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# CREATING OUR FUTURE

IDENIX PHARMACEUTICALS, INC.  
Annual Report 2011

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# About Idenix

Idenix Pharmaceuticals is a biopharmaceutical company engaged in the discovery and development of drugs for the treatment of human viral diseases. Currently, the company's sole research and development focus is on the treatment of hepatitis C virus (HCV) infection. Idenix has previously discovered and developed an antiviral drug for the treatment of hepatitis B virus (HBV) infection called Tyzeka®/Sebivo®. The company is headquartered in Cambridge, Massachusetts. Its clinical development operations and drug discovery operations are conducted in Cambridge and in Montpellier, France.

The chemists and biologists leading the Idenix drug discovery team have substantial experience in the creation or modification of antiviral drugs. Idenix is able to rapidly discover compounds amenable to robust development and manufacturing processes. Building on its expertise in nucleoside/nucleotide chemistry and other small molecule chemistry and in biology, the company believes it is well positioned to become a leader in antiviral pharmaceuticals.

## Antiviral Pipeline

Product Candidate	Indication	Preclinical	Phase I	Phase IIa	Phase IIb	Phase III	Market
<b>Partnered Programs</b>							
Tyzeka®/Sebivo® (telbivudine)*	HBV						
<b>Independent Development Programs</b>							
IDX184, Nucleotide Inhibitor	HCV						
IDX719, NS5A Inhibitor	HCV						
IDX19368, Next-Generation Nucleotide Inhibitor	HCV						
Additional Nucleotide Inhibitors	HCV						

\* Tyzeka®/Sebivo® was co-developed by Idenix and Novartis Pharma AG, and Novartis has exclusive worldwide commercialization rights.

## Dear Fellow Shareholders,

Our company currently has one focus – the discovery and development of drugs for the treatment of hepatitis C virus (HCV) infection. Our employees are dedicated to creating a future for HCV patients in which they can be cured with an all-oral combination treatment regimen. It is our goal to bring innovative drug candidates forward that can be key components of such future treatments. Idenix took important steps toward achieving this goal in 2011 while successfully overcoming significant challenges. In addition to initiating a phase IIb clinical trial for IDX184, we filed an investigational new drug application (IND) for IDX719 and synthesized more than 1,500 new nucleotides to advance our nucleotide prodrug discovery program. With two drug candidates in clinical testing and another anticipated to enter clinical testing this year, we believe we will be among the leading companies driving the advancement of HCV treatment.

Our strategy at Idenix remains unchanged despite the rapidly evolving HCV drug development landscape. We are confident that an all-oral combination of direct-acting-antivirals, or DAAs, will be the future paradigm for HCV treatment. An optimal regimen may include two or more classes of drugs with distinct modes of action, complementary resistance profiles and broad genotypic activity, with or without ribavirin. With our expertise and experience in developing antivirals, we believe we will play an integral role in developing these combinations, with our own internal candidates and/or through external collaborations.

Our lead clinical candidate is a nucleotide polymerase inhibitor, IDX184. In July of 2011, we initiated a 12-week phase IIb clinical trial of IDX184 in combination with pegylated interferon and ribavirin. After reviewing interim 4-week data demonstrating favorable safety and antiviral activity from the ongoing study, the FDA removed the partial clinical hold for IDX184. This allows us to now explore the full potential of this promising nucleotide polymerase inhibitor in combination with other DAAs in a broad phase IIb program. Our ultimate goal is to give IDX184 the best chance to succeed by placing it in combination with other DAAs to create regimens that achieve the optimal sustained virologic response (SVR) for the broadest population of patients with HCV.

We also advanced our clinical pipeline with the initiation of a phase I clinical trial for our NS5A inhibitor, IDX719. In preclinical studies, this promising compound has shown

**Ronald C. Renaud, Jr.**  
President and Chief  
Executive Officer



the potential for potent pan-genotypic activity. Early clinical results are promising and we look forward to evaluating its safety and activity in multiple genotypes in a proof-of-concept study in the second quarter of this year.

Additionally, in 2011, we embarked on a robust discovery effort to identify next-generation nucleotide prodrug compounds and have selected IDX19368 as a lead candidate from this program. We are excited about the potential of this compound as it has generated encouraging preclinical data and we anticipate filing an IND by mid-2012. We will continue our discovery efforts in this area, leveraging our significant nucleotide chemistry expertise as well as our strong intellectual property position.

I am proud of the progress our company made in 2011. Our focus for 2012 will be to build on these achievements through the continued advancement of our pipeline of novel HCV drug candidates. We believe that the potent and pan-genotypic profiles of our drug candidates support their potential role in future combination regimens to treat HCV-infected patients.

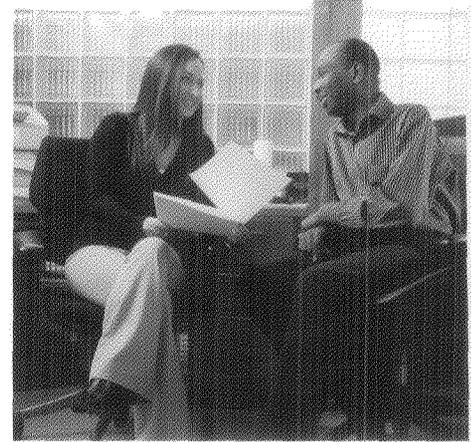
I would like to thank our shareholders for their continued support and our Board of Directors for their valued contributions and guidance. Additionally, I am particularly proud of how our employees rose to every challenge that the company faced in 2011 with enthusiasm and drive. I am grateful for their steadfast commitment and hard work.

Sincerely,

A handwritten signature in black ink that reads "Ronald C. Renaud, Jr." The signature is written in a cursive, flowing style.

