****(in thousands, except per share amounts)**

	Year Ended December 31,		
	2011	2010	2009
<b>Revenues:</b>			
Product revenues, net	\$ 950,889	\$	\$
Royalty revenues	50,015	30,244	28,320
Collaborative revenues	409,722	113,126	73,569
<b>Total revenues</b>	<b>1,410,626</b>	<b>143,370</b>	<b>101,889</b>
<b>Costs and expenses:</b>			
Cost of product revenues	63,625		
Royalty expenses	16,880	12,730	14,202
Research and development expenses	707,706	637,416	550,274
Sales, general and administrative expenses	400,721	187,800	130,192
Restructuring expense	2,074	1,501	6,240
Intangible asset impairment charge	105,800		7,200
Acquisition-related expenses			7,793
<b>Total costs and expenses</b>	<b>1,296,806</b>	<b>839,447</b>	<b>715,901</b>
<b>Income (loss) from operations</b>	<b>113,820</b>	<b>(696,077)</b>	<b>(614,012)</b>
Interest income	1,878	1,955	5,010
Interest expense	(38,452)	(19,275)	(13,192)
Change in fair value of derivative instruments	(16,801)	(41,229)	(1,847)
Loss on exchanges of convertible senior subordinated notes (due 2013)			(18,137)
<b>Income (loss) before provision for income taxes</b>	<b>60,445</b>	<b>(754,626)</b>	<b>(642,178)</b>
Provision for income taxes	19,266		
<b>Net income (loss)</b>	<b>41,179</b>	<b>(754,626)</b>	<b>(642,178)</b>
Net income attributable to noncontrolling interest (Alios)	11,605		
<b>Net income (loss) attributable to Vertex</b>	<b>\$ 29,574</b>	<b>\$ (754,626)</b>	<b>\$ (642,178)</b>
<b>Net income (loss) per share attributable to Vertex common shareholders:</b>			
Basic	\$ 0.14	\$ (3.77)	\$ (3.71)
Diluted	\$ 0.14	\$ (3.77)	\$ (3.71)
<b>Shares used in per share calculations:</b>			
Basic	204,891	200,402	173,259
Diluted	208,807	200,402	173,259

The accompanying notes are an integral part of the consolidated financial statements.

Table of Contents**VERTEX PHARMACEUTICALS INCORPORATED****Consolidated Balance Sheets****(in thousands, except share and per share amounts)**

	<b>December 31,</b>	
	<b>2011<sup>(1)</sup></b>	<b>2010</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 475,320	\$ 243,197
Marketable securities, available for sale	493,602	788,214
Restricted cash and cash equivalents (Alios)	51,878	
Accounts receivable, net	183,135	12,529
Inventories	112,430	
Prepaid expenses and other current assets	14,889	13,099
<b>Total current assets</b>	<b>1,331,254</b>	<b>1,057,039</b>
Restricted cash	34,090	34,090
Property and equipment, net	133,176	72,333
Intangible assets	663,500	518,700
Goodwill	30,992	26,102
Other assets	11,268	17,182
<b>Total assets</b>	<b>\$ 2,204,280</b>	<b>\$ 1,725,446</b>
<b>Liabilities and Shareholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 74,642	\$ 35,851
Accrued expenses and other current liabilities	252,299	134,414
Accrued interest	3,363	3,462
Deferred revenues, current portion	45,037	74,619
Accrued restructuring expense, current portion	4,932	5,497
Secured notes (due 2012)		136,991
Liability related to sale of milestone payments		77,799
Income taxes payable (Alios)	12,075	
Other obligations		6,150
<b>Total current liabilities</b>	<b>392,348</b>	<b>474,783</b>
Deferred revenues, excluding current portion	118,095	160,049
Accrued restructuring expense, excluding current portion	21,381	24,098
Convertible senior subordinated notes (due 2015)	400,000	400,000
Deferred tax liability	243,707	160,278
Construction financing obligation	55,950	
Other liabilities	7,287	2,265
<b>Total liabilities</b>	<b>1,238,768</b>	<b>1,221,473</b>
Commitments and contingencies (Note T and Note U)		
Redeemable noncontrolling interest (Alios)	37,036	
Shareholders' equity:		
Preferred stock, \$0.01 par value; 1,000,000 shares authorized; none issued and outstanding at December 31, 2011 and 2010		
Common stock, \$0.01 par value; 300,000,000 shares authorized at December 31, 2011 and 2010; 209,303,995 and 203,522,976 shares issued and outstanding at December 31, 2011 and 2010, respectively	2,072	2,016
Additional paid-in capital	4,200,659	3,947,433
Accumulated other comprehensive loss	(1,053)	(1,067)
Accumulated deficit	(3,414,835)	(3,444,409)

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Total Vertex shareholders' equity	786,843	503,973
Noncontrolling interest (Alios)	141,633	
Total shareholders' equity	928,476	503,973
Total liabilities and shareholders' equity	\$ 2,204,280	\$ 1,725,446

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- (1) Amounts include the assets and liabilities of Vertex's variable interest entity ("VIE"), Alios BioPharma, Inc. ("Alios"). Vertex's interests and obligations with respect to the VIE's assets and liabilities are limited to those accorded to Vertex in its agreement with Alios. See Note B, "Collaborative Arrangements," to these consolidated financial statements for amounts.

The accompanying notes are an integral part of the consolidated financial statements.

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## Vertex Pharmaceuticals Incorporated

## Consolidated Statements of Shareholders' Equity, Comprehensive Income (Loss) and Noncontrolling Interest

(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income Accumulated Deficit		Total Vertex Shareholders' Equity	Noncontrolling Interest (Alios)	Total Shareholders' Equity	Redeemable Noncontrolling Interest (Alios)
	Shares	Amount		(Loss)					
Balance, December 31, 2008	151,245	\$ 1,494	\$ 2,281,817	\$ 3,168	\$ (2,047,605)	\$ 238,874	\$	\$ 238,874	\$
Unrealized holding losses on marketable securities				(3,178)		(3,178)		(3,178)	
Foreign currency translation adjustment				(630)		(630)		(630)	
Net loss					(642,178)	(642,178)		(642,178)	
Comprehensive loss						(645,986)		(645,986)	
Issuances of common stock:									
Convertible senior subordinated notes (due 2013) exchanges	11,582	116	270,776			270,892		270,892	
Acquisition of ViroChem	10,734	107	290,450			290,557		290,557	
Equity offerings	23,000	230	801,155			801,385		801,385	
Benefit plans	3,394	35	53,867			53,902		53,902	
Stock-based compensation expense			86,722			86,722		86,722	
Balance, December 31, 2009	199,955	\$ 1,982	\$ 3,784,787	\$ (640)	\$ (2,689,783)	\$ 1,096,346	\$	\$ 1,096,346	\$
Unrealized holding gains on marketable securities				46		46		46	
Foreign currency translation adjustment				(473)		(473)		(473)	
Net loss					(754,626)	(754,626)		(754,626)	
Comprehensive loss						(755,053)		(755,053)	
Issuances of common stock:									
Convertible senior subordinated notes (due 2013) conversion	1,386	14	31,551			31,565		31,565	
Benefit plans	2,182	20	39,971			39,991		39,991	
Stock-based compensation expense			91,124			91,124		91,124	
Balance, December 31, 2010	203,523	\$ 2,016	\$ 3,947,433	\$ (1,067)	\$ (3,444,409)	\$ 503,973	\$	\$ 503,973	\$
Unrealized holding losses on marketable securities				(119)		(119)		(119)	
Foreign currency translation adjustment				133		133		133	
Net income					29,574	29,574	11,605	41,179	
Comprehensive income						29,588	11,605	41,193	
Issuances of common stock:									
Benefit plans	5,781	56	133,362			133,418	(25)	133,393	
Stock-based compensation expense			118,964			118,964	304	119,268	
Tax benefit from equity compensation			900			900		900	
							130,486	130,486	36,299

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Alios noncontrolling interest  
upon consolidation

Dividends on redeemable noncontrolling interest												(737)	(737)	737
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Balance, December 31, 2011	209,304	\$ 2,072	\$ 4,200,659	\$ (1,053)	\$ (3,414,835)	\$ 786,843	\$ 141,633	\$ 928,476	\$ 37,036
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The accompanying notes are an integral part of the consolidated financial statements.

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Table of Contents**VERTEX PHARMACEUTICALS INCORPORATED****Consolidated Statements of Cash Flows****(in thousands)**

	<b>Year Ended December 31,</b>		
	<b>2011</b>	<b>2010</b>	<b>2009</b>
<b>Cash flows from operating activities:</b>			
Net income (loss)	\$ 41,179	\$ (754,626)	\$ (642,178)
<b>Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:</b>			
Depreciation and amortization expense	35,041	30,459	30,107
Stock-based compensation expense	118,226	91,124	86,722
Other non-cash based compensation expense	8,525	6,552	6,044
Intangible asset impairment charge	105,800		7,200
Secured notes (due 2012) discount amortization expense	18,409	13,589	3,125
Change in fair value of derivative instruments	16,801	41,229	1,847
Deferred income taxes	(7,501)		(2,225)
Loss on disposal of property and equipment	55	39	2,211
Loss on exchanges of convertible senior subordinated notes (due 2013)			18,137
Other non-cash items, net	264	(31)	
<b>Changes in operating assets and liabilities, excluding the effects of the acquisitions of a variable interest entity (Alios) and business (ViroChem) :</b>			
Accounts receivable, net	(170,606)	(2,923)	13,900
Inventories	(111,388)		
Prepaid expenses and other current assets	(1,717)	(600)	2,070
Accounts payable	37,468	(1,182)	(15,057)
Accrued expenses and other liabilities	116,921	8,182	8,924
Excess tax benefit from share-based payment arrangements	(900)		
Accrued restructuring expense	(3,282)	(4,422)	(47)
Accrued interest	(99)	3,031	(1,423)
Income taxes payable (Alios)	12,075		
Deferred revenues	(71,536)	(65,863)	53,057
<b>Net cash provided by (used in) operating activities</b>	<b>143,735</b>	<b>(635,442)</b>	<b>(427,586)</b>
<b>Cash flows from investing activities:</b>			
Purchases of marketable securities	(721,545)	(1,234,719)	(1,186,701)
Sales and maturities of marketable securities	1,016,040	1,284,806	788,263
Payment for acquisition of ViroChem, net of cash acquired			(87,422)
Payment for acquisition of a variable interest entity (Alios)	(60,000)		
Expenditures for property and equipment	(34,595)	(38,054)	(23,496)
Increase in restricted cash and cash equivalents		(3,777)	(55)
Decrease in restricted cash and cash equivalents (Alios)	12,695		
Decrease (increase) in other assets	(183)	(955)	679
<b>Net cash provided by (used in) investing activities</b>	<b>212,412</b>	<b>7,301</b>	<b>(508,732)</b>
<b>Cash flows from financing activities:</b>			
Excess tax benefit from share-based payment arrangements	900		
Issuances of common stock from employee benefit plans, net	124,862	33,434	47,850
Issuances of common stock from stock offerings, net			801,385
Issuance of convertible senior subordinated notes (due 2015), net		391,645	
Issuance of secured notes (due 2012) and sale of milestone payments, net			149,902
Payments to redeem secured notes (due 2012)	(155,000)		
Settlement of milestone derivatives	(95,000)		
Debt conversion/exchange costs		(22)	(131)
<b>Net cash (used in) provided by financing activities</b>	<b>(124,238)</b>	<b>425,057</b>	<b>999,006</b>
Effect of changes in exchange rates on cash	214	(377)	(5,145)

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Net increase (decrease) in cash and cash equivalents	232,123	(203,461)	57,543
Cash and cash equivalents beginning of period	243,197	446,658	389,115
Cash and cash equivalents end of period	\$ 475,320	\$ 243,197	\$ 446,658
Supplemental disclosure of cash flow information:			
Cash paid for interest	\$ 13,512	\$ 761	\$ 10,248
Cash paid for taxes	\$	\$	\$
Conversion/exchange of convertible senior subordinated notes (due 2013) for common stock	\$	\$ 32,071	\$ 255,429
Accrued interest offset to additional paid-in capital on conversion/exchange of convertible senior subordinated notes (due 2013)	\$	\$ 140	\$ 3,355
Unamortized debt issuance costs of converted/exchanged convertible senior subordinated notes (due 2013) offset to additional paid-in capital	\$	\$ 624	\$ 5,899
Capitalization of construction in-process related to financing lease transactions	\$ 54,655	\$	\$
Fair value of common stock issued to acquire ViroChem	\$	\$	\$ 290,557

The accompanying notes are an integral part of the consolidated financial statements.

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**VERTEX PHARMACEUTICALS INCORPORATED**

**Notes to Consolidated Financial Statements**

**A. Nature of Business and Accounting Policies**

*Business*

Vertex Pharmaceuticals Incorporated ("Vertex" or the "Company") is in the business of discovering, developing, manufacturing and commercializing small molecule drugs for the treatment of serious diseases. The Company's two products are INCIVEK™ (telaprevir), which is approved in the United States and Canada for the treatment of adults with genotype 1 hepatitis C virus infection, and KALYDECO™ (ivacaftor), which is approved in the United States for the treatment of patients six years of age or older with cystic fibrosis who have a specific genetic mutation that is referred to as the G551D mutation. The Company began recognizing net product revenues from sales of INCIVEK and related cost of product revenues in the second quarter of 2011. The Company's collaborator, Janssen Pharmaceutica, N.V. ("Janssen"), began marketing telaprevir in its territories under the brand name INCIVO in September 2011. The Company is seeking approval to market ivacaftor from the European Commission and plans to seek approval to market ivacaftor in a number of other countries, including Canada and Australia. The Company's net income attributable to Vertex for 2011 was \$29.6 million, or \$0.14 per diluted common share. As of December 31, 2011, the Company had cash, cash equivalents and marketable securities of \$968.9 million. The Company expects that the cash flows it expects to generate from the sales of its products and the royalties it expects to receive from Janssen, together with the Company's cash, cash equivalents and marketable securities, will be sufficient to fund its operations for at least the next twelve months.

Vertex is subject to risks common to companies in its industry including, but not limited to, the dependence on revenues from INCIVEK, competition, uncertainty about clinical trial outcomes, uncertainties relating to pharmaceutical pricing and reimbursement, rapid technological change, uncertain protection of proprietary technology, the need to comply with government regulations, share price volatility, dependence on collaborative relationships and potential product liability.