Ronald C. Renaud, Jr.  
President and Chief Executive Officer

# OUR FUTURE...



# ...GREATER THAN THE SUM OF ITS PARTS

We are pursuing a combination development strategy to advance the future of HCV treatments

## HCV and Combination Therapy

Idenix's current focus is on the discovery and development of drugs for the treatment of HCV due to the large medical need that exists for these patients. It is estimated by the World Health Organization that approximately three percent of the world's population is infected with HCV. Eighty percent of those people are unaware that they are infected. Chronic HCV infection can go unnoticed for years until the disease develops life-threatening complications such as cirrhosis, liver cancer or liver failure. It is the leading cause of liver transplants in the United States.

In 2011, two direct-acting antivirals (DAAs) were approved by the U.S Food and Drug Administration (FDA) which improved response rates, but the need still remains for improved efficacy and safety. These new treatments are administered with the previous standard of care, pegylated interferon and ribavirin, which is often very poorly tolerated by patients.

Idenix's strategic goal is to benefit patients by developing all-oral combination DAA regimens that could eliminate the need for interferon and potentially ribavirin. The company believes that a combination of two or more DAAs with different mechanisms of action and non-overlapping resistance profiles, acting together to attack the virus, can successfully clear the virus from the body and ultimately cure HCV. Having all-oral combination regimens could not only increase the response rates but also improve safety and convenience for patients.

There are several characteristics of an optimal combination regimen. Potency and safety/tolerability are critical for a regimen to be effective. The regimen will also need to be

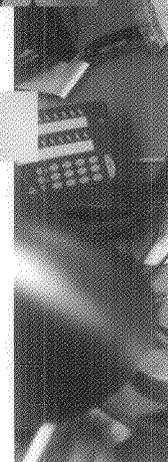
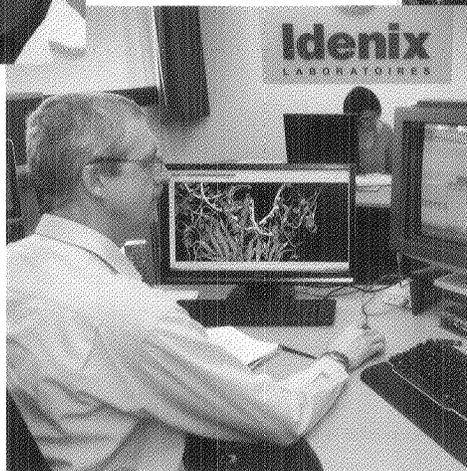
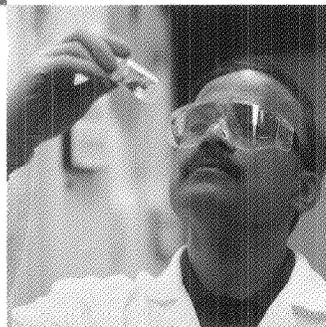
easy for physicians to administer and convenient for patients. Ultimately, a regimen that is pan-genotypic, i.e. one that can address many or all of the HCV genotypes, will be a key feature for a competitive all-oral combination.

Idenix's rationale for combination therapy in HCV is based on similarities in the evolution of HIV treatment over the last 30 years. In HIV, combinations of drugs with different mechanisms of action and non-overlapping resistance patterns have resulted in optimal treatment therapies. Furthermore, it has been shown that drug combinations must be potent and safe to achieve durable viral suppression and to prevent the emergence of resistance. An important point of difference is that with HCV, potent viral suppression

Idenix believes the unique profiles of its drug candidates support their potential to become key components in the evolution of HCV treatment.

can ultimately cure the disease. Lastly, nucleosides are the backbone of many HIV drug combinations. Idenix believes that nucleosides/nucleotides will play an important role in HCV as well. For this important reason,

nucleosides/nucleotides as a drug class continue to be the company's primary research and development focus. Idenix believes the unique profiles of its drug candidates support their potential to become key components in the evolution of HCV treatment.



## Through discovery and development, we are becoming a leader in antiviral pharmaceuticals

### IDX184, a Nucleotide Polymerase Inhibitor

IDX184 is Idenix's lead HCV drug candidate currently in a phase IIb clinical trial. It is a once- or twice-daily, oral nucleotide polymerase inhibitor which has exhibited a high barrier to resistance and broad genotypic coverage in *in vitro* studies.

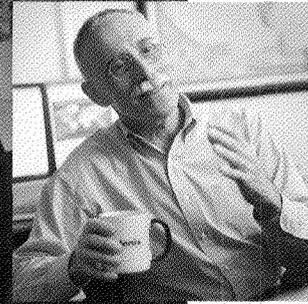
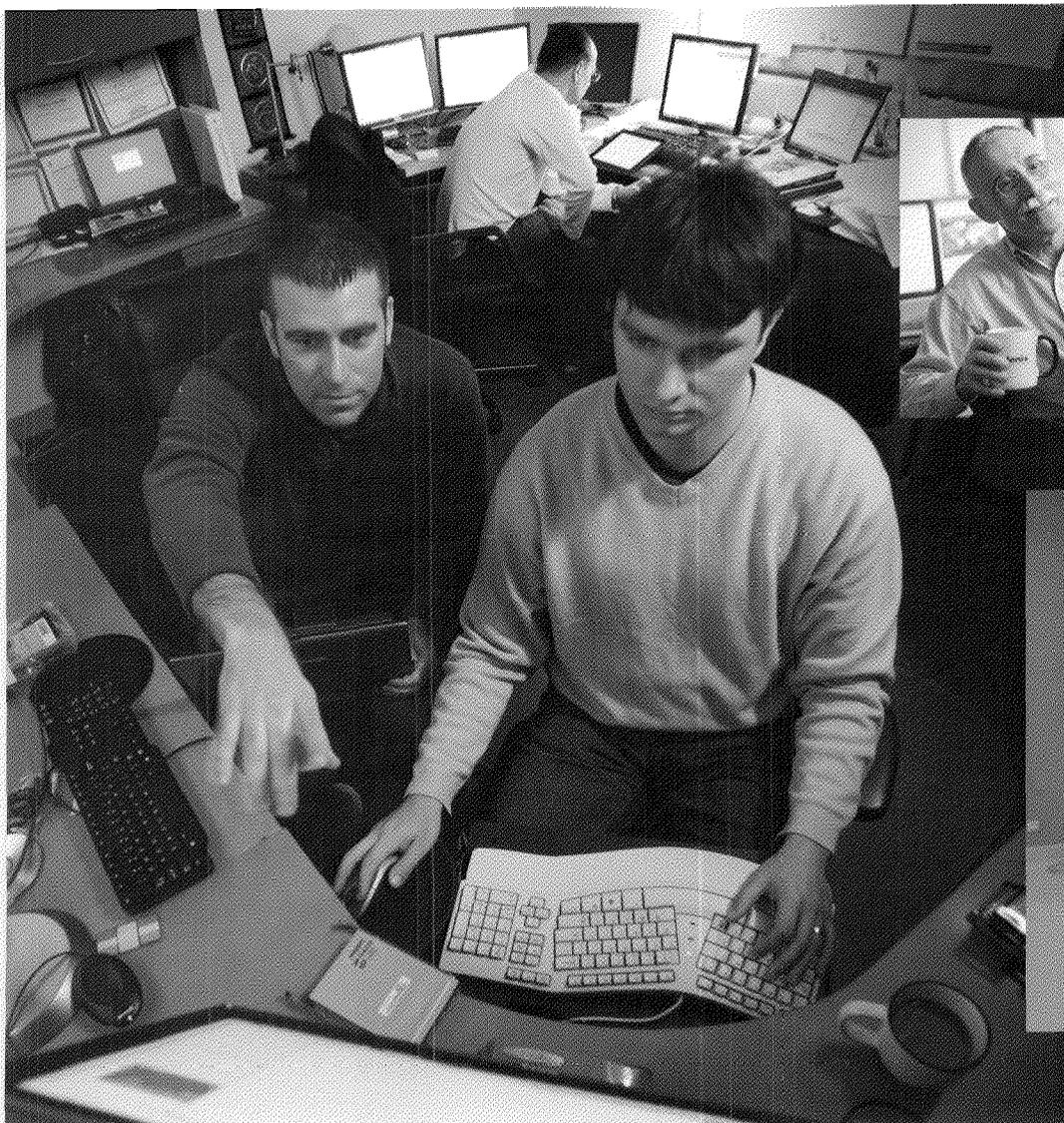
In July 2011, the company initiated a randomized, double-blind, parallel group phase IIb clinical trial of IDX184 in treatment-naïve genotype 1 HCV-infected patients. The study features two treatment arms, either 50 mg or 100 mg of IDX184 administered once-daily for 12 weeks, each arm in combination with pegylated interferon and ribavirin (PegIFN/RBV). An interim analysis from this study of the first 31 patients who completed 12 weeks of treatment

demonstrated that the Complete Early Virologic Response (cEVR, the percentage of patients with viral levels < 25 IU/mL) was 93 percent for the 100 mg IDX184 arm (n=15) and 81 percent for the 50 mg IDX184 arm (n=16). The side effect

Idenix believes  
IDX184 could be a  
backbone of future  
HCV treatments.

profile of the combined therapy has remained consistent with the known safety profile for PegIFN/RBV. The FDA removed the partial clinical hold on IDX184 based on interim 4-week data from the ongoing phase IIb clinical trial and Idenix plans to

initiate additional phase IIb trials to evaluate IDX184 in combination with other direct-acting antivirals in 2012. With the favorable clinical profile to date, and the preclinical properties supporting its pan-genotypic activity and its ability to be combined with other agents, Idenix believes IDX184 could be a backbone of future HCV treatments.



### IDX719, an NS5A Inhibitor

IDX719 is Idenix's NS5A inhibitor candidate which has completed a single-dose dose-escalation phase I clinical trial in healthy volunteers and HCV-infected patients. Early data show favorable safety and potent antiviral activity. A three-day proof-of-concept segment of the study is underway in treatment-naïve HCV genotype 1, 2, 3 or 4-infected patients. Idenix believes the early profile of this drug candidate supports its potential role in a pan-genotypic all-oral HCV combination regimen.

### Nucleotide Discovery Program

At the start of 2011, Idenix commenced an intensive discovery effort to identify novel next-generation nucleotide prodrugs. Idenix scientists are evaluating how new prodrug approaches, including novel bases and sugars, affect triphosphate production, kinetics of metabolism and

cytotoxicity. IDX19368 was selected as a lead candidate from this program. In *in vivo* preclinical studies, this drug candidate has generated very high liver triphosphate levels, which have been associated with strong potency in the clinic for other nucleotides in development. Idenix expects to submit an investigational new drug application for IDX19368 in mid-2012 and looks forward to evaluating its activity and safety in healthy volunteers and HCV-infected patients in the second half of the year. The company continues to identify new promising compounds and evaluate multiple candidates for further development from this discovery program.

# Corporate Values

At Idenix, our corporate values — Innovation, Teamwork, Respect, Quality and Ownership — reflect a unique and dynamic culture. Our company was built and founded on these values, and our dedicated and capable employees are committed to living these values as they aim to create a successful future not only for Idenix but ultimately for patients who live with life-threatening diseases.

## Innovation

Idenix is an innovative company striving for excellence in the discovery, development and commercialization of breakthrough advances for the treatment of life-threatening infectious diseases. By cultivating an environment of responsiveness and entrepreneurial spirit, we believe we can deliver better medicines to patients faster. Innovation and creativity are at the heart of all that we do.

## Teamwork

One team, many strengths. We can only be a successful company if we work together as a team — a team that is focused on action and results; one that communicates openly and honestly; one that maintains an engaging and positive spirit. We share in our successes, as well as in the insight we gain from the challenges we face.

## Quality

Idenix is committed to achieving the highest level of quality in all that we do, while maintaining our sense of urgency to produce effective treatments for life-threatening infectious diseases.