*Basis of Presentation*

The consolidated financial statements reflect the operations of (i) the Company, (ii) its wholly-owned subsidiaries and (iii) Alios BioPharma, Inc. ("Alios"), a collaborator that is a variable interest entity (a "VIE") for which the Company is deemed under applicable accounting guidance to be the primary beneficiary. All material intercompany balances and transactions have been eliminated. The Company operates in one segment, pharmaceuticals. Please refer to Note W, "Geographic Information," for information regarding the geographic breakout of the Company's revenues.

*Use of Estimates*

The preparation of consolidated financial statements in accordance with accounting principles generally accepted in the United States of America ("GAAP") 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, restructuring expense, the fair value of intangible assets, noncontrolling interest (Alios), income tax provision, 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



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**VERTEX PHARMACEUTICALS INCORPORATED**

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

**A. Nature of Business and Accounting Policies (Continued)**

circumstances. Actual results could differ from those estimates. Changes in estimates are reflected in reported results in the period in which they become known.

*Revenue Recognition*

**Product Revenues, Net**

The Company sells INCIVEK principally to a limited number of major wholesalers, as well as selected regional wholesalers and specialty pharmacy providers (collectively, its "Distributors"), that subsequently resell INCIVEK to patients and health care providers. The Company recognizes net product revenues from sales of INCIVEK upon delivery to the Distributor as long as (i) there is persuasive evidence that an arrangement exists between the Company and the Distributor, (ii) collectibility is reasonably assured and (iii) the price is fixed or determinable.

The Company has written contracts with its Distributors and delivery occurs when a Distributor receives INCIVEK. The Company evaluates the creditworthiness of each of its Distributors to determine whether revenues can be recognized upon delivery, subject to satisfaction of the other requirements, or whether recognition is required to be delayed until receipt of payment. In order to conclude that the price is fixed or determinable, the Company must be able to (i) calculate its gross product revenues from the sales to Distributors and (ii) reasonably estimate its net product revenues. The Company calculates gross product revenues based on the wholesale acquisition cost that the Company charges its Distributors for INCIVEK. The Company estimates its net product revenues by deducting from its gross product revenues (a) trade allowances, such as invoice discounts for prompt payment and distributor fees, (b) estimated government and private payor rebates, chargebacks and discounts, such as Medicaid reimbursements, (c) reserves for expected product returns and (d) estimated costs of incentives offered to certain indirect customers, including patients.

*Trade Allowances:* The Company generally provides invoice discounts on INCIVEK sales to its Distributors for prompt payment and pays fees for distribution services, such as fees for certain data that Distributors provide to the Company. The payment terms for sales to Distributors generally include a 2% discount for payment within 30 days. The Company expects its Distributors to earn these discounts and fees, and deducts the full amount of these discounts and fees from its gross product revenues and accounts receivable at the time such revenues are recognized.

*Rebates, Chargebacks and Discounts:* The Company contracts with Medicaid, other government agencies and various private organizations (collectively, its "Third-party Payors") so that INCIVEK will be eligible for purchase by, or partial or full reimbursement from, such Third-party Payors. The Company estimates the rebates, chargebacks and discounts it will provide to Third-party Payors and deducts these estimated amounts from its gross product revenues at the time the revenues are recognized. The Company estimates the rebates, chargebacks and discounts that it will provide to Third-party Payors based upon (i) the Company's contracts with these Third-party Payors, (ii) the government-mandated discounts applicable to government-funded programs and (iii) information obtained from the Company's Distributors and other third parties regarding the payor mix for INCIVEK.

*Product Returns:* The Company estimates the amount of INCIVEK that will be returned and deducts these estimated amounts from its gross revenues at the time the revenues are recognized. The Company's Distributors have the right to return unopened unprescribed INCIVEK beginning

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## VERTEX PHARMACEUTICALS INCORPORATED

## Notes to Consolidated Financial Statements (Continued)

## A. Nature of Business and Accounting Policies (Continued)

six months prior to the labeled expiration date and ending twelve months after the labeled expiration date. The expiration date for INCIVEK is two years after it has been converted into tablet form, which is the last step in the manufacturing process for INCIVEK and generally occurs within a few months before INCIVEK is delivered to Distributors. As of December 31, 2011, the Company had not received any material product returns. From May 23, 2011 (the date the Company began selling INCIVEK) through December 31, 2011, the Company was able to reasonably estimate product returns based on its specialty distribution model with sales to a limited number of distributors, data provided to the Company by its Distributors (including weekly reporting of Distributors' sales and inventory held by Distributors that provided the Company with visibility into the distribution channel in order to determine what quantities, if any, were eligible to be returned), data provided to the Company by other third parties, historical industry information regarding return rates for similar specialty pharmaceutical products, the estimated remaining shelf life of INCIVEK previously shipped and currently being shipped to Distributors, and contractual agreements intended to limit the amount of inventory maintained by the Company's Distributors. Based on the Company's visibility into the distribution channel and available prescription data, the Company believes that most of the INCIVEK inventory held by its Distributors on December 31, 2011 has already been dispensed to patients in the first quarter of 2012.

*Other Incentives:* Other incentives that the Company offers to indirect customers include co-pay mitigation rebates provided by the Company to commercially insured patients who have coverage for INCIVEK and who reside in states that permit co-pay mitigation programs. The Company's co-pay mitigation program is intended to reduce each participating patient's portion of the financial responsibility for INCIVEK's purchase price to a specified dollar amount. Based upon the terms of the program and information regarding programs provided for similar specialty pharmaceutical products, the Company estimates the average co-pay mitigation amounts and the percentage of patients that it expects to participate in the program in order to establish its accruals for co-pay mitigation rebates and deducts these estimated amounts from its gross product revenues at the time the revenues are recognized. The Company's co-pay mitigation rebates offered to date expire six months from the date of issuance. A portion of the co-pay mitigation rebates the Company issued in the second quarter of 2011 expired in the fourth quarter of 2011. Based on this information, beginning in the fourth quarter, the Company began adjusting its accruals for co-pay mitigation rebates based on its estimates regarding the portion of issued rebates that it estimates will not be redeemed.

The following table summarizes activity in each of the product revenue allowance and reserve categories described above from May 23, 2011 through December 31, 2011:

	Trade Allowances	Rebates, Chargebacks and Discounts	Product Returns	Other Incentives	Total
	(in thousands)				
<b>Balance at May 23, 2011</b>	\$	\$	\$	\$	\$
Provision related to current period sales	38,228	75,145	553	9,692	123,618
Credits/payments made for current period sales	(27,066)	(22,486)	(213)	(4,490)	(54,255)
<b>Balance at December 31, 2011</b>	\$ 11,162	\$ 52,659	\$ 340	\$ 5,202	\$ 69,363

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**VERTEX PHARMACEUTICALS INCORPORATED**

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

**A. Nature of Business and Accounting Policies (Continued)**

**Royalty Revenues**

The Company's royalty revenues on commercial sales of INCIVO (telaprevir) by Janssen are based on net sales of licensed products in licensed territories as provided by Janssen. The Company recognizes royalty revenues in the period the sales occur.

The Company has sold its rights to receive certain royalties on sales of an HIV protease inhibitor (fosamprenavir) and recognizes the revenues related to this sale as royalty revenues. 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 payable to the purchaser of the future royalty rights), 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 pursuant to the units-of-revenue method. The Company's estimates regarding the estimated remaining royalty payments due to the purchaser have changed in the past and may change in the future.

**Collaborative Revenues**

The Company also recognizes revenues generated 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; development and commercial milestone payments; funding of research and/or development activities; payments for services the Company provides through its third-party manufacturing network; and royalties on net sales of licensed products. Each of these types of payments results in collaborative revenues, except for revenues from royalties on net sales of licensed products, which are classified as royalty revenues.

Agreements Entered into prior to January 1, 2011

Collaborative research, development and/or commercialization agreements entered into prior to January 1, 2011 that contain multiple elements of revenue 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 Company allocates consideration it receives among the separate units either on the basis of each unit's fair value or using the residual method, and applies the applicable revenue recognition criteria to each of the separate units.

*Up-front License Fees*

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 period over which the research and development is expected to occur or manufacturing services are expected to be provided. In order to estimate the period of performance, the Company is required to make estimates regarding the drug development and commercialization timelines for drugs and drug candidates being developed pursuant to the applicable agreement. The Company's estimates regarding the period of performance under certain of its collaboration agreements did not change during 2011, but have changed in the past and may change in the future.

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**VERTEX PHARMACEUTICALS INCORPORATED**

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

**A. Nature of Business and Accounting Policies (Continued)**

*Milestone Payments*

At the inception of each agreement that includes research and development 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. The Company recognizes revenues related to substantive milestones in full in the period in which the substantive milestone is achieved if payment is reasonably assured. If a milestone is not considered substantive, the Company recognizes the applicable milestone payment over the period of performance. Commercial milestone payments are recognized in full upon achievement, if payment is reasonably assured.

*Research and Development Activities/Manufacturing Services*

Under certain of its collaboration agreements, the Company is entitled to reimbursement from its collaborators for specified research and development expenses and/or payments for specified manufacturing services that the Company provides through its third-party manufacturing network. The Company considers the nature and contractual terms of the arrangement and the nature of the Company's business operations in order to determine whether research and development funding will result in collaborative revenues or an offset to research and development expenses. The Company typically recognizes the revenues related to these reimbursable expenses and manufacturing services in the period in which the reimbursable expenses are incurred or the manufacturing services are provided.

Agreements Entered into or Materially Modified on or after January 1, 2011

On January 1, 2011, updated guidance on the recognition of revenues for agreements with multiple deliverables became effective and applies to any agreements entered into or materially modified by the Company on or after January 1, 2011. This updated guidance (i) relates to whether multiple deliverables exist, how the deliverables in a revenue arrangement should be separated and how the consideration should be allocated; (ii) requires companies to allocate revenues in an arrangement using management's best estimate of selling prices of deliverables if a vendor does not have vendor-specific objective evidence or third-party evidence of selling price; and (iii) eliminates the use of the residual method and requires companies to allocate revenues using the relative selling price method. During 2011, the Company did not enter into any material agreements or material modifications to existing agreements that would be accounted for by the Company pursuant to this updated guidance. If the Company enters into or materially modifies an agreement with multiple deliverables, this updated guidance could have a material effect on the Company's consolidated financial statements in future periods.

*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.

Table of Contents**VERTEX PHARMACEUTICALS INCORPORATED****Notes to Consolidated Financial Statements (Continued)****A. Nature of Business and Accounting Policies (Continued)**

In 2011, the Company's revenues were generated from net product sales to Distributors and a limited number of collaborators in the United States, Europe and Japan. Management believes the credit risks associated with these customers are not significant. The following table summarizes gross revenues and accounts receivable, net from each of the Company's customers who individually accounted for 10% or more of total gross revenues and/or 10% or more of total accounts receivable, net:

	Percent of Total Gross Revenues			Percent of Accounts Receivable, Net	
	Year Ended December 31,			At December 31,	
	2011	2010	2009	2011	2010
AmerisourceBergen Drug Corporation	25%			35%	
McKesson Corporation	24%			30%	
Cardinal Health Incorporated	15%			20%	
Janssen	19%	21%	54%	10%	12%
Mitsubishi Tanabe Pharma Corporation	<10%	57%	18%	<10%	55%
GlaxoSmithKline plc	<10%	<10%	<10%	<10%	23%

*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 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.

*Restricted Cash*

Restricted cash consists of balances 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. The Company also separately discloses on its consolidated balance sheets restricted cash and cash equivalents (Alios). Please refer to Note B, "Collaborative Arrangements," for further information.

*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 its 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 shareholders' 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 2011, 2010 or 2009. Realized gains and losses are determined using the specific

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**VERTEX PHARMACEUTICALS INCORPORATED**

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

**A. Nature of Business and Accounting Policies (Continued)**

identification method and are included in interest income in the consolidated statements of operations. There were no gross realized gains and losses recognized in 2011, 2010 or 2009.

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. Please refer to Note F, "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 estimates the likelihood of satisfaction of the performance conditions, which affects 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 each period to reflect actual forfeitures and the outcomes of certain market and performance conditions. Please refer to Note M, "Stock-based Compensation Expense," for further information.

*Research and Development Expenses*

The Company expenses as incurred all research and development expenses, including amounts funded by research and development collaborations. The Company defers and capitalizes nonrefundable advance payments made by the Company for research and development activities until the related goods are delivered or the related services are performed.

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 costs, including clinical trial and pharmaceutical development costs; expenses associated with drug supplies that are not being capitalized; and infrastructure costs, including facilities costs and depreciation expense.

The Company's collaborators funded portions of the Company's research and development programs related to specific drugs, drug candidates and research targets, including, in 2011 telaprevir, VX-661 and research directed toward identifying additional corrector compounds for the treatment of cystic fibrosis, and in 2010 and 2009 telaprevir. The Company's collaborative revenues, including amortization of up-front license fees and milestone revenues, were \$409.7 million \$113.1 million and \$73.6 million, respectively, in 2011, 2010 and 2009. 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 \$146 million, \$156 million and \$149 million, respectively, in 2011, 2010 and 2009.

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**VERTEX PHARMACEUTICALS INCORPORATED**

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

**A. Nature of Business and Accounting Policies (Continued)**

*Sales, General and Administrative Expenses*

Sales, general and administrative expenses consist primarily of personnel costs, related benefits and stock-based compensation expense for the Company's sales, marketing, and managed markets personnel and personnel serving executive, finance, medical affairs, business development, legal, quality assurance, information technology and human resource functions. Other costs include facility costs not otherwise included in research and development expenses as well as professional fees for legal and accounting services. Advertising costs, which were \$30.8 million in 2011, also are included in sales, general and administrative expenses and are expensed as incurred.

*Inventories*

The Company values its inventories at the lower of cost or market. The Company determines the cost of its inventories, which includes amounts related to materials and manufacturing overhead, on a first-in, first-out basis. If the Company identifies excess, obsolete or unsalable items, its inventories are written down to their realizable value in the period in which the impairment is first identified. Shipping and handling costs incurred for inventory purchases and product shipments are recorded in cost of product revenues in the Company's consolidated statements of operations.