## Respect

Idenix values all people with whom we work. We conduct our business with high ethical standards and operate with integrity. We respect the diversity of experiences, opinions and ideas that come from our employees. We are committed to delivering treatments that will improve the quality of life of patients. We respect the roles that all of our stakeholders play in driving Idenix forward to achieve this goal.

## Ownership

Idenix fosters "pride of ownership." Everyone contributes to our success and each individual makes a difference. Our employees are accountable for their actions, encouraged to lead, and empowered to make decisions and identify opportunities to help Idenix reach its goals.

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

**Form 10-K**

(Mark One)

**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**

**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 000-49839**

**Idenix Pharmaceuticals, Inc.**

(Exact Name of Registrant as Specified in its Charter)

Delaware  
(State or Other Jurisdiction of  
Incorporation or Organization)  
60 Hampshire Street,  
Cambridge, Massachusetts  
(Address of Principal Executive Offices)

45-0478605  
(I.R.S. Employer  
Identification No.)

02139  
(Zip Code)

(617) 995-9800

(Registrant's telephone number, including area code)

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

Common Stock, \$0.001 par value  
(Title of class)

The NASDAQ Global Market  
(Name of exchange on which registered)

**Securities registered pursuant to Section 12(g) of the Act:**

NONE

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 15(d) of the 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 Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to the 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 the 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  (Do not check if a smaller reporting company)

Smaller reporting company

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

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant based on the last reported sale price of the common stock on the NASDAQ Global Market on June 30, 2011 was approximately \$313.0 million. For this purpose, the registrant considers its directors and officers and Novartis Pharma AG to be affiliates.

The number of shares outstanding of the registrant's class of common stock as of February 21, 2012 was 107,592,574 shares.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Proxy Statement to be filed in connection with the solicitation of proxies for the Annual Meeting of Stockholders to be held on June 7, 2012 are incorporated by reference into Part III of this Annual Report on Form 10-K.

**Idenix Pharmaceuticals, Inc.**

**Form 10-K**

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## CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains 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, as amended, concerning our business, operations and financial condition, including statements with respect to the expected timing and results of completion of phases of development of our drug candidates, the safety, efficacy and potential benefits of our drug candidates, expectations with respect to development and commercialization of our drug candidates, expectations with respect to licensing arrangements with third-parties, the timing and results of the submission, acceptance and approval of regulatory filings, the scope of patent protection with respect to these drug candidates and information with respect to the other plans and strategies for our business. All statements other than statements of historical facts included in this Annual Report on Form 10-K may be deemed forward-looking statements. Without limiting the foregoing, “expect”, “anticipate”, “intend”, “may”, “plan”, “believe”, “seek”, “estimate”, “projects”, “will”, “would” and similar expressions or express or implied discussions regarding potential new products or regarding future revenues from such products, potential future expenditures or liabilities or by discussions of strategy, plans or intentions are also intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Because these forward-looking statements involve known and unknown risks and uncertainties, actual results, performance or achievements could differ materially from those expressed or implied by these forward-looking statements for a number of important reasons, including those discussed under “Risk Factors”, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this Annual Report on Form 10-K. In particular, management’s expectations could be affected by, among other things, uncertainties involved in the development of new pharmaceutical products, including unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; our ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; industry trends; and uncertainties regarding necessary levels of expenditures in the future. There can be no guarantee that development of any drug candidates described will succeed or that any new products will obtain necessary regulatory approvals required for commercialization or otherwise be brought to market. Similarly, there can be no guarantee that we or one or more of our current or future products, if any, will achieve any particular level of revenue.

You should read these forward-looking statements carefully because they discuss our expectations regarding our future performance, future operating results or future financial condition, or state other “forward-looking” information. You should be aware that the occurrence of any of the events described under “Risk Factors” and elsewhere in this Annual Report on Form 10-K could substantially harm our business, results of operations and financial condition and that upon the occurrence of any of these events, the price of our common stock could decline.

We cannot guarantee any future results, levels of activity, performance or achievements. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described in this Annual Report on Form 10-K as anticipated, believed, estimated or expected. The forward-looking statements contained in this Annual Report on Form 10-K represent our expectations as of the date of this Annual Report on Form 10-K (unless another date is indicated) and should not be relied upon as representing our expectations as of any other date. While we may elect to update these forward-looking statements, we specifically disclaim any obligation to do so, even if our expectations change.

## PART I

### Item 1. Business

#### Overview

Idenix Pharmaceuticals, Inc., which we refer to together with our wholly owned subsidiaries as Idenix, we, us or our, is a biopharmaceutical company engaged in the discovery and development of drugs for the treatment of human viral diseases with operations in the United States and Europe. Currently, our primary research and development focus is on the treatment of hepatitis C virus, or HCV. HCV is a leading cause of liver disease. According to the World Health Organization, HCV is responsible for 50% to 76% of all liver cancer cases worldwide and two thirds of all liver transplants in the developed world. The World Health Organization also has estimated that approximately 170 million people worldwide are chronically infected with HCV and an additional three to four million people are infected each year. We believe that large market opportunities exist for new treatments of HCV because the current treatments have substantial side effects and only treat a portion of the HCV-infected patient population. Our strategic goal is to develop all oral combinations of direct-acting antiviral, or DAA, drug candidates that will eliminate the need for interferon and/or ribavirin as currently used in the treatment for HCV. Our objective is to develop low dose, once- or twice-daily agents with broad genotypic activity that have low potential for drug-drug interaction, high tolerability and are designed for use in multiple combination regimens. We may seek to build a combination development strategy, both internally and with partners, to advance the future of HCV treatments.