The Company capitalizes inventories produced in preparation for initiating sales of a drug candidate when the related drug candidate is considered to have a high likelihood of regulatory approval and the related costs are expected to be recoverable through sales of the inventories. In determining whether or not to capitalize such inventories, the Company evaluates, among other factors, information regarding the drug candidate's safety and efficacy, the status of regulatory submissions and communications with regulatory authorities and the outlook for commercial sales, including the existence of current or anticipated competitive drugs and the availability of reimbursement. In addition, the Company evaluates risks associated with manufacturing the drug candidate and the remaining shelf life of the inventories. Please refer to Note G, "Inventories," for further information.

*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 estimated 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.

The Company records certain construction costs incurred by a landlord as an asset and corresponding financing obligation on the Company's consolidated balance sheets. Please refer to Note I, "Fan Pier Leases" for further information.

*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

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**VERTEX PHARMACEUTICALS INCORPORATED**

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

**A. Nature of Business and Accounting Policies (Continued)**

assets and liabilities. A valuation allowance is applied against any net deferred tax asset if, based on the 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 offerings and the financial transactions that the Company entered into in September 2009 were deferred and included in other assets on the Company's consolidated balance sheets. The issuance costs are amortized using the effective interest rate method over the term of the related debt or financial 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 sheets and are amortized in the same manner and over the same period during 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.

*Variable Interest Entities*

The Company reviews each collaboration agreement pursuant to which the Company licenses assets owned by a collaborator in order to determine whether or not the collaborator is a VIE. If the collaborator is a VIE, the Company assesses whether or not the Company is the primary beneficiary of that VIE based on a number of factors, including (i) which party has the power to direct the activities that most significantly affect the VIE's economic performance, (ii) the parties' contractual rights and responsibilities pursuant to the collaboration and (iii) which party has the obligation to absorb losses or the right to receive benefits from the VIE. If the Company determines it is the primary beneficiary of a VIE, the Company consolidates the statements of operations and financial condition of the VIE into the Company's consolidated financial statements. As of June 13, 2011 (the effective date of the Company's collaboration agreement with Alios) and December 31, 2011, the Company evaluated its collaboration with Alios (the "Alios Collaboration") and determined that Alios is a VIE and that the Company is Alios' primary beneficiary. The Company will re-evaluate the Alios Collaboration each reporting period in order to determine if there are changes in circumstances that would result in the Company ceasing to consolidate the statements of operations and financial condition of Alios into the Company's consolidated financial statements. The Company would deconsolidate Alios if Alios ceased to be a VIE or if the Company was no longer Alios' primary beneficiary. Please refer to Note B, "Collaborative Arrangements," for further information.

*Business Combinations*

The Company assigns the value of consideration, including contingent consideration, transferred in business combinations based on its fair value as of the effective date of the transaction. The Company accounts for the Alios Collaboration as a business combination due to its determination that (i) Alios is a VIE, (ii) Alios is a business and (iii) the Company is Alios' primary beneficiary. Transaction costs and any restructuring costs associated with these transactions are expensed as incurred.



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**VERTEX PHARMACEUTICALS INCORPORATED**

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

**A. Nature of Business and Accounting Policies (Continued)**

*Fair Value of In-process Research and Development Assets and Contingent Payments in Business Combinations*

The Company assesses the fair value of assets, including the fair value of in-process research and development assets and contingent payments pursuant to collaborations accounted for as business combinations, from the perspective of a market participant, using a variety of methods. The present-value models used to estimate the fair values of research and development assets and contingent payments pursuant to collaborations incorporate significant assumptions, including: assumptions regarding the probability of obtaining marketing approval and/or achieving relevant development milestones for a drug candidate; estimates regarding the timing of and the expected costs to develop a drug candidate; estimates of future cash flows from potential product sales and/or the potential to achieve certain commercial milestones with respect to a drug candidate; and the appropriate discount rates.

*In-process Research and Development Assets*

In-process research and development assets relate to (i) the Company's acquisition of ViroChem Pharma Inc. ("ViroChem") in March 2009 and (ii) the Alios Collaboration. The Company records the value of in-process research and development assets at their fair value as of the transaction date. Each of these assets is accounted for as an indefinite-lived intangible asset and maintained on the Company's consolidated balance sheet until either the project underlying it is completed or the asset becomes impaired. If a project is completed, the carrying value of the related intangible asset is amortized as a part of cost of product revenues over the remaining estimated life of the asset beginning in the period in which the project is completed. If the asset 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, and more frequently if indicators are present or changes in circumstances suggest that impairment may exist. Please refer to Note B, "Collaborative Arrangements," and Note C, "Acquisition of ViroChem Pharma Inc.," for further information.

*Goodwill*

The difference between the purchase price and the fair value of assets acquired and liabilities assumed in a business combination, or deemed to be acquired or assumed in other transactions treated as business combinations for accounting purposes, is allocated to goodwill. As of December 31, 2010, goodwill consisted of goodwill related to the Company's acquisition of ViroChem. As of December 31, 2011, goodwill consisted of goodwill related to the Company's acquisition of ViroChem and the Alios Collaboration. Goodwill is evaluated for impairment on an annual basis as of October 1, and more frequently if indicators are present or changes in circumstances suggest that impairment may exist.

*Derivative Instruments and Embedded Derivatives*

The Company has entered into financial transactions involving free-standing derivative instruments and embedded derivatives. These financial transactions include arrangements involving secured notes, the sale of contingent milestone payments and senior subordinated convertible notes. 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 and at the end of each quarterly

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**VERTEX PHARMACEUTICALS INCORPORATED**

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

**A. Nature of Business and Accounting Policies (Continued)**

period. The estimates of the fair value of these derivatives, particularly with respect to derivatives related to the achievement of milestones in the development of telaprevir, included significant assumptions regarding the estimates market participants would make in order to evaluate these derivatives. Please refer to Note K, "Common Stock Offerings and Convertible Senior Subordinated Notes," and Note N, "September 2009 Financial Transactions," for further information.

*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 the initial measurement, the Company measures changes to the liability using the credit-adjusted risk-free discount rate applied in the initial period. The Company evaluates and adjusts these liabilities as appropriate for changes in circumstances at least on a quarterly basis. Please refer to Note R, "Restructuring Expense," for further information.

*Comprehensive Income (Loss)*

Comprehensive income (loss) consists of net income (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 income (loss) disclosures, the Company does not record tax provisions 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*

All material consolidated entities have the U.S. dollar as their functional currency except the functional currency of the Company's United Kingdom subsidiaries is the local currency. Non-U.S. dollar functional currency subsidiaries have assets and liabilities 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 accumulated other comprehensive income (loss), which is a separate component of shareholders' equity. Included in accumulated other comprehensive income (loss) is a net unrealized loss related to foreign currency translation of \$0.9 million, \$1.1 million and \$0.6 million at December 31, 2011, 2010, and 2009, respectively.

*Recent Accounting Pronouncements*

In September 2011, the Financial Accounting Standards Board ("FASB") amended guidance regarding testing goodwill for impairment. This amended guidance allows an entity the option to first assess qualitative factors to determine whether it is necessary to perform a two-step impairment test. If an entity believes, as a result of its qualitative assessment, that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, the quantitative two-step impairment test is required; otherwise, no further testing is required. These amendments do not change the current guidance for testing other indefinite-lived intangible assets for impairment. This amended guidance became effective for annual and interim goodwill impairment tests performed by the Company for fiscal years beginning on January 1, 2012. The Company adopted this amended guidance early in connection with its October 1, 2011 goodwill assessment. The adoption of this guidance did not have a material effect on the Company's consolidated financial statements.

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**VERTEX PHARMACEUTICALS INCORPORATED**

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

**A. Nature of Business and Accounting Policies (Continued)**

In June 2011, the FASB issued amended guidance intended to increase the prominence of items reported in other comprehensive income (loss). This amended guidance requires that all non-owner changes in shareholders' equity be presented either in a single continuous statement of comprehensive income (loss) or in two separate but consecutive statements. The amended guidance became effective on January 1, 2012. The Company will apply this guidance retrospectively beginning with its quarterly report for the three months ending March 31, 2012. This amended guidance will affect presentation, but will not have a material effect on the Company's consolidated financial statements.

In May 2011, the FASB amended guidance regarding the measurement of the fair value of assets and liabilities to harmonize the fair value measurement guidance under GAAP and under the International Financial Reporting Standards. This amended guidance clarifies the FASB's intent regarding the application of existing fair value measurement requirements and changes a particular principle or requirement for measuring fair value or for disclosing information about fair value measurements. The amended guidance became effective on January 1, 2012. The Company will adopt this guidance on a prospective basis. The adoption of this amended guidance will not have a material effect on the Company's consolidated financial statements.

The Company did not adopt any new accounting pronouncements during 2011 that had a material effect on the Company's consolidated financial statements.

**B. Collaborative Arrangements**

*Janssen Pharmaceutica, N.V.*

In June 2006, the Company entered into a collaboration agreement with Janssen for the development, manufacture and commercialization of telaprevir, which Janssen began marketing under the brand name INCIVO in certain of its territories in September 2011. Under the agreement, Janssen 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.

Janssen pays the Company a tiered royalty averaging in the mid-20% range, subject to adjustment for generic competition, as a percentage of net sales of INCIVO in Janssen's territories. Janssen is required pursuant to the agreement to use diligent efforts to maximize net sales of INCIVO in its territories through its commercial marketing, pricing and contracting strategies. In addition, Janssen is responsible for certain third-party royalties on net sales of INCIVO in its territories.

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, 2009 and 2010, as a result of changes in the global development plan for telaprevir, which includes the conduct of certain development activities in the post-approval period. These adjustments were made on a prospective basis beginning in the periods in which the changes were identified and resulted in a decrease in the amount of revenues the Company recognized from the Janssen agreement by \$2.6 million per quarter for the first adjustment, by \$1.1 million per quarter for the second adjustment and by \$1.4 million per quarter for the third adjustment. As of December 31, 2011, there were \$55.9 million in deferred revenues related

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**VERTEX PHARMACEUTICALS INCORPORATED**

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

**B. Collaborative Arrangements (Continued)**

to this up-front license payment that the Company expects to recognize over the remaining estimated period of performance.

Under the agreement, Janssen agreed to make contingent milestone payments for successful development, approval and launch of telaprevir as a product in its territories. At the inception of the agreement, the Company determined that all of these contingent milestones were substantive and would result in revenues in the period in which the milestone was achieved. As of December 31, 2011, the Company had earned \$350.0 million of these contingent milestone payments, including a \$50.0 million milestone payment in the first quarter of 2011 in connection with the European Medicines Agency's ("EMA") acceptance of the marketing authorization application ("MAA") for INCIVO and an aggregate of \$200.0 million in milestone payments in the third quarter of 2011 related to the approval of INCIVO by the European Commission and launch of INCIVO in the European Union. The Company does not expect to receive any further milestone payments pursuant to this agreement. On September 30, 2009, the Company entered into two financial transactions related to the \$50.0 million milestone payment that was earned in the first quarter of 2011 and the \$200.0 million in milestone payments that were earned in the third quarter of 2011. Please refer to Note N, "September 2009 Financial Transactions," for further information.

Under the collaboration agreement for telaprevir, each party incurs internal and external reimbursable expenses related to the telaprevir development program and is reimbursed for 50% of these expenses. The Company recognizes the full amount of the reimbursable costs it incurs as research and development expenses on its consolidated statements of operations. The Company recognizes the amounts that Janssen is obligated to pay the Company with respect to reimbursable expenses net of reimbursable expenses incurred by Janssen as collaborative revenues. During 2011, Janssen incurred more reimbursable costs than the Company, and the net amounts payable by the Company to reimburse Janssen for expenses for 2011 were recorded as a reduction of collaborative revenues.

Each of the parties is responsible for drug supply in their respective territories. The Company provides Janssen certain services through the Company's third-party manufacturing network for telaprevir. Reimbursements from Janssen for manufacturing services are recorded as collaborative revenues.

Janssen may terminate the agreement upon the later of (i) one year's advance notice and (ii) such period as may be required to assign and transfer to the Company specified filings and approvals. The agreement also may be terminated by either party for a material breach by the other, subject to notice and cure provisions. Unless earlier terminated, the agreement will continue in effect until the expiration of Janssen's royalty obligations, which expire on a country-by-country basis with the last-to-expire patent covering telaprevir. In the European Union, the Company has a patent covering the composition-of-matter of telaprevir that expires in 2021 and expects to obtain extensions to the term of this patent through 2026.

Table of Contents**VERTEX PHARMACEUTICALS INCORPORATED****Notes to Consolidated Financial Statements (Continued)****B. Collaborative Arrangements (Continued)**

During the three years ended December 31, 2011, the Company recognized the following collaborative revenues attributable to the Janssen collaboration:

	2011	2010	2009
	(in thousands)		
Amortized portion of up-front payment	\$ 12,428	\$ 12,428	\$ 20,196
Milestone revenues	250,000		
Net reimbursement (payment) for telaprevir development costs	(8,418)	9,245	27,711
Reimbursement for manufacturing services	20,383	9,077	6,733
<b>Total collaborative revenues attributable to the Janssen collaboration</b>	<b>\$ 274,393</b>	<b>\$ 30,750</b>	<b>\$ 54,640</b>

In 2011, the Company also recognized \$20.3 million in royalty revenues from net sales of INCIVO by Janssen.

*Mitsubishi Tanabe Pharma Corporation*

The Company has a collaboration agreement with Mitsubishi Tanabe (the "MTPC Agreement") pursuant to which Mitsubishi Tanabe has a fully-paid license to manufacture and commercialize TELAVIC (telaprevir) to treat HCV infection in Japan and specified other countries in the Far East. In September 2011, Mitsubishi Tanabe obtained approval to market TELAVIC in Japan.

The MTPC Agreement was entered into in 2004 and amended in 2009. Pursuant to the MTPC Agreement, Mitsubishi Tanabe provided financial and other support for the development and commercialization of telaprevir, made a \$105.0 million payment in connection with the 2009 amendment of the collaboration agreement and made a \$65.0 million commercial milestone payment in the fourth quarter of 2011 related to the commercialization of TELAVIC in Japan. There are no further milestone payments under this collaboration agreement. Mitsubishi Tanabe is responsible for its own development and manufacturing costs in its territory.

Mitsubishi Tanabe may terminate the MTPC Agreement at any time without cause upon 60 days' prior written notice to the Company. The agreement also may be terminated by either party for a material breach by the other, subject to notice and cure provisions. Unless earlier terminated, the agreement will continue in effect until the expiration of the last-to-expire patent covering TELAVIC. In Japan, the Company has a patent covering the composition-of-matter of TELAVIC that expires in 2021.

Prior to the 2009 amendment to the MTPC Agreement, the Company recognized revenues based on an amortized portion of the 2004 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 in connection with the amendment is a nonrefundable, up-front license fee and revenues related to this payment are being recognized on a straight-line basis over the expected period of performance of the Company's obligations under the amended agreement. As of December 31, 2011, there were \$12.7 million in deferred revenues related to this up-front license payment that will be recognized over the remaining period of performance of the Company's obligations under the MTPC Agreement. In connection with the amendment to the MTPC Agreement, the Company agreed to supply manufacturing services to Mitsubishi Tanabe, until April 2012, through the Company's third-party manufacturing network for telaprevir.

Table of Contents**VERTEX PHARMACEUTICALS INCORPORATED****Notes to Consolidated Financial Statements (Continued)****B. Collaborative Arrangements (Continued)**

During the three years ended December 31, 2011, the Company recognized the following collaborative revenues attributable to the Mitsubishi Tanabe collaboration:

	2011	2010	2009
	(in thousands)		
Amortized portion of up-front payments	\$ 38,232	\$ 38,232	\$ 16,027
Milestone revenues	68,515		
Reimbursement for telaprevir development costs			1,265
Payments for manufacturing services	14,928	43,636	1,419
<b>Total collaborative revenues attributable to the Mitsubishi Tanabe collaboration</b>	<b>\$ 121,675</b>	<b>\$ 81,868</b>	<b>\$ 18,711</b>

*Cystic Fibrosis Foundation Therapeutics Incorporated*

In April 2011, the Company entered into an amendment (the "April 2011 Amendment") to its existing collaboration agreement with Cystic Fibrosis Foundation Therapeutics Incorporated ("CFFT") pursuant to which CFFT agreed to provide financial support for (i) development activities for VX-661, a corrector compound discovered under the collaboration, and (ii) additional research and development activities directed at discovering new corrector compounds.

The Company entered into the original collaboration agreement with CFFT in 2004 and amended it several times prior to 2011 to provide partial funding for its cystic fibrosis drug discovery and development efforts. In 2006, the Company received a \$1.5 million milestone payment from CFFT. There are no additional milestones payable by CFFT to the Company pursuant to the collaboration agreement, as amended. Under the April 2011 Amendment, CFFT agreed to provide the Company with up to \$75.0 million in funding over approximately five years for corrector-compound research and development activities. The Company retains the right to develop and commercialize KALYDECO (ivacaftor), VX-809, VX-661 and any other compounds discovered during the course of the research collaboration with CFFT. During the year ended December 31, 2011, the Company recognized \$13.7 million in collaborative revenues pursuant to this collaboration.

In the original agreement, as amended prior to the April 2011 Amendment, the Company agreed to pay CFFT tiered royalties calculated as a percentage, ranging from single digits to sub-teens, of annual net sales of any approved drugs discovered during the research term that ended in 2008, including KALYDECO, VX-809 and VX-661. The April 2011 Amendment provides for a tiered royalty in the same range on net sales of corrector compounds discovered during the research term that began in 2011. The Company also is obligated to make two one-time commercial milestone payments upon achievement of certain sales levels for a potentiator compound such as KALYDECO and two one-time commercial milestone payments upon achievement of certain sales levels for a corrector compound such as VX-809 or VX-661. KALYDECO was approved by the FDA on January 31, 2012, and the Company filed its MAA with the EMA for ivacaftor in October 2011.

The Company has royalty obligations to CFFT for each compound commercialized pursuant to this collaboration until the expiration of patents covering that compound. The Company has patents in the United States and European Union covering the composition-of-matter of ivacaftor that expire in 2027 and 2025, respectively, subject to potential patent life extensions. CFFT may terminate its funding obligations under the collaboration, as amended, in certain circumstances, in which case there will be a

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**VERTEX PHARMACEUTICALS INCORPORATED**

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

**B. Collaborative Arrangements (Continued)**

proportional adjustment to the royalty rates and commercial milestone payments for certain corrector compounds. The collaboration also may be terminated by either party for a material breach by the other, subject to notice and cure provisions.

*Alios BioPharma, Inc.*

License and Collaboration Agreement

On June 13, 2011, the Company entered into a license and collaboration agreement (the "Alios Agreement") with Alios, a privately-held biotechnology company. The Company and Alios are collaborating on the research, development and commercialization of two hepatitis C virus ("HCV") nucleotide analogues discovered by Alios, ALS-2200 and ALS-2158, which are designed to act on the HCV polymerase. As of June 13, 2011, these two HCV nucleotide analogues were being evaluated in nonclinical studies and had not begun Phase 1 clinical development. Alios and the Company began clinical development of these two HCV nucleotide analogues in December 2011. The Company is responsible for all costs related to development and commercialization of the compounds incurred after the effective date of the Alios Agreement, and manufacturing costs for the supply of ALS-2200 and ALS-2158 used after the effective date, and is providing funding to Alios to conduct the Phase 1 clinical trials for ALS-2200 and ALS-2158 and a research program directed to the discovery of additional HCV nucleotide analogues that act on the HCV polymerase.

Under the terms of the Alios Agreement, the Company received exclusive worldwide rights to ALS-2200 and ALS-2158, and has the option to select additional compounds discovered in the research program. The Company paid Alios a \$60.0 million up-front payment, and Alios is eligible to receive research and development milestone payments of up to \$715.0 million if two compounds are approved and commercialized. As of December 31, 2011, Alios had earned \$35.0 million of these research and development milestones. Alios also is eligible to receive commercial milestone payments of up to \$750.0 million, as well as tiered royalties on net sales of approved drugs.

The Company may terminate the Alios Agreement (a) upon 30 days' notice to Alios if the Company ceases development after both ALS-2200 and ALS-2158 have experienced a technical failure and/or (b) upon 60 days' notice to Alios at any time after the Company completes specified Phase 2a clinical trials. The Alios Agreement also may be terminated by either party for a material breach by the other, and by Alios for the Company's inactivity or if the Company challenges certain Alios patents, in each case subject to notice and cure provisions. Unless earlier terminated, the Alios Agreement will continue in effect until the expiration of the Company's royalty obligations, which expire on a country-by-country basis on the later of (i) the date the last-to-expire patent covering a licensed product expires or (ii) ten years after the first commercial sale in the country.

Alios is continuing to operate as a separate entity, is engaged in other programs directed at developing novel drugs that are not covered by the Alios Agreement, and maintains ownership of the underlying patent rights that are licensed to the Company pursuant to the Alios Agreement. Under applicable accounting guidance, the Company has determined that Alios is a VIE, that Alios is a business and that the Company is Alios' primary beneficiary. The Company based these determinations on, among other factors, the significance to Alios of the two licensed compounds and on the Company's power, through the joint steering committee for the licensed compounds established under the Alios Agreement, to direct the activities that most significantly affect the economic performance of Alios.

Table of Contents**VERTEX PHARMACEUTICALS INCORPORATED****Notes to Consolidated Financial Statements (Continued)****B. Collaborative Arrangements (Continued)**

Accordingly, the Company consolidated Alios' statements of operations and financial condition with the Company's consolidated financial statements beginning on June 13, 2011. However, the Company's interests in Alios are limited to those accorded to the Company in the Alios Agreement. In particular, the Company did not acquire any equity interest in Alios, any interest in Alios' cash and cash equivalents or any control over Alios' activities that do not relate to the Alios Agreement. Alios does not have any right to the Company's assets except as provided in the Alios Agreement.

The initial consolidation of a VIE that is determined to be a business is accounted for as a business combination. As a result, as of June 13, 2011 the Company recorded all of Alios' assets and liabilities at fair value on the Company's consolidated balance sheet. The Company continues to consolidate Alios' financial statements, (A) eliminating all intercompany balances and transactions and (B) allocating loss (gain) attributable to the noncontrolling interest in Alios to net loss (gain) attributable to noncontrolling interest (Alios) in the Company's consolidated statement of operations and reflecting noncontrolling interest (Alios) on the Company's consolidated balance sheet.

Consideration for the Alios Collaboration

The consideration from the Company to Alios pursuant to the Alios Agreement consisted of (i) a \$60.0 million up-front payment paid by the Company to Alios, (ii) the estimated fair value on the effective date of the Alios Agreement of the contingent research, development and commercialization milestones potentially payable by the Company to Alios and (iii) the estimated fair value on the effective date of the Alios Agreement of potential royalty payments payable by the Company to Alios. The Company used present-value models to determine the estimated fair value of the potential contingent milestone and royalty payments, based on assumptions regarding the probability of achieving the relevant milestones, estimates regarding the time to develop the drug candidate(s), estimates of future cash flows from potential product sales and assumptions regarding the appropriate discount rates. The Company valued the contingent milestone and royalty payments using (a) discount rates ranging from 3.6% to 6.5% for the research and development milestones and (b) a discount rate of 9.4% for commercial milestones and royalties. The consideration paid and the fair value of the contingent milestone and royalty payments payable by the Company pursuant to the Alios Agreement are set forth in the table below:

	<b>As of June 13, 2011 (in thousands)</b>
Up-front payment	\$ 60,000
Fair value of contingent milestone and royalty payments	197,720
<b>Total</b>	<b>\$ 257,720</b>

Allocation of Assets and Liabilities

On June 13, 2011, the Company recorded \$250.6 million of intangible assets on the Company's consolidated balance sheet for Alios' in-process research and development assets. These in-process research and development assets relate to Alios' HCV nucleotide analogue program, including the intellectual property related to ALS-2200 and ALS-2158. The Company used a 9.5% discount rate in the present-value models used to estimate the fair value of the in-process research and development assets. The Company also conducted an evaluation of Alios' other programs and determined that



Table of Contents**VERTEX PHARMACEUTICALS INCORPORATED****Notes to Consolidated Financial Statements (Continued)****B. Collaborative Arrangements (Continued)**

market participants would not have ascribed value to those assets because Alios had not yet identified drug candidates for clinical development, and because of the uncertainties related to (i) identifying compounds suitable for clinical development and (ii) the potential clinical development of these compounds. The difference between the fair value of the consideration and the fair value of Alios' assets, including the fair value of intangible assets and liabilities was allocated to goodwill. This goodwill related to the potential synergies from the possible development of combination therapies involving the acquired drug candidates and telaprevir and/or VX-222. None of the goodwill is expected to be deductible for income tax purposes. The Company completed its valuations of in-process research and development assets and the contingent milestone and royalty payments as of September 30, 2011 and completed its valuation of the deferred tax liability, Alios' net other assets (liabilities) and goodwill in the fourth quarter of 2011. There were no material changes to the preliminary amounts the Company recorded. The following table summarizes the fair values of the assets and liabilities recorded on the effective date of the Alios Collaboration:

	<b>Fair Values as of June 13, 2011 (in thousands)</b>
Intangible assets	\$ 250,600
Goodwill	4,890
Deferred tax liability	(90,935)
Net other assets	2,230
<b>Net assets attributable to noncontrolling interest (Alios)</b>	<b>\$ 166,785</b>

If the Company is successful in developing an Alios HCV nucleotide analogue, it will amortize as part of cost of product revenues the carrying value of the related in-process research and development asset over the remaining estimated life of the asset, beginning in the period in which the project is completed. If the Company determines that an in-process research and development asset has become impaired or abandons development of the Alios HCV nucleotide analogues, it 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.

The Company tests Alios' intangible assets and goodwill for impairment on an annual basis as of October 1, and more frequently if indicators are present or changes in circumstance suggest that impairment may exist. In connection with each annual impairment assessment and any interim impairment assessment, the Company will compare the fair value of the asset as of the date of the assessment with the carrying value of the asset on the Company's consolidated balance sheet.

Noncontrolling Interest (Alios)

The Company recorded noncontrolling interest (Alios) on two lines on its consolidated balance sheet beginning as of the effective date of the Alios Agreement. The noncontrolling interest (Alios) is reflected on two separate lines because Alios has both common shareholders and preferred shareholders that are entitled to redemption rights in certain circumstances. The aggregate fair value of the noncontrolling interest on June 13, 2011 was equal to the up-front payment and the fair value of the contingent payments under the Alios Collaboration less the deferred tax liability.

The Company records net income (loss) attributable to noncontrolling interest (Alios) on its consolidated statements of operations, reflecting Alios' net income (loss) for the reporting period,

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## VERTEX PHARMACEUTICALS INCORPORATED

## Notes to Consolidated Financial Statements (Continued)

**B. Collaborative Arrangements (Continued)**

adjusted for changes in fair value of contingent milestone and royalty payments, which are evaluated each reporting period. During 2011, the fair value of contingent milestone and royalties increased by \$70.0 million based on the advancement of ALS-2200 and ALS-2158 into Phase 1 clinical trials, which reduced net income attributable to Vertex. If the Alios HCV nucleotide analogues continue to advance in clinical development, the Company expects it will record increases in the fair value of the contingent milestone and royalty payments.

Activity Related to the Alios Collaboration

A summary of net income attributable to noncontrolling interest (Alios) from June 13, 2011 to December 31, 2011 was as follows:

	<b>June 13, 2011 to December 31, 2011</b>	
	<b>(in thousands)</b>	
Loss before provision for income taxes	\$	(9,536)
Provision for income taxes		(48,809)
Change in fair value of contingent milestone and royalty payments		69,950
Net income attributable to noncontrolling interest (Alios)	\$	11,605

Since the effective date of the collaboration, the Company has consolidated all of Alios' expenses and revenues into its consolidated statement of operations, eliminating all intercompany balances and transactions. Pro forma results of operations for 2011, 2010 and 2009, assuming the transaction had taken place at the beginning of each period, would not differ significantly from Vertex's actual reported results.