#### *Business Highlights*

Our HCV discovery program is focused on nucleoside/nucleotide polymerase inhibitors and NS5A inhibitors:

*Nucleoside/Nucleotide Polymerase Inhibitors.* We believe that nucleoside/nucleotide polymerase inhibitors will be a backbone in the future treatment regimens of HCV due to their high barrier to resistance and broad genotypic activity. We believe we have strong nucleoside/nucleotide scientific expertise within our organization and should be able to leverage our intellectual patent portfolio to discover multiple novel nucleoside/nucleotide drug candidates.

The most advanced of our development programs is IDX184, a novel liver-targeted nucleotide prodrug candidate. In July 2011, we initiated a phase IIb clinical trial of IDX184 in combination with pegylated interferon and ribavirin, or Peg-IFN/RBV, in treatment-naïve HCV genotype 1-infected patients. After 31 patients completed 28 days of treatment, the side effect profile of IDX184 was consistent with that seen with Peg-IFN/RBV and there were no serious adverse events. Rapid virologic response, or RVR, findings demonstrated that 73% of patients in the 100 mg IDX184 arm and 63% in the 50 mg arm had undetectable virus (< 25 IU/ml) at 28 days. As of January 9, 2012, 87% of patients in the 100 mg arm and 94% in the 50 mg arm had undetectable virus at a median of 8 weeks of treatment.

We provided an interim analysis of the first 31 patients following 28 days of treatment to an independent data safety monitoring board, or DSMB, and to the U.S. Food and Drug Administration, or FDA. The DSMB reviewed the data for the first 31 patients and recommended the continuation of enrollment in the phase IIb IDX184 clinical trial. We submitted the interim data, along with the DSMB's recommendations, to the FDA and requested the continuation of this study and removal of the partial clinical hold for IDX184. In February 2012, the FDA removed the partial clinical hold on IDX184 and as a result we can continue enrollment of the phase IIb study of IDX184 and evaluate IDX184 in future interferon-free combination regimens with other DAAs. In addition, the FDA allowed us to truncate the phase IIb study from 100 patients, as in the original protocol, to a total of 60 patients, and to expand the enrollment criteria as recommended by the DSMB. Refer to the "Products and Drug Candidates" heading below for more information about the partial clinical hold.

We believe that nucleosides/nucleotides will have a significant role in a combination DAA strategy for the treatment of HCV and therefore we are currently concentrating a substantial amount of our

discovery efforts on this class of drugs. In 2011, we selected two additional nucleotide polymerase inhibitors, IDX19368 and IDX19370, to advance into preclinical testing. We selected IDX19368 as our lead candidate for our next generation nucleotide polymerase inhibitor program and we expect to submit an investigational new drug application, or IND, for this candidate in the middle of 2012. We are also evaluating other nucleotide prodrugs in preclinical testing.

As a result of allocating most of our discovery resources to additional nucleoside/nucleotide polymerase inhibitor drug candidates, we did not devote significant resources to our protease inhibitor and non-nucleoside programs in 2011. We may evaluate potential partnerships and licensing agreements for our drug candidates in the protease inhibitor and non-nucleoside programs as well as related intellectual property.

*NS5A Inhibitors.* Our lead drug candidate for our NS5A inhibitor program is IDX719, which has demonstrated potent, pan-genotypic activity in preclinical tests. In December 2011, we filed an IND for IDX719 and in January 2012, we initiated a phase I clinical study in healthy volunteers. We expect to begin a proof-of-concept study in the second quarter of 2012.

In April 2011 and November 2011, we issued approximately 21.1 million and 10.8 million shares, respectively, of our common stock pursuant to underwritten offerings and received \$60.2 million and \$65.8 million in net proceeds, respectively.

### ***Novartis Collaboration***

In May 2003, we entered into a collaboration with Novartis Pharma AG, or Novartis, relating to the worldwide development and commercialization of our drug candidates, which we refer to as the development and commercialization agreement. In addition, Novartis also purchased approximately 54% of our then outstanding capital stock in May 2003. Under the development and commercialization agreement, we successfully developed and received worldwide marketing approval for telbivudine (Tyzeka<sup>®</sup>/Sebivo<sup>®</sup>), a drug for the treatment of hepatitis B virus, or HBV, that we licensed to Novartis. In 2007, we began receiving royalties from Novartis based on a percentage of net sales of Tyzeka<sup>®</sup>/Sebivo<sup>®</sup>. As part of this agreement, Novartis has an option to license any of our development-stage drug candidates after demonstration of activity and safety in a proof-of-concept clinical trial so long as Novartis maintains at least 30% ownership of our common stock. As of February 21, 2012, Novartis owned approximately 31% of our outstanding common stock. In October 2009, Novartis waived its option to license IDX184. As a result, we retain the worldwide rights to develop, manufacture, commercialize and license IDX184. We may seek a partner that will assist in the future development and commercialization of this drug candidate.

## **Products and Drug Candidates**

### ***Hepatitis C***

#### ***HCV Background***

We believe that combining two or more direct-acting HCV antiviral agents, particularly agents directed against different HCV targets, could lead to a more potent inhibition of HCV replication and to a better suppression of the emergence of drug resistance compared to the use of single agents or two agents directed against the same HCV target. A DAA combination regimen approach could expand the treatable HCV population by including those patients who cannot be treated with interferon-based therapies or those for whom existing treatment regimens have been ineffective.

We are currently developing nucleoside/nucleotide polymerase inhibitors and NS5A inhibitors to inhibit HCV replication:

*Nucleoside/Nucleotide Polymerase Inhibitors.* During HCV replication, the viral polymerase, also called the NS5B polymerase, is the key enzyme that replicates the viral genetic information contained in the HCV viral genetic material, which is known as viral ribonucleic acid, or RNA, and is therefore essential for the virus to

reproduce itself. Nucleosides/nucleotides are small, natural chemical compounds that function as the building blocks of human and viral genetic material. Nucleoside polymerase inhibitors prevent HCV replication by interfering with the activity of the viral polymerase. Mimicking the role of natural nucleosides, nucleoside polymerase inhibitors bind directly to the active site of the polymerase and are incorporated by viral polymerases into replicating viral genomes. This event leads to chain termination, preventing the virus from reproducing its genetic material. As drugs, nucleoside/nucleotide polymerase inhibitors have a proven record of success as antiviral agents and generally offer selectivity, antiviral activity, a high barrier to resistance, long duration of action and the potential for convenient oral administration. As a result, nucleosides/nucleotides may be particularly well suited for the treatment of chronic viral diseases.