Alios Balance Sheet Information

The following summarizes items related to Alios included in the Company's consolidated balance sheets as of June 13, 2011 and December 31, 2011:

	<b>As of</b>	
	<b>June 13, 2011</b>	<b>December 31, 2011</b>
	<b>(in thousands)</b>	
Restricted cash and cash equivalents (Alios)	\$ 4,575	\$ 51,878
Accounts receivable, net		
Prepaid expenses and other current assets	69	2,299
Property and equipment, net	885	1,925
Intangible assets	250,600	250,600
Goodwill	4,890	4,890
Other assets	76	133
Accounts payable	1,189	4,132
Accrued expenses and other current liabilities	1,504	4,291
Accrued interest		13
Income taxes payable (Alios)		12,075
Deferred tax liability	90,935	116,121
Other liabilities	682	1,030
Redeemable noncontrolling interest (Alios)	36,299	37,036
Noncontrolling interest (Alios)	130,486	141,633

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**VERTEX PHARMACEUTICALS INCORPORATED**

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

**B. Collaborative Arrangements (Continued)**

The Company has recorded Alios' cash and cash equivalents as restricted cash and cash equivalents (Alios) because (i) the Company does not have any interest in or control over Alios' cash and cash equivalents and (ii) the Alios Agreement does not provide for these assets to be used for the development of the assets that the Company licensed from Alios pursuant to the collaboration. Assets recorded as a result of consolidating Alios' financial condition into the Company's consolidated balance sheets do not represent additional assets that could be used to satisfy claims against the Company's general assets.

**C. 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 non-nucleoside HCV polymerase inhibitors to Vertex's HCV drug development portfolio. As of December 31, 2011, the Company is continuing development of one of these two non-nucleoside HCV polymerase inhibitors, VX-222. At the time of the acquisition, ViroChem also was 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 Company accounted for the transaction under the acquisition method of accounting. The Company recognized all of the assets acquired and liabilities assumed in the transaction at their acquisition-date fair values and expensed as incurred all transaction costs and restructuring costs associated with the transaction. The intangible assets and goodwill related to the ViroChem acquisition are tested for impairment on an annual basis as of October 1, and more frequently if indicators are present or changes in circumstance suggest that impairment may exist.

The Company consolidated ViroChem's operating results with those of Vertex beginning on the date of the acquisition. ViroChem had no revenues in the period from the acquisition date through December 31, 2009. Pro forma results of operations for the year ended December 31, 2009, assuming the acquisition of ViroChem had taken place at the beginning of 2009, would not differ significantly from Vertex's actual reported results.

The Company allocated the purchase price of \$390.6 million for the acquisition of 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. All of the intangible assets acquired in the ViroChem acquisition related to in-process research and development assets. The in-process research and development assets primarily related to ViroChem's two clinical development-stage non-nucleoside HCV polymerase inhibitors, VX-222 and VX-759. As of December 31, 2011 and 2010, VX-222 accounted for \$412.9 million of the intangible assets reflected on the Company's consolidated balance sheets. No impairment has been found for VX-222 since the acquisition date.

As of December 31, 2010, VX-759 accounted for \$105.8 million of the intangible assets reflected on the Company's consolidated balance sheet. In connection with its preparation of its financial statements for the third quarter of 2011, the Company identified certain factors that were considered impairment indicators related to VX-759. As a result, the Company determined that the value of VX-759, the back-up to VX-222, had become impaired. The Company evaluated VX-759 for impairment in the third quarter of 2011 after receiving (A) information from its ongoing Phase 2a

Table of Contents**VERTEX PHARMACEUTICALS INCORPORATED****Notes to Consolidated Financial Statements (Continued)****C. Acquisition of ViroChem Pharma Inc. (Continued)**

clinical trials of VX-222 including (i) interim data from treatment arms involving the administration of telaprevir, VX-222, pegylated-interferon and ribavirin that suggested the potential to treat patients with genotype 1 HCV infection in as few as 12 weeks and no more than 24 weeks, (ii) in September 2011, final sustained viral response data from these treatment arms and (iii) in the third quarter of 2011, completion of enrollment in the two all-oral treatment arms of this clinical trial, and (B) information regarding potentially competitive drug candidates. Based on the review and consideration of the information regarding the Phase 2a clinical trial, the Company decided to continue developing VX-222, and determined that based on the advancement of VX-222 it was not likely to pursue further development of VX-759. In connection with its impairment evaluation, the Company considered the fair value that would be attributed to VX-759 by a market participant, based on present-value models that were based upon multiple scenarios involving the development and potential commercialization of VX-759, and determined that a market participant would assign a negative fair value to the potential development of VX-759. The Company based this determination on the following: (i) VX-759 was not being evaluated in clinical trials and had only been evaluated in Phase 1 clinical trials in a small number of patients and (ii) drug candidates that would potentially be competitive to VX-759, including VX-222 and drug candidates being developed by the Company's competitors, had been evaluated in Phase 2 clinical trials and therefore, if successful, these drug candidates would reach the market in advance of VX-759. In addition, other drug candidates, including VX-222, continued to have more promising clinical and nonclinical data to support their continued development and commercial potential than the clinical and nonclinical data available for VX-759. Based on this evaluation, the Company determined that the probability of VX-759 reaching the market had decreased significantly and the resulting revenues and market share assumptions included in the Company's present value models also had decreased significantly. Accordingly, the Company determined that the fair value of VX-759 was zero dollars as of September 30, 2011, resulting in a \$105.8 million impairment charge, which was recorded as an operating expense during the three months ended September 30, 2011. In connection with this impairment charge, the Company recorded an adjustment of \$32.7 million to its deferred tax liability.

In addition to the two non-nucleoside HCV polymerase inhibitors, at the time of the acquisition 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. In 2009, the Company determined that the fair value of VCH-286 was zero dollars, 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.

The Company's consolidated balance sheets also reflect goodwill that relates to the potential synergies from the possible development of combination therapies involving telaprevir and the acquired drug candidates. No impairment has been found for goodwill since the acquisition date. None of the goodwill is expected to be deductible for income tax purposes.

The deferred tax liability related to ViroChem of \$127.6 million and \$160.3 million, respectively, recorded as of December 31, 2011 and 2010 primarily relates to the tax impact of future amortization or impairments associated with the identified intangible assets acquired from ViroChem, which are not deductible for tax purposes.

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**VERTEX PHARMACEUTICALS INCORPORATED**

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

**C. Acquisition of ViroChem Pharma Inc. (Continued)**

*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 statement of operations for 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 programs. As a result of this restructuring plan, which was completed in the second quarter of 2009, Vertex recorded a \$2.1 million expense due to employee severance, benefits and related costs in 2009.

**D. Earnings Per Share**

Basic net loss attributable to Vertex 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 attributable to Vertex 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.

Basic and diluted net income attributable to Vertex per common share are presented in conformity with the two-class method required for participating securities. Under the two-class method, earnings are allocated to (i) Vertex common shares, excluding shares of restricted stock that have been issued but have not yet vested, and (ii) participating securities, based on their respective weighted-average shares outstanding for the period. The shares of unvested restricted stock have the non-forfeitable right to receive dividends on an equal basis with other outstanding common stock. As a result, these unvested shares of restricted stock are considered participating securities that must be included in the calculation of basic and diluted net income attributable to Vertex per common share using the two-class method. Potentially dilutive shares result from the assumed exercise of outstanding stock options (the

Table of Contents**VERTEX PHARMACEUTICALS INCORPORATED****Notes to Consolidated Financial Statements (Continued)****D. Earnings Per Share (Continued)**

proceeds of which are then assumed to have been used to repurchase outstanding stock using the treasury stock method) and the assumed conversion of convertible notes.

	Year Ended December 31,		
	2011	2010	2009
	(in thousands)		
<i>Basic net income (loss) attributable to Vertex per common share calculation:</i>			
Net income (loss) attributable to Vertex common shareholders	\$ 29,574	\$ (754,626)	\$ (642,178)
Less: Undistributed earnings allocated to participating securities	(291)		
Net income (loss) attributable to Vertex common shareholders basic	\$ 29,283	\$ (754,626)	\$ (642,178)
Basic weighted-average common shares outstanding	204,891	200,402	173,259
Basic net income (loss) attributable to Vertex per common share	\$ 0.14	\$ (3.77)	\$ (3.71)
<i>Diluted net income (loss) attributable to Vertex per common share calculation:</i>			
Net income (loss) attributable to Vertex common shareholders	\$ 29,574	\$ (754,626)	\$ (642,178)
Less: Undistributed earnings allocated to participating securities	(285)		
Net income (loss) attributable to Vertex common shareholders diluted	\$ 29,289	\$ (754,626)	\$ (642,178)
Weighted-average shares used to compute basic net income (loss) per common share	204,891	200,402	173,259
Effect of potentially dilutive securities:			
Stock options	3,863		
Other	53		
Weighted average shares used to compute diluted net income (loss) per common share	208,807	200,402	173,259
Diluted net income (loss) attributable to Vertex per common share	\$ 0.14	\$ (3.77)	\$ (3.71)

The Company did not include the securities described in the following table in the computation of the net income (loss) attributable to Vertex per common share calculations because the effect would have been anti-dilutive during each such period:

	Year Ended December 31,		
	2011	2010	2009
	(in thousands)		
Stock options	9,626	21,293	19,232
Convertible senior subordinated notes	8,192	8,192	1,386
Unvested restricted stock and restricted stock units	8	1,950	1,727

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**VERTEX PHARMACEUTICALS INCORPORATED**

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

**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 the credit quality standards outlined in the Company's investment policy. This policy also limits the amount of credit exposure to any one issue or type of instrument. As of December 31, 2011, the Company's investments were in money market funds, short-term U.S. Treasury securities and short-term government-sponsored enterprise securities.

As of December 31, 2011, 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. Treasury securities and government-sponsored enterprise securities. The Company's money market fund also invests in government-sponsored enterprise securities. During 2011, 2010 and 2009, the Company did not record an other-than-temporary impairment charge related to its financial assets. During the third quarter of 2011, the Company evaluated VX-759 for impairment using Level 3 inputs. Please refer to Note C, "Acquisition of ViroChem Pharma Inc." for further information. 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 and were valued based on Level 3 inputs. Please refer to Note N, "September 2009 Financial Transactions," for further information. The Company's noncontrolling interest (Alios) includes the fair value of the contingent milestone and royalty payments, which is valued based on Level 3 inputs. Please refer to Note B, "Collaborative Arrangements," for further information.

Table of Contents**VERTEX PHARMACEUTICALS INCORPORATED****Notes to Consolidated Financial Statements (Continued)****E. Fair Value of Financial Instruments (Continued)**

The following table sets forth the Company's financial assets (excluding Alios' cash equivalents) subject to fair value measurements as of December 31, 2011:

	Fair Value Measurements as of December 31, 2011			
	Total	Fair Value Hierarchy		
		Level 1	Level 2	Level 3
				(in thousands)
Financial assets carried at fair value:				
Cash equivalents:				
Money market funds	\$ 222,225	\$ 222,225	\$	\$
Government-sponsored enterprise securities	113,285	113,285		
Marketable securities:				
U.S. Treasury securities	22,107	22,107		
Government-sponsored enterprise securities	471,495	471,495		
Restricted cash	34,090	34,090		
<b>Total</b>	<b>\$ 863,202</b>	<b>\$ 863,202</b>	<b>\$</b>	<b>\$</b>

Alios' cash equivalents of \$49.0 million as of December 31, 2011 consist of money market funds, which are valued based on Level 1 inputs.

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

	Year Ended December 31, 2011
	(in thousands)
Balance, December 31, 2010	\$ 89,888
Change in fair value of derivative instruments	16,801
Redemption of the 2012 Notes and settlement of the liability related to the sale of milestone rights	(106,689)
Balance, December 31, 2011	\$

As of December 31, 2011, the Company had \$400.0 million in aggregate principal amount of 3.35% convertible senior subordinated notes due 2015 (the "2015 Notes") on its consolidated balance sheet. At December 31, 2011, these 2015 Notes had a fair value of approximately \$414 million as obtained from a quoted market source.



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## VERTEX PHARMACEUTICALS INCORPORATED

## Notes to Consolidated Financial Statements (Continued)

**F. Marketable Securities**

A summary of the Company's cash, cash equivalents and marketable securities is shown below:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(in thousands)			
<b>December 31, 2011</b>				
Cash and cash equivalents:				
Cash and money market funds	\$ 362,035	\$	\$	\$ 362,035
Government-sponsored enterprise securities	113,302		(17)	113,285
<b>Total cash and cash equivalents</b>	<b>\$ 475,337</b>	<b>\$</b>	<b>\$ (17)</b>	<b>\$ 475,320</b>
Marketable securities:				
U.S. Treasury securities (due within 1 year)	\$ 22,105	\$ 2	\$	\$ 22,107
Government-sponsored enterprise securities (due within 1 year)	471,589	8	(102)	471,495
<b>Total marketable securities</b>	<b>\$ 493,694</b>	<b>\$ 10</b>	<b>\$ (102)</b>	<b>\$ 493,602</b>
<b>Total cash, cash equivalents and marketable securities</b>	<b>\$ 969,031</b>	<b>\$ 10</b>	<b>\$ (119)</b>	<b>\$ 968,922</b>
<b>December 31, 2010</b>				
Cash and cash equivalents:				
Cash and money market funds	\$ 193,845	\$	\$	\$ 193,845
U.S. Treasury securities	4,770			4,770
Government-sponsored enterprise securities	44,587	1	(6)	44,582
<b>Total cash and cash equivalents</b>	<b>\$ 243,202</b>	<b>\$ 1</b>	<b>\$ (6)</b>	<b>\$ 243,197</b>
Marketable securities:				
U.S. Treasury securities (due within 1 year)	\$ 103,230	\$ 1	\$ (11)	\$ 103,220
Government-sponsored enterprise securities (due within 1 year)	684,969	87	(62)	684,994
<b>Total marketable securities</b>	<b>\$ 788,199</b>	<b>\$ 88</b>	<b>\$ (73)</b>	<b>\$ 788,214</b>
<b>Total cash, cash equivalents and marketable securities</b>	<b>\$ 1,031,401</b>	<b>\$ 89</b>	<b>\$ (79)</b>	<b>\$ 1,031,411</b>

Alios' \$51.9 million of cash and money market funds as of December 31, 2011, recorded on the Company's consolidated balance sheet in "Restricted cash and cash equivalents (Alios)," are not included in the above table.

**G. Inventories**

As of December 31, 2011, all of the Company's inventories related to INCIVEK. The following table sets forth the Company's inventories:

	At December 31,	
	2011	2010
	(in thousands)	
Raw materials	\$ 32,213	\$
Work in process	47,010	
Finished goods	33,207	

Total \$ 112,430 \$

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Table of Contents**VERTEX PHARMACEUTICALS INCORPORATED****Notes to Consolidated Financial Statements (Continued)****G. Inventories (Continued)**

On January 1, 2011, the Company began capitalizing inventory costs for INCIVEK manufactured in preparation for the product launch in the United States based on its evaluation of, among other factors, information regarding INCIVEK's safety and efficacy and the status of the INCIVEK new drug application. The FDA approved INCIVEK on May 23, 2011. In periods prior to January 1, 2011, the Company expensed costs associated with INCIVEK raw materials, work in process and finished goods as development expenses. As of December 31, 2011, the Company has not capitalized inventory costs related to its other drug development programs. The Company expects to begin capitalizing KALYDECO inventories as of January 1, 2012.