*NS5A Inhibitors.* NS5A is a multifunctional, nonstructural HCV protein that is important for the formation of viral replication complexes, the process of viral replication and virus assembly. We believe that NS5A inhibitor agents could complement nucleoside/nucleotide polymerase inhibitors in future HCV combination regimens.

#### *Nucleoside/Nucleotide Polymerase Inhibitors Development*

IDX184 is a novel liver-targeted nucleotide prodrug that enables the delivery of nucleoside monophosphate to the liver, leading to the formation of high levels of nucleoside triphosphate, thus potentially maximizing drug efficacy and limiting systemic side effects. IDX184 has demonstrated activity across multiple HCV genotypes, a high barrier to resistance and synergy with ribavirin *in vitro*.

In October 2008, we successfully completed a phase I clinical study, which demonstrated favorable pharmacokinetics and safety properties in healthy volunteers, and we subsequently initiated a proof-of-concept clinical trial. We successfully completed the proof-of-concept clinical trial in treatment-naïve HCV genotype 1-infected patients in July 2009. In the fourth quarter of 2009, we initiated a phase IIa clinical trial for IDX184. The clinical study was a randomized, double-blind, placebo-controlled, sequential cohort, dose-escalation study evaluating the safety, tolerability, pharmacokinetics and antiviral activity of IDX184 in combination with Peg-IFN/RBV in treatment-naïve HCV genotype 1-infected patients. Patients received a daily dose of IDX184 or placebo plus Peg-IFN/RBV for 14 days and continued on Peg-IFN/RBV for an additional 14 days. All patients in the study had the option to continue Peg-IFN/RBV for up to 48 weeks. Four dosing regimens of IDX184 ranging from 50 mg to 200 mg per day were evaluated. In the 100 mg and 200 mg cohorts, once-daily (QD) and twice-daily (BID) regimens were compared. Each cohort of the study evaluated 20 patients randomized four to IDX184 and one to placebo. IDX184, at doses at or above 100 mg combined with Peg-IFN/RBV at 14 days, demonstrated similar antiviral activity. Mean HCV RNA reductions ranged from 3.7 to 4.3 log<sub>10</sub> IU/mL and 29% to 50% of subjects achieved undetectable HCV RNA levels compared to 1.5 log<sub>10</sub> IU/mL reduction in the placebo plus Peg-IFN/RBV. Alanine aminotransferase, or ALT, and aspartate aminotransferase, or AST, levels, which are markers for liver injury, improved significantly faster in patients treated with IDX184 and Peg-IFN/RBV as compared to patients receiving only Peg-IFN/RBV. At daily doses of IDX184 up to 200 mg in combination with Peg-IFN/RBV for 14 days, the side effect profile of IDX184 combined with Peg-IFN/RBV has been consistent with the known side effect profile of Peg-IFN/RBV.

In September 2010, the FDA placed IDX184 and IDX320 on clinical hold and in February 2011, the full clinical hold on IDX184 was removed. The program was placed on partial clinical hold, which allowed us to initiate a phase IIb 12-week clinical trial of IDX184 in July 2011. Refer to the "Combination Drug-Drug Interaction Study" heading below for more details on the clinical hold.

The phase IIb clinical trial of IDX184 is double-blind and will include treatment-naïve HCV genotype 1-infected patients. Patients will be randomized to receive either 50 mg or 100 mg of IDX184, each for 12 weeks in combination with Peg-IFN/RBV. Patients will receive an additional 12 or 36 weeks of Peg-IFN/RBV, depending on the virologic response. Our interim data of 31 patients that completed 28 days of treatment demonstrated that the side effect profile of IDX184 was consistent with that seen with Peg-IFN/RBV and there were no serious adverse events. The interim data also demonstrated 73% of patients in the 100 mg

IDX184 arm (n=15) and 63% in the 50 mg arm (n=16) had undetectable virus (< 25 IU/ml) at 28 days. As of January 9, 2012, 87% of patients in the 100 mg arm and 94% in the 50 mg arm had undetectable virus at a median of 8 weeks of treatment.

We provided an interim analysis of the first 31 patients following 28 days of treatment to an independent DSMB and to the FDA. The DSMB reviewed the data for the first 31 patients and recommended the continuation of enrollment in the phase IIb IDX184 clinical trial. We submitted the interim data, along with the DSMB's recommendations, to the FDA and requested the continuation of this study and removal of the partial clinical hold for IDX184. In February 2012, the FDA removed the partial clinical hold on IDX184 and as a result we can continue enrollment of the phase IIb study of IDX184 and evaluate IDX184 in future interferon-free combination regimens with other DAAs. In addition, the FDA allowed us to truncate the phase IIb study from 100 patients, as in the original protocol, to a total of 60 patients, and to expand the enrollment criteria as recommended by the DSMB.

In October 2009, Novartis waived its option to license IDX184 under the development and commercialization agreement. As a result, we retain the worldwide rights to develop, manufacture, commercialize and license IDX184. We may seek a partner who will assist in the future development and commercialization of this drug candidate.

We believe that nucleosides/nucleotides will have a significant role in a combination DAA strategy for the treatment of HCV and therefore we are currently concentrating a substantial amount of our discovery efforts on this class of drugs. In 2011, we selected two additional nucleotide polymerase inhibitors, IDX19368 and IDX19370, to advance into preclinical testing. We selected IDX19368 as our lead candidate for our next generation nucleotide polymerase inhibitor program and we expect to submit an IND for this candidate in the middle of 2012. We are also evaluating other nucleotide prodrugs in preclinical testing.

#### *NS5A Inhibitors Development*

Our lead drug candidate for our NS5A inhibitor program is IDX719. Preclinical studies have shown that IDX719 has potent, pan-genotypic activity *in vitro* with the potential for once-daily dosing. In December 2011, we filed an IND for IDX719 and in January 2012, we initiated a phase I clinical study in healthy volunteers. This study will evaluate safety, pharmacokinetics and food effect of IDX719 in 48 healthy volunteers. We expect to begin a proof-of-concept study in treatment-naïve HCV genotype 1-infected patients in the second quarter of 2012.

#### *Protease Inhibitors Development*

Our lead drug candidate from our protease inhibitor program was IDX320, a non-covalent macrocyclic inhibitor. The IDX320 program was discontinued following the three serious adverse events of liver injury in the 14-day phase I drug-drug interaction study of IDX184 and IDX320, discussed below.

In 2011, we identified two potential protease inhibitor drug candidates, IDX077 and IDX791, with broad genotypic activity. Subsequently, we elected not to devote significant resources to our protease inhibitor program and reallocated these resources to the discovery and development of additional nucleoside/nucleotide drug candidates. We may evaluate potential partnerships and licensing agreements for these drug candidates and related intellectual property.

#### *Non-Nucleoside Polymerase Inhibitors Development*

Our lead drug candidate for our non-nucleoside polymerase inhibitor program was IDX375, a novel palm-binding polymerase inhibitor that had demonstrated a favorable preclinical pharmacokinetic profile in several species, high liver to plasma concentrations in rodents and adequate safety in animal studies.

In November 2009, we initiated a single ascending dose phase I clinical study evaluating the safety, tolerability and pharmacokinetics of a choline salt form of IDX375 in healthy volunteers. The study was a randomized, double-blind, placebo-controlled study with five dosing regimens of IDX375 ranging from 25 mg QD to 200 mg BID for one day. Each cohort of the study evaluated eight subjects randomized six to IDX375 and two to placebo. The data demonstrated favorable plasma exposure of IDX375 with a long elimination half-life of approximately 30 to 40 hours suggesting the potential for once- or twice-daily dosing in patients. IDX375 was well tolerated and demonstrated a favorable safety profile. There were no significant laboratory abnormalities.

During 2010, we continued the phase I clinical study evaluating single and multiple doses of the free acid form of IDX375 in healthy volunteers. This clinical study was completed in the fourth quarter of 2010 and demonstrated favorable safety and pharmacokinetics properties. In the fourth quarter of 2010, we initiated a three-day proof-of-concept clinical trial in treatment-naïve genotype 1-infected patients. After three days of dosing with 100 mg, 200 mg and 400 mg BID of IDX375 with Peg-IFN/RBV, mean HCV viral load reductions were 1.3, 2.3 and 2.7 log<sub>10</sub> IU/mL, respectively, whereas patients who received placebo experienced an increase of 0.1 log<sub>10</sub> IU/mL. In this three-day study of IDX375, the exposure in HCV-infected patients was comparable to healthy volunteers and IDX375 was safe and well tolerated.

In 2011, we elected not to devote significant resources to our non-nucleoside program and reallocated these resources to the discovery and development of additional nucleoside/nucleotide drug candidates. We may evaluate potential partnerships and licensing agreements for this drug candidate and related intellectual property.

#### *Combination Drug-Drug Interaction Study*

In July 2010, we conducted a 14-day phase I, randomized, double-blind, placebo-controlled study to evaluate the pharmacokinetic drug-drug interaction between IDX184 and IDX320 in 20 healthy volunteers. Two cohorts were evaluated in the study with 10 subjects in each cohort randomized eight to active drug and two to placebo. Subjects in the first cohort received 400 mg QD of IDX320 plus placebo for the first week, subsequently adding 100 mg QD of IDX184 for the second week. Subjects in the second cohort received 100 mg QD of IDX184 plus placebo for the first week, subsequently adding 400 mg QD of IDX320 for the second week. There was no clinically significant pharmacokinetic drug-drug interaction between IDX184 and IDX320 observed in this study. There were no adverse events or laboratory abnormalities observed during the two weeks of drug exposure. There were three serious adverse events of elevated liver function tests that were detected during post drug exposure safety visits following the 14-day drug-drug interaction study. The liver function tests returned to normal levels in the three subjects during follow-up visits. Due to these serious adverse events, in September 2010, the FDA placed IDX184 and IDX320 on clinical hold. We believe the hepatotoxicity observed in this drug-drug interaction study was caused by IDX320 and therefore discontinued the clinical development of this drug candidate. In February 2011, the full clinical hold on IDX184 was removed by the FDA. The program was placed on partial clinical hold, which allowed us to initiate a phase IIb 12-week clinical trial of IDX184 in July 2011 with safety evaluations of the patients that will be shared with the FDA at certain intervals in the trial. In February 2012, the FDA removed the partial clinical hold on IDX184 and as a result we can continue enrollment of the phase IIb study of IDX184 and evaluate IDX184 in future interferon-free combination regimens with other DAAs. Refer to the “Nucleoside/Nucleotide Polymerase Inhibitors Development” heading above for more details on the advancement of IDX184 into a phase IIb clinical trial.