**H. Property and Equipment**

Property and equipment, net consisted of the following:

	<b>At December 31,</b>	
	<b>2011</b>	<b>2010</b>
	<b>(in thousands)</b>	
Furniture and equipment	\$ 151,961	\$ 137,904
Leasehold improvements	107,169	102,720
Software	56,923	50,211
Computers	33,116	28,817
Construction-in-progress	55,070	
Total property and equipment, gross	404,239	319,652
Less accumulated depreciation and amortization	271,063	247,319
Total property and equipment, net	\$ 133,176	\$ 72,333

Construction-in-progress as of December 31, 2011 included \$54.7 million related to construction costs incurred by the landlord at Fan Pier in Boston, Massachusetts. Please refer to Note I, "Fan Pier Leases," for further information.

Depreciation and amortization expense for the years ended December 31, 2011, 2010 and 2009 was \$28.9 million, \$27.9 million and \$28.3 million, respectively.

In 2011, 2010 and 2009, 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 \$55,000 in 2011, \$39,000 in 2010 and \$2.2 million in 2009.

**I. Fan Pier Leases**

On May 5, 2011, the Company entered into two leases, pursuant to which the Company agreed to lease approximately 1.1 million square feet of office and laboratory space in two buildings to be built at Fan Pier in Boston, Massachusetts (the "Fan Pier Leases"). The Fan Pier Leases will commence upon completion of the buildings (the "Buildings"), scheduled for late 2013, and will extend for 15 years from the commencement date. The Company has an option to extend the term of the Fan Pier Leases for an additional ten years.

Because the Company is involved in the construction project, including having responsibility to pay for a portion of the costs of tenant improvements and structural elements of the Buildings, the

Table of Contents**VERTEX PHARMACEUTICALS INCORPORATED****Notes to Consolidated Financial Statements (Continued)****I. Fan Pier Leases (Continued)**

Company is deemed for accounting purposes to be the owner of the Buildings during the construction period. Accordingly, the Company has recorded, as of December 31, 2011, \$54.7 million of project construction costs incurred by the landlord as an asset and a corresponding financing obligation in "Property and equipment, net" and "Construction financing obligation," respectively, on the Company's consolidated balance sheet.

The Company bifurcates its future lease payments pursuant to the Fan Pier Leases into (i) a portion that is allocated to the Buildings and (ii) a portion that is allocated to the land on which the Buildings are being built. Although the Company will not begin making lease payments pursuant to the Fan Pier Leases until the Company occupies the Buildings, the portion of the lease obligations allocated to the land is treated for accounting purposes as an operating lease that commenced in the second quarter of 2011. The Company recorded \$3.9 million in expense related to this operating lease during 2011.

Once the construction of the Buildings is completed, the Company will evaluate the Fan Pier Leases in order to determine whether or not the leases meet the criteria for "sale-leaseback" treatment. The Company expects that upon completion of construction of the Buildings the Fan Pier Leases will not meet the "sale-leaseback" criteria. If the Fan Pier Leases do not meet "sale-leaseback" criteria, the Company will treat the Buildings as a financing obligation and the asset will be depreciated over its estimated useful life. If the Fan Pier Leases meet the "sale-leaseback" criteria, the Company will remove the asset and the related liability from its consolidated balance sheet and treat the Fan Pier Leases as either operating or capital leases based on the Company's assessment of the accounting guidance.

**J. Accrued Expenses and Other Current Liabilities**

Accrued expenses and other current liabilities consisted of the following:

	<b>At December 31,</b>	
	<b>2011</b>	<b>2010</b>
	<b>(in thousands)</b>	
Research and development contract costs	\$ 66,426	\$ 55,506
Payroll and benefits	57,453	50,041
Product revenue allowances	58,201	
Royalty payable	28,603	2,869
State income taxes	3,691	
Unrecognized tax benefits	4,360	2,374
Professional fees	12,785	8,629
Other	20,780	14,995
<b>Total</b>	<b>\$ 252,299</b>	<b>\$ 134,414</b>

**K. Common Stock Offerings and Convertible Senior Subordinated Notes****Common Stock Offerings**

In December 2009, the Company completed an offering of 13,000,000 shares of common stock, which were sold at a price of \$38.50 per share. This offering resulted in \$488.1 million of net proceeds

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**VERTEX PHARMACEUTICALS INCORPORATED**

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

**K. Common Stock Offerings and Convertible Senior Subordinated Notes (Continued)**

to the Company. The underwriting discount of \$12.1 million and other expenses of \$0.3 million were recorded as an offset to additional paid-in capital.

In February 2009, the Company completed an offering of 10,000,000 shares of common stock, 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 were recorded as an offset to additional paid-in capital.

**Convertible Senior Subordinated Notes**

*Convertible Senior Subordinated Notes (due 2015)*

In September 2010, the Company completed an offering of \$400.0 million in aggregate principal amount of 2015 Notes. This offering resulted in \$391.6 million of net proceeds to the Company. The underwriting discount of \$8.0 million and other expenses of \$0.4 million were recorded as debt issuance costs and are included in other assets on the Company's consolidated balance sheets. The 2015 Notes were issued pursuant to and are governed by the terms of an indenture (as supplemented, the "Indenture").

The 2015 Notes are convertible at any time, at the option of the holder, into common stock at a price equal to approximately \$48.83 per share, or 20.4794 shares of common stock per \$1,000 principal amount of the 2015 Notes, subject to adjustment. The 2015 Notes bear interest at the rate of 3.35% per annum, and the Company is required to make semi-annual interest payments on the outstanding principal balance of the 2015 Notes on April 1 and October 1 of each year. The 2015 Notes mature on October 1, 2015.

Prior to October 1, 2013, if the closing price of the Company's common stock has exceeded 130% of the then applicable conversion price for at least 20 trading days within a period of 30 consecutive trading days, the Company may redeem the 2015 Notes at its option, in whole or in part, at a redemption price equal to 100% of the principal amount of the 2015 Notes to be redeemed. If the Company elects to redeem the 2015 Notes prior to October 1, 2013, or the holder elects to convert the 2015 Notes after receiving notice of such redemption, the Company will be obligated to make an additional payment, payable in cash or, subject to certain conditions, shares of the Company's common stock, so that the Company's total interest payments on the 2015 Notes being redeemed and such additional payment shall equal three years of interest. On or after October 1, 2013, the Company may redeem the 2015 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 2015 Notes upon the occurrence of certain fundamental changes of Vertex, as set forth in the Indenture, at 100% of the principal amount of the 2015 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 2015 Notes in connection with any such transaction by increasing the applicable conversion rate on such 2015 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 2015 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

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**VERTEX PHARMACEUTICALS INCORPORATED**

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

**K. Common Stock Offerings and Convertible Senior Subordinated Notes (Continued)**

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.

Based on the Company's evaluation of the 2015 Notes, the Company determined that the 2015 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 securities reporting obligations pursuant to the 2015 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 September 28, 2010, the issue date of the 2015 Notes, December 31, 2010, and December 31, 2011.

*Convertible Senior Subordinated Notes (due 2013)*

On January 1, 2009, the Company had outstanding \$287.5 million in aggregate principal amount of 4.75% convertible senior subordinated notes due 2013 (the "2013 Notes"). The 2013 Notes were convertible, at the option of the holder, into common stock at a price equal to \$23.14 per share or 43.22 shares of common stock per \$1,000 in principal amount of the 2013 Notes. The 2013 Notes bore interest at the rate of 4.75% per annum, and the Company was 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 Company had the right to redeem the 2013 Notes, in whole or in part, on or after February 15, 2010, at the redemption prices stated in the indenture, plus accrued and unpaid interest to, but excluding, the redemption date. The 2013 Notes would have matured on February 15, 2013.

In 2009, the Company exchanged \$255.4 million in aggregate principal amount of the 2013 Notes, plus accrued interest, for 11,581,838 shares of newly-issued common stock. As a result of these exchanges, the Company incurred non-cash charges of \$18.1 million related to the incremental shares that were issued to induce the holders of the 2013 Notes to enter into these exchanges. In addition, accrued interest of \$3.4 million and unamortized debt issuance costs of the 2013 Notes of \$5.9 million were recorded as an offset to additional paid-in capital.

In the first quarter of 2010, the Company announced that it would redeem the remaining \$32.1 million in aggregate principal amount of the 2013 Notes on March 19, 2010. Instead, the holders of the remaining 2013 Notes elected to convert their 2013 Notes, pursuant to the original terms of the 2013 Notes, into 1,386,006 shares of newly-issued common stock in full satisfaction of the 2013 Notes. Accrued interest of \$0.1 million and unamortized debt issuance costs of the 2013 Notes of \$0.6 million were recorded as an offset to additional paid-in capital.

**L. Preferred Stock, Common Stock and Equity Plans**

The Company is authorized to issue 1,000,000 shares of preferred stock in one or more series and to fix the powers, designations, preferences and relative participating, option or other rights thereof, including dividend rights, conversion rights, voting rights, redemption terms, liquidation preferences and the number of shares constituting any series, without any further vote or action by the Company's shareholders. As of December 31, 2011 and 2010, the Company had no shares of preferred stock issued or outstanding.

The Company is authorized to issue 300,000,000 shares of common stock. Holders of common stock are entitled to one vote per share. Holders of common stock are entitled to receive dividends, if

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## VERTEX PHARMACEUTICALS INCORPORATED

## Notes to Consolidated Financial Statements (Continued)

**L. Preferred Stock, Common Stock and Equity Plans (Continued)**

and when declared by the Company's Board of Directors, and to share ratably in the Company's assets legally available for distribution to the Company's shareholders in the event of liquidation. Holders of common stock have no preemptive, subscription, redemption or conversion rights. The holders of common stock do not have cumulative voting rights.

*Stock and Option Plans*

The purpose of each of the Company's stock and option plans is to attract, retain and motivate its employees, consultants and directors. Awards granted under these plans can be incentive stock options ("ISOs"), nonstatutory stock options ("NSOs"), restricted stock ("RSs"), restricted stock units ("RSUs") or other equity-based awards, as specified in the individual plans.

Shares issued under all of the Company's plans are funded through the issuance of new shares. The following table contains information about the Company's equity plans:

Title of Plan	Group Eligible	Type of Award Granted	As of December 31, 2011	
			Awards Outstanding	Additional Awards Authorized for Grant
2006 Stock and Option Plan	Employees, Non-employee Directors and Consultants	NSO, ISO, RS and RSU	19,889,776	8,631,417
1996 Stock and Option Plan	Employees, Non-employee Directors, Advisors and Consultants	NSO, ISO and RS	3,177,457	
<b>Total</b>			<b>23,067,233</b>	<b>8,631,417</b>

All options granted under the Company's 2006 Stock and Option Plan ("2006 Plan") and 1996 Stock and Option Plan were granted with an exercise price equal to the fair value of the underlying common stock on the date of grant. As of December 31, 2011, the only stock and option plan under which the Company makes new equity awards is the Company's 2006 Plan. Under the 2006 Plan, no stock options can be awarded with an exercise price less than the fair market value on the date of grant. The Company's shareholders approved increases in the number of shares authorized for issuance pursuant to the 2006 Plan of 12,000,000 shares and 7,700,000 shares, respectively, in 2010 and 2009.

During the three years ended December 31, 2011, grants to current employees and directors had a grant date that was the same as the date the award was approved by the Company's Board of Directors. During the three years ended December 31, 2011, for grants to new employees and directors, the date of grant for awards was the employee's first day of employment or the date the director was elected to the Company's Board of Directors. All options awarded under the Company's stock and option plans expire not more than ten years from the grant date.

During the three years ended December 31, 2011, all shares of outstanding restricted stock and restricted stock units have been granted at price equal to \$0.01, the par value of the Company's common stock. Vesting of options, restricted stock and restricted stock units generally is ratable over specified periods, usually four years, and is determined by the Company's Board of Directors.

Table of Contents**VERTEX PHARMACEUTICALS INCORPORATED****Notes to Consolidated Financial Statements (Continued)****L. Preferred Stock, Common Stock and Equity Plans (Continued)**

The following table summarizes information related to the outstanding and vested options during the year ended December 31, 2011:

	Stock Options (in thousands)	Weighted-average Exercise Price (per share)	Weighted-average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2010	21,293	\$ 30.50		
Granted	5,754	43.55		
Exercised	(4,119)	26.60		
Forfeited	(1,554)	36.78		
Expired	(451)	37.81		
Outstanding at December 31, 2011	20,923	\$ 34.23	6.84	\$ 56,376
Exercisable at December 31, 2011	12,225	\$ 30.59	5.55	\$ 53,552
Total exercisable or expected to vest at December 31, 2011	19,922	\$ 33.94	6.74	\$ 56,108

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 30, 2011 (the last trading day of 2011), which was \$32.92 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 2011, 2010 and 2009 was \$90.5 million, \$10.5 million and \$36.4 million, respectively. The total cash received from employees as a result of employee stock option exercises during 2011, 2010 and 2009 was \$109.6 million, \$22.2 million and \$38.2 million, respectively.

The following table summarizes information about stock options outstanding and exercisable at December 31, 2011:

Range of Exercise Prices	Number Outstanding (in thousands)	Options Outstanding		Options Exercisable	
		Remaining Contractual Life (in years)	Weighted-average Exercise Price (per share)	Number Exercisable (in thousands)	Weighted-average Exercise Price (per share)
\$ 9.07 \$20.00	2,751	2.99	\$ 15.52	2,689	\$ 15.44
\$20.01 \$30.00	1,902	6.71	\$ 28.89	1,363	\$ 28.61
\$30.01 \$40.00	13,790	7.16	\$ 35.70	7,804	\$ 35.17
\$40.01 \$50.00	403	9.04	\$ 44.53	69	\$ 44.54
\$50.01 \$57.27	2,077	9.47	\$ 52.17	300	\$ 53.12

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Table of Contents**VERTEX PHARMACEUTICALS INCORPORATED****Notes to Consolidated Financial Statements (Continued)****L. Preferred Stock, Common Stock and Equity Plans (Continued)**

The following table summarizes the restricted stock activity of the Company during the year ended December 31, 2011:

	<b>Restricted Stock</b>	<b>Weighted-average Grant-date Fair Value</b>
	<b>(in thousands)</b>	<b>(per share)</b>
Unvested at December 31, 2010	1,931	\$ 33.35
Granted	1,185	41.04
Vested	(747)	33.97
Cancelled	(269)	36.01
Unvested at December 31, 2011	2,100	\$ 37.13

The total fair value of the restricted stock vesting during 2011, 2010 and 2009 (measured on the date of vesting) was \$34.6 million, \$20.1 million and \$26.5 million, respectively.

*Employee Stock Purchase Plan*

The Company has an employee stock purchase plan (the "ESPP"). 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. As of December 31, 2011, there were 482,000 shares of common stock authorized for issuance pursuant to the ESPP.

During the year ended December 31, 2011, the following shares were issued to employees under the ESPP:

	<b>Year Ended December 31, 2011 (in thousands, except per share amount)</b>
Number of shares	557
Average price paid per share	\$ 27.47

**M. 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 and restricted stock units typically is based on the intrinsic value on the date of grant. Stock-based compensation, measured at the grant date based on the fair value of the award, is typically recognized as expense ratably over the service period. The expense recognized over the service period includes an estimate of awards that will be forfeited.

Table of Contents**VERTEX PHARMACEUTICALS INCORPORATED****Notes to Consolidated Financial Statements (Continued)****M. Stock-based Compensation Expense (Continued)**

The effect of stock-based compensation expense during the three years ended December 31, 2011 was as follows:

	2011	2010	2009
	(in thousands)		
Stock-based compensation expense by line item:			
Research and development expenses	\$ 75,574	\$ 65,198	\$ 64,128
Sales, general and administrative expenses	42,652	25,926	22,594
Total stock-based compensation expense included in costs and expenses	\$ 118,226	\$ 91,124	\$ 86,722

During 2011, the Company capitalized \$1.0 million of stock-based compensation expense to inventories, all of which was attributable to employees who supported the Company's manufacturing operations related to INCIVEK.

The stock-based compensation expense by type of award during the three years ended December 31, 2011 was as follows:

	2011	2010	2009
	(in thousands)		
Stock-based compensation expense by type of award:			
Stock options	\$ 83,098	\$ 64,005	\$ 63,397
Restricted stock and restricted stock units	30,708	22,960	18,983
ESPP share issuances	5,462	4,159	4,342
Less stock-based compensation expense capitalized to inventories	(1,042)		
Total stock-based compensation expense included in costs and expenses	\$ 118,226	\$ 91,124	\$ 86,722

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 and severance arrangements with certain of the Company's former executive officers. 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 and severance arrangements with certain of the Company's former executive officers.

The following table sets forth the Company's unrecognized stock-based compensation expense, net of estimated forfeitures, as of December 31, 2011 by type of award and the weighted-average period over which that expense is expected to be recognized:

	As of December 31, 2011	
	Unrecognized Expense Net of Estimated Forfeitures (in thousands)	Weighted-average Recognition Period (in years)
Type of award:		
Stock options	\$ 139,165	2.73
Restricted stock and restricted stock units	44,744	2.25
ESPP share issuances	5,128	0.65
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Table of Contents**VERTEX PHARMACEUTICALS INCORPORATED****Notes to Consolidated Financial Statements (Continued)****M. Stock-based Compensation Expense (Continued)***Stock Options*

The Company issues stock options with service conditions, which are generally the vesting periods of the awards. In 2009, the Company also issued, to certain members of senior management, stock options that vest upon the earlier of the satisfaction of (1) performance conditions or (2) a service condition. If the Company estimates that it is probable that a performance condition will be met over a period shorter than the vesting period, the Company recognizes stock-based compensation expense related to the shares that would vest upon the performance condition over an implicit service period equal to the period that the Company estimates will be required to meet the performance condition. 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 options granted during 2011, 2010 and 2009 had a weighted-average grant-date fair value per share of \$20.88, \$18.52 and \$19.11, respectively.

The fair value of each option granted during 2011, 2010 and 2009 was estimated on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions:

	2011	2010	2009
Expected stock price volatility	49.53%	52.17%	57.77%
Risk-free interest rate	2.09%	2.44%	2.85%
Expected term of options	5.74 years	5.71 years	6.31 years
Expected annual dividends			

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.

*Restricted Stock and Restricted Stock Units*

The Company issues restricted stock and restricted stock units with service conditions, which are generally the vesting periods of the awards. The Company also issues, to certain members of senior

Table of Contents**VERTEX PHARMACEUTICALS INCORPORATED****Notes to Consolidated Financial Statements (Continued)****M. Stock-based Compensation Expense (Continued)**

management, restricted stock and restricted stock units that vest upon the earlier of the satisfaction of (i) a market or performance condition or (ii) a service condition.

*Employee Stock Purchase Plan*

The weighted-average fair value of each purchase right granted during 2011, 2010 and 2009 was \$9.80, \$10.19 and \$11.31, respectively. The following table reflects the weighted-average assumptions used in the Black-Scholes option pricing model for 2011, 2010 and 2009:

	2011	2010	2009
Expected stock price volatility	51.32%	43.92%	54.22%
Risk-free interest rate	0.08%	0.24%	0.39%
Expected term	0.72 years	0.71 years	0.76 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.

**N. September 2009 Financial Transactions***2012 Notes*

In September 2009, the Company sold \$155.0 million in aggregate 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 were 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. 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 telaprevir milestone payments that the Company was eligible to earn from Janssen for the filing, approval and launch of telaprevir in the European Union.

The 2012 Notes were issued at a discount and did not pay current interest prior to maturity. The 2012 Notes were scheduled to mature on October 31, 2012, subject to earlier mandatory redemption to the extent that specified milestone events set forth in the Company's collaboration with Janssen occurred prior to October 31, 2012. In February 2011, the Company received a milestone payment of \$50.0 million and subsequently redeemed \$50.0 million of 2012 Notes pursuant to their terms. The remaining \$105.0 million of 2012 Notes were redeemed on October 31, 2011, with the proceeds of milestone payments received from Janssen in October 2011.

The 2012 Notes contained an embedded derivative related to the potential mandatory redemption or early repayment of the 2012 Notes at the face 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. The Company determined the fair value of the embedded derivative based on a probability-weighted model of the discounted value that market participants would ascribe to the potential mandatory redemption and early repayment features

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**VERTEX PHARMACEUTICALS INCORPORATED**

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

**N. September 2009 Financial Transactions (Continued)**

of the outstanding 2012 Notes. The fair value of this embedded derivative was evaluated quarterly, with any changes in the fair value of the embedded derivative resulting in a corresponding loss or gain. The Company recorded quarterly interest expense related to the 2012 Notes using the effective interest rate method. The liabilities related to the 2012 Notes, including the embedded derivative, were reflected together on the Company's consolidated balance sheet as of December 31, 2010.

*Sale of Contingent 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 contingent milestone payments under the Janssen agreement related to the launch of telaprevir in the European Union, for nonrefundable payments totaling \$32.8 million. The purchase agreements contained representations, warranties, covenants and indemnification obligations of each party. The Purchaser received the \$95.0 million in milestone payments from Janssen in October 2011.

The Company determined that this sale of a future revenue stream should be accounted for as a liability because the Company had significant continuing involvement in the generation of the 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 were 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 were free-standing derivative instruments. The aggregate fair value of the free-standing derivatives created by the sale of the rights to contingent milestone payments to the Purchaser pursuant to the purchase agreements was 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 required 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 was 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 estimates of the fair value of the rights to the contingent milestone payments included the application of a discount rate to reflect the time-value of money, the Company recorded costs related to this liability each quarter.

Table of Contents**VERTEX PHARMACEUTICALS INCORPORATED****Notes to Consolidated Financial Statements (Continued)****N. September 2009 Financial Transactions (Continued)***Expenses and Liabilities Related to September 2009 Financial Transactions*

The tables below set forth the total expenses related to the September 2009 financial transactions for 2011, 2010 and 2009, and the liabilities reflected on the Company's consolidated balance sheets related to these transactions as of December 31, 2011 and 2010.

	<b>Year Ended December 31,</b>		
	<b>2011</b>	<b>2010</b>	<b>2009</b>
	<b>(in thousands)</b>		
<b>Expenses and Losses (Gains):</b>			
Interest expense related to 2012 Notes	\$ 21,687	\$ 15,068	\$ 3,465
Change in fair value of embedded derivative related to 2012 Notes	(400)	1,637	(200)
Change in fair value of free-standing derivatives related to the sale of milestone payments	17,201	39,592	2,047
<b>Total September 2009 financial transaction expenses</b>	<b>\$ 38,488</b>	<b>\$ 56,297</b>	<b>\$ 5,312</b>

	<b>At December 31,</b>	
	<b>2011</b>	<b>2010</b>
	<b>(in thousands)</b>	
<b>Liabilities:</b>		
2012 Notes, excluding fair value of embedded derivative	\$	\$ 124,902
Embedded derivative related to 2012 Notes		12,089
Derivatives related to the sale of milestone payments		77,799
<b>Total liabilities related to September 2009 financial transactions</b>	<b>\$</b>	<b>\$ 214,790</b>

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

In 2008, the Company sold to a third party its rights to receive royalty payments from GlaxoSmithKline plc, net of royalty amounts to be earned by and due to a third party, for a one-time cash payment of \$160.0 million. These royalty payments relate to net sales of HIV protease inhibitors, which had been developed pursuant to a collaboration agreement between the Company and GlaxoSmithKline plc. As of December 31, 2011, the Company had \$94.0 million in deferred revenues related to the one-time cash payment, which it is recognizing over the life of the collaboration agreement with GlaxoSmithKline plc based on the units-of-revenue method. In addition, the Company continues to recognize royalty revenues equal to the amount of the third-party subroyalty and an offsetting royalty expense for the third-party subroyalty payment.

**P. Credit Agreement**

On January 7, 2011, the Company entered into a credit agreement with Bank of America, N.A., as administrative agent and lender. The credit agreement provides for a \$100.0 million revolving credit facility that is initially unsecured. As of December 31, 2011, the Company had not borrowed any amount under the credit agreement.

The Company may elect that the loans under the credit agreement bear interest at a rate per annum equal to (i) LIBOR plus 1.50%, or (ii) the rate of interest publicly announced from time to time by Bank of America as its prime rate. The Company may prepay the loans, in whole or in part, in



Table of Contents**VERTEX PHARMACEUTICALS INCORPORATED****Notes to Consolidated Financial Statements (Continued)****P. Credit Agreement (Continued)**

minimum amounts without premium or penalty, other than customary breakage costs with respect to LIBOR borrowings. The Company may borrow, repay and reborrow under the facility until July 6, 2012, at which point the facility terminates.

The agreement contains customary representations and warranties, affirmative and negative covenants and events of default, including payment defaults, defaults for breaches of representations and warranties, covenant defaults and cross defaults. The credit agreement also requires that the Company comply with certain financial covenants, including a covenant that requires the Company to maintain at least \$400.0 million in cash, cash equivalents and marketable securities in domestic deposit and securities accounts, and a covenant that limits the Company's quarterly net losses.

The obligation of the lender to make an initial advance under the credit agreement is subject to a number of conditions, including a satisfactory due diligence review of the Company's financial position and business. Also, if, prior to an initial borrowing under the credit agreement, the Company engages in certain investment, acquisition or disposition transactions or prepays indebtedness, such activities could restrict the Company's ability to borrow under the credit agreement.

If the Company borrows under the credit agreement, the Company will become subject to certain additional negative covenants, subject to exceptions, restricting or limiting the Company's ability and the ability of the Company's subsidiaries to, among other things, grant liens, make certain investments, incur indebtedness, make certain dispositions and prepay indebtedness.

If the Company defaults under certain provisions of the credit agreement, including any default of a financial covenant, the loans will become secured by the Company's cash, cash equivalents and marketable securities with a margined value of \$100.0 million. In addition, if an event of default occurs, the interest rate would increase and the administrative agent would be entitled to take various actions, including the acceleration of payment of amounts due under the loan.

**Q. Income Taxes**

The components of income (loss) before provision for (benefit from) income taxes during the three years ended December 31, 2011 consisted of the following:

	2011	2010	2009
	(in thousands)		
United States	\$ 343,515	\$ (719,859)	\$ (621,455)
Foreign	(283,070)	(34,767)	(20,723)
Income (loss) before provision for income taxes	\$ 60,445	\$ (754,626)	\$ (642,178)



Table of Contents**VERTEX PHARMACEUTICALS INCORPORATED****Notes to Consolidated Financial Statements (Continued)****Q. Income Taxes (Continued)**

The components of provision for income taxes during the three years ended December 31, 2011 consisted of the following:

	2011	2010	2009
	(in thousands)		
<b>Current taxes:</b>			
United States	\$ 22,275	\$	\$
Foreign	(561)		
State	8,655		
	\$ 30,369	\$	\$
<b>Deferred taxes:</b>			
United States	\$ 19,629	\$	\$
Foreign	(32,692)		
State	1,960		
	\$ (11,103)	\$	\$
Provision for income taxes	\$ 19,266	\$	\$

The Company's federal statutory income tax rate for 2011 was 35% and for 2010 and 2009 was 34%. The Company had income from operations in 2011 and incurred losses from operations in 2010 and 2009. The Company 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 to income (loss) before provision for income taxes, and actual tax is reconciled as follows:

	2011	2010	2009
	(in thousands)		
Income (loss) before provision for income taxes	\$ 60,445	\$ (754,626)	\$ (642,178)
Expected tax provision (benefit)	21,156	(256,574)	(218,341)
State taxes, net of federal benefit	10,624	(46,108)	(38,965)
Foreign rate differential	43,629	632	674
Tax credits	(51,086)	(23,292)	(13,027)
Unbenefited operating losses	(6,286)	322,551	260,741
Non-deductible expenses	1,953	2,158	8,244
Other	(724)	633	674
Income tax provision	\$ 19,266	\$	\$

For federal income tax purposes, as of December 31, 2011, the Company has net operating loss carryforwards of approximately \$2.7 billion, and tax credits of \$121.9 million, 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 tax credits of approximately \$56 million, which may be used to offset future state income and tax liability, respectively. These operating loss carryforwards began to expire in 2006, and the tax credit carryforwards began to expire in 2005. After consideration of all the evidence, both positive and negative, management has established a valuation allowance for the full amount of the 2011 deferred tax asset because 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

Table of Contents**VERTEX PHARMACEUTICALS INCORPORATED****Notes to Consolidated Financial Statements (Continued)****Q. Income Taxes (Continued)**

allowance would be decreased, (ii) a portion or all of the deferred tax asset would be reflected on the Company's 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 Company's consolidated balance sheet.

Unrecognized tax benefits during the two years ended December 31, 2011 consisted of the following:

	2011	2010
	(in thousands)	
Unrecognized tax benefits beginning of year	\$ 2,374	\$ 1,858
Gross change for current year positions	2,564	516
Increase for prior period positions		
Decrease for prior period positions		
Decrease due to settlements and payments	(23)	
Decrease due to statute limitations	(560)	
Unrecognized tax benefits end of year	\$ 4,360	\$ 2,374

The Company had gross unrecognized tax benefits of \$4.4 million as of December 31, 2011 and \$2.4 million as of December 31, 2010. At December 31, 2011, \$4.4 million represented the amount of unrecognized tax benefits that, if recognized, would result in a reduction of the Company's effective tax rate. In the next twelve months it is reasonably possible that the Company will reduce the balance of its unrecognized tax benefits by \$0.5 million due to the application of statute of limitations and settlements with taxing authorities, all of which would reduce the Company's effective tax rate.

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:

	2011	2010
	(in thousands)	
Deferred tax assets:		
Net operating loss	\$ 870,367	\$ 944,275
Tax credit carryforwards	167,759	112,467
Property and equipment	15,537	22,483
Intangibles	71,076	
Deferred revenues	59,939	138,809
Stock-based compensation	90,563	81,211
Inventory	23,883	38,810
Accrued expenses and other	30,636	30,078
Unrealized Loss	245	
Gross deferred tax assets	1,330,005	1,368,133
Valuation allowance	(1,329,775)	(1,368,133)
Total deferred tax assets	230	
Deferred tax liabilities:		
Contingent consideration	(14,241)	
Acquired intangibles	(229,696)	(160,278)
Net deferred tax liabilities	\$ (243,707)	\$ (160,278)

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**VERTEX PHARMACEUTICALS INCORPORATED**

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

**Q. Income Taxes (Continued)**

Generally, tax return deductions are allowable on stock-based compensation plans, but, may arise in different amounts and periods from when stock-based compensation expense is recognized in the financial statements. If the tax return deduction for an award exceeds the cumulative stock-based compensation expense recognized in the financial statements, any excess tax benefit is 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, 2011 was approximately \$114 million. As of December 31, 2011, the gross amount of this excess tax deduction in the net operating loss carryforward was approximately \$525 million.

The valuation allowance decreased by \$38.4 million from December 31, 2010 to December 31, 2011 because the Company had net income in 2011.

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 changes. The Company is currently under examination by Revenue Quebec for the year ended March 11, 2009 and the year ended December 31, 2007. No adjustments have been reported. The Company is not under examination by any other jurisdictions for any tax year.

The Company currently intends to reinvest the total amount of its unremitted earnings in the local international jurisdiction or to repatriate the earnings only when tax-effective. As such, the Company has not provided for U.S. federal income taxes on the unremitted earnings of its international subsidiaries. Upon repatriation of those earnings, in the form of dividends or otherwise, the Company would be subject to U.S. federal income taxes (subject to an adjustment for foreign tax credits) and withholding taxes payable to the various foreign countries. Determination of the amount of the unrecognized deferred U.S. federal income tax liability is not practical due to the complexity associated with this hypothetical calculation; however, unrecognized foreign tax credits would be available to reduce some portion of the U.S. federal income tax liability.

**R. 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. At that time, 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

Table of Contents**VERTEX PHARMACEUTICALS INCORPORATED****Notes to Consolidated Financial Statements (Continued)****R. Restructuring Expense (Continued)**

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 is not occupying and 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 occupies and uses for its operations, are recorded as rental expense in the period incurred. 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. Changes to 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 records 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 \$26.3 million at December 31, 2011 related solely to the portion of the Kendall Square Facility that the Company does not intend to use for its operations and included other related lease obligations, recorded at net present value. The Company classified \$4.9 million of the total restructuring liability at December 31, 2011 as short-term, and \$21.4 million as long-term. The short-term portion of the restructuring liability represented the net amount the Company expects to pay in 2012.

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 thousands)			
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

Table of Contents**VERTEX PHARMACEUTICALS INCORPORATED****Notes to Consolidated Financial Statements (Continued)****R. Restructuring Expense (Continued)**

In 2003, the lease restructuring and other operating lease expense included \$78.7 million of lease restructuring expense and \$6.0 million of lease operating expense incurred prior to the decision not to occupy the Kendall Square Facility. The restructuring accrual as of December 31, 2003 related only to the lease restructuring expense.

The activity related to restructuring for 2004 through 2011 was as follows:

	Restructuring Liability			
	2011	2010	2009	2004-2011
	(in thousands)			
Liability, beginning of the period	\$ 29,595	\$ 34,017	\$ 34,064	\$ 69,526
Cash payments	(14,904)	(14,759)	(14,924)	(148,844)
Cash received from subleases	9,548	8,836	8,637	55,014
Credit for portion of facility Vertex decided to occupy in 2005				(10,018)
Restructuring expense	2,074	1,501	6,240	60,635
Liability, end of the period	\$ 26,313	\$ 29,595	\$ 34,017	\$ 26,313

In each period, the Company recorded lease restructuring expense attributable to imputed interest related to the restructuring liability. In certain periods, the restructuring expense also reflected the revision of certain key estimates and assumptions about building operating expenses and sublease income.

**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 common stock fund as they choose. As of December 31, 2011, 96,000 shares of common stock remained available for grant under the Vertex 401(k) Plan. The Company declared matching contributions to the Vertex 401(k) Plan as follows:

	2011	2010	2009
	(in thousands)		
Discretionary matching contributions during the year ended December 31,	\$ 8,619	\$ 6,552	\$ 6,044
Shares issued during the year ended December 31,	183	174	198
Shares issuable as of the year ended December 31,	62	42	35

**T. Commitments**

The Company leases its facilities and certain equipment. The Company's leases have terms through 2028. The leases of the Company's current primary facilities in Cambridge were extended in 2009 through December 2015. The term of the Kendall Square Lease began on January 1, 2003. Rent payments pursuant to the Kendall Square Lease 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. The Company occupies and uses for its operations approximately 120,000

Table of Contents**VERTEX PHARMACEUTICALS INCORPORATED****Notes to Consolidated Financial Statements (Continued)****T. Commitments (Continued)**

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 terms that expire in April 2015 and August 2015. See Note R, "Restructuring Expense," for further information. In 2011, the Company entered into two leases for approximately 1.1 million square feet of office and laboratory space in Boston, Massachusetts. The Company expects that it will begin occupying and making lease payments for this space in late 2013. Please see Note I, "Fan Pier Leases," for additional information regarding this commitment.

As of December 31, 2011, future minimum commitments under Fan Pier Leases, facility operating leases with terms of more than one year and expected sublease income under the Company's subleases for the Kendall Square Facility were as follows:

Year	Fan Pier Leases	Kendall Square Lease	Sublease Income	Other Operating Leases	Total Lease Commitments (Net of Sublease Income)
					(in thousands)
2012	\$	\$ 18,260	\$ (7,850)	\$ 36,455	\$ 46,865
2013		18,260	(8,424)	37,942	47,778
2014	67,206	18,260	(8,424)	29,025	106,067
2015	67,206	18,260	(3,942)	22,678	104,202
2016	67,206	18,260		4,611	90,077
Thereafter	887,211	24,346		10,018	921,575
Total minimum lease payments	\$ 1,088,829	\$ 115,646	\$ (28,640)	\$ 140,729	\$ 1,316,564

Rental expense for 2011 was \$49.4 million, which included \$11.2 million related to the Kendall Square Facility. Rental expense for 2010 was \$46.6 million, which included \$11.6 million related to the Kendall Square Facility. Rental expense for 2009 was \$39.1 million, which included \$11.5 million related to the Kendall Square Facility.

In addition, the Company has committed to make potential future milestone and royalty payments pursuant to the Alios Agreement. Payments generally become due and payable upon the achievement of certain developmental, regulatory and/or commercial milestones.

In September 2010, the Company issued \$400.0 million in aggregate principal of 2015 Notes. See Note K, "Common Stock Offerings and Convertible Senior Subordinated Notes," for further information.

**U. Contingencies**

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 material contingent liabilities accrued as of December 31, 2011 or 2010.

**V. 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

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**VERTEX PHARMACEUTICALS INCORPORATED**

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

**V. Guarantees (Continued)**

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 currently are 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 trial 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, 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.

The Company entered into underwriting agreements with Merrill Lynch, Pierce, Fenner & Smith Incorporated dated February 18, 2009 and September 23, 2010, and with Goldman, Sachs & Co. dated December 2, 2009 (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 senior subordinated notes. The Underwriting Agreement relating to each offering requires the Company to indemnify the underwriters of that public offering against any loss they may suffer by reason of the Company's breach of any representation or warranty 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, covenants and indemnification provisions 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.

Table of Contents**VERTEX PHARMACEUTICALS INCORPORATED****Notes to Consolidated Financial Statements (Continued)****W. Geographic Information**

The following table summarizes total revenues from external customers and collaborators by geographic region. Product revenues are attributed to countries based on the location of the customer. Collaborative revenues are attributed to the operations of the Company in the United States. Royalty revenues are attributed to countries based on the location of the collaborator.

	Year Ended December 31,		
	2011	2010	2009
	(in thousands)		
United States	\$ 1,389,568	\$ 143,370	\$ 101,889
Outside of the United States			
Belgium	20,289		
Canada	769		
<b>Total revenues outside of the United States</b>	<b>21,058</b>		
<b>Total revenues</b>	<b>\$ 1,410,626</b>	<b>\$ 143,370</b>	<b>\$ 101,889</b>

At December 31, 2011, the net book value of the Company's property and equipment in the United States and United Kingdom was \$109.5 million and \$21.4 million, respectively, which comprised approximately 98% of the total net book value of the Company's property and equipment. At December 31, 2010, the net book value of the Company's property and equipment in the United States and United Kingdom was \$55.6 million and \$15.3 million, respectively, which comprised approximately 98% of the total net book value of the Company's property and equipment.



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## VERTEX PHARMACEUTICALS INCORPORATED

## Notes to Consolidated Financial Statements (Continued)

## X. Quarterly Financial Data (unaudited)

	Three Months Ended			
	March 31, 2011	June 30, 2011	Sept. 30, 2011	Dec. 31, 2011
	(in thousands, except per share amounts)			
<b>Revenues:</b>				
Product revenues, net	\$	\$ 74,535	\$ 419,595	\$ 456,759
Royalty revenues		6,061	10,010	8,539
Collaborative revenues		67,601	29,879	231,066
				81,176
<b>Total revenues</b>		<b>73,662</b>	<b>114,424</b>	<b>659,200</b>
<b>Costs and expenses:</b>				
Cost of product revenues			5,404	35,285
Royalty expenses		2,666	3,902	7,191
Research and development expenses		158,612	173,604	189,052
Sales, general and administrative expenses		71,523	96,663	110,654
Restructuring expense (credit)		760	741	(419)
Intangible asset impairment charge			105,800	
<b>Total costs and expenses</b>		<b>233,561</b>	<b>280,314</b>	<b>443,493</b>
				339,438
<b>Income (loss) from operations</b>		<b>(159,899)</b>	<b>(165,890)</b>	<b>215,707</b>
Interest income		1,402	202	77
Interest expense		(12,001)	(6,962)	(7,059)
Change in fair value of derivative instruments		(5,598)	(2,220)	(8,115)
				(868)
<b>Income (loss) before provision for (benefit from) income taxes</b>		<b>(176,096)</b>	<b>(174,870)</b>	<b>200,610</b>
Provision for (benefit from) income taxes			24,448	(27,842)
				22,660
<b>Net income (loss)</b>		<b>(176,096)</b>	<b>(199,318)</b>	<b>228,452</b>
Net income (loss) attributable to noncontrolling interest (Alios)			(25,249)	7,342
				29,512
<b>Net income (loss) attributable to Vertex</b>	<b>\$</b>	<b>(176,096)</b>	<b>\$ (174,069)</b>	<b>\$ 221,110</b>
				<b>\$ 158,629</b>
<b>Net income (loss) per share attributable to Vertex common shareholders:</b>				
Basic	\$	(0.87)	\$ (0.85)	\$ 1.06
				\$ 0.76
Diluted	\$	(0.87)	\$ (0.85)	\$ 1.02
				\$ 0.74
<b>Shares used in per share calculations:</b>				
Basic		202,329	204,413	206,002
Diluted		202,329	204,413	219,349
				206,758
				217,602

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## VERTEX PHARMACEUTICALS INCORPORATED

## Notes to Consolidated Financial Statements (Continued)

## X. Quarterly Financial Data (unaudited) (Continued)

	March 31, 2010	June 30, 2010	Sept. 30, 2010	Dec. 31, 2010
	(in thousands, except per share amounts)			
Revenues:				
Royalty revenues	\$ 6,407	\$ 7,262	\$ 8,173	\$ 8,402
Collaborative revenues	16,022	24,360	15,622	57,122
Total revenues	22,429	31,622	23,795	65,524
Costs and expenses:				
Royalty expenses	3,367	3,086	3,228	3,049
Research and development expenses	143,012	155,082	170,434	168,888
Sales, general and administrative expenses	35,552	40,915	48,855	62,478
Restructuring expense (credit)	780	2,112	866	(2,257)
Total costs and expenses	182,711	201,195	223,383	232,158
Loss from operations	(160,282)	(169,573)	(199,588)	(166,634)
Interest income	455	484	493	523
Interest expense	(3,955)	(3,683)	(3,951)	(7,686)
Change in fair value of derivative instruments	(1,489)	(27,234)	(5,911)	(6,595)
Net loss attributable to Vertex	\$ (165,271)	\$ (200,006)	\$ (208,957)	\$ (180,392)
Basic and diluted net loss per share attributable to Vertex common shareholders	\$ (0.83)	\$ (1.00)	\$ (1.04)	\$ (0.90)
Basic and diluted weighted-average number of common shares outstanding	198,935	200,397	200,887	201,355

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