#### **HIV**

We have developed a non-nucleoside reverse transcriptase inhibitor, or NNRTI, drug candidate, IDX899, for the treatment of human immunodeficiency virus type-1, or HIV, and acquired immune deficiency syndrome, or AIDS, for use in combination therapy. In 2008, we successfully completed a proof-of-concept clinical trial of IDX899 in treatment-naïve HIV-infected patients. In February 2009, we licensed our NNRTI compounds to GlaxoSmithKline, or GSK. This agreement, which we refer to as the ViiV license agreement, was assigned to ViiV Healthcare Company, or ViiV, which is an affiliate of GSK. The ViiV license agreement granted ViiV an

exclusive worldwide license to develop, manufacture and commercialize our NNRTI compounds, including IDX899, now known as '761, for the treatment of human diseases, including HIV/AIDS. In 2009, ViiV performed long-term chronic toxicology studies and drug-drug interaction studies in healthy volunteers with '761, which demonstrated a favorable safety and drug-drug interaction profile. In the fourth quarter of 2010, ViiV initiated a phase IIb clinical study of '761 in HIV-infected patients. In February 2011, ViiV informed us that the FDA placed '761 on clinical hold. As a result of further evaluation, ViiV determined that it would not continue development of '761 or develop any other compound licensed under the ViiV license agreement. In December 2011, ViiV notified us that it would terminate the ViiV license agreement effective March 15, 2012. Upon such termination, ViiV will relinquish all rights it has in the intellectual property licensed from us and grants us an exclusive, perpetual and irrevocable license to any intellectual property relating to the licensed products it may have developed during the term of the ViiV license agreement. As a result of this termination, we will not receive any additional milestone or royalty payments under the ViiV license agreement. We are not subject to early termination penalties under the ViiV license agreement.

### ***Hepatitis B***

In collaboration with Novartis, we developed telbivudine (Tyzeka®/Sebivo®) through commercialization for the treatment of patients with HBV. In October 2006, the FDA approved Tyzeka® in the United States and Sebivo® was approved in 2007 in more than 50 countries outside the United States, including major Asian countries and several countries included in the European Union. In October 2007, we transferred to Novartis our worldwide development, commercialization and manufacturing rights and obligations related to telbivudine in exchange for royalty payments equal to a percentage of net sales, with such percentage increasing according to specified tiers of net sales. Since the fourth quarter of 2007, Novartis has been solely responsible for clinical trial costs and related expenditures associated with telbivudine.

### **Antiviral Research**

Our scientists have a highly developed set of skills in compound generation, target selection, screening and pharmacology, preclinical development and lead optimization. We are utilizing these skills and capabilities in our discovery and development of antiviral drug candidates.

### ***Our Scientists***

Our scientists are engaged in drug discovery and development. Our scientists have expertise in the areas of medicinal chemistry, molecular virology and pharmacology. They also have substantial experience in applying this expertise to the discovery and development of nucleoside/nucleotide and NS5A inhibitors which target the viral replication cycle.

### ***Focused Compound Library***

Our focused compound library contains a diverse set of structures, which have been synthesized for the principal purpose of targeting and inhibiting viral replication. These structures consist of various nucleosides, nucleoside analogs, nucleotides, selected non-nucleosides and other small molecule compounds, including protease and NS5A inhibitors.

### ***Target Selection***

We focus on viral diseases representing large and growing market opportunities with significant unmet medical needs. Our selection of a particular therapeutic target within those viral diseases takes into consideration the experience and expertise of our scientific management team, and the potential that our nucleoside analog, nucleotide and NS5A inhibitor libraries, and those libraries to which we have access, could yield a small molecule lead. The final selection is based on the possibility of being able to generate robust medicinal chemistry structure-activity relationships to assist lead optimization and secure relevant intellectual property rights.

## **Screening**

We believe that our efficiency in selecting a lead chemical structure from our focused library, and the libraries which we access, distinguishes us from our competitors. Our ability to synthesize multiple compounds with antiviral activity in our Montpellier, France facility enhances early progress toward lead optimization in our Cambridge, Massachusetts facility.

## **Pharmacology, Preclinical Development and Lead Optimization**

Once we have identified lead compounds, they are tested using *in vitro* and *in vivo* pharmacology studies and *in vivo* animal models of antiviral efficacy. Using *in vitro* studies, our scientists are able to ascertain the relevance of intracellular activation, metabolism and protein binding. The *in vivo* pharmacokinetic studies identify the percentage of oral bioavailability and whole body metabolism of the compound. The animal models provide data on the efficacy of the compound and firmly establish a proof-of-concept in a biologically relevant system.

## **Collaborations**

### **Novartis Collaboration**

On May 8, 2003, we entered into a collaboration with Novartis, which included the following agreements and transactions:

- the development and commercialization agreement, under which we collaborate with Novartis to develop, manufacture and commercialize our drug candidates which it licenses from us;
- the manufacturing and supply agreement, under which Novartis manufactured for us the active pharmaceutical ingredient, or API, for the clinical development and commercial supply of drug candidates it licensed from us and the finishing and packaging of licensed products for commercial sale;
- the stockholders' agreement, which was subsequently amended and restated in July 2004 and amended in April 2011 in connection with our underwritten offering; and
- the stock purchase agreement, under which Novartis purchased approximately 54% of our then outstanding capital stock from our stockholders for \$255.0 million in cash, with an additional aggregate amount of up to \$357.0 million contingently payable to these stockholders if we achieve predetermined milestones with respect to the development of specific HCV drug candidates, including valopicitabine, which we ceased developing in July 2007, and prodrugs.

In July 2004 and October 2005, in connection with our public offerings, Novartis purchased from us additional shares of our common stock to maintain its equity interest following each offering. Specifically, Novartis purchased 5.4 million shares of our common stock for an aggregate purchase price of \$75.6 million in connection with our July 2004 initial public offering and approximately 3.9 million shares of common stock for an aggregate purchase price of \$81.2 million in connection with our October 2005 public offering. Additionally, in connection with the consummation of our initial public offering, we sold to Novartis 1.1 million shares of common stock for a purchase price of \$0.001 per share in exchange for the termination of certain stock subscription rights held by Novartis. Novartis did not purchase shares of our common stock pursuant to our underwritten offerings in August 2009, April 2010 or November 2011. We issued 1.8 million shares of our common stock to Novartis pursuant to a private placement agreement in conjunction with our underwritten offering in April 2011. Novartis' ownership was subsequently diluted from approximately 53% prior to the August 2009 offering to approximately 31% as of February 21, 2012.

In conjunction with the underwritten offering and private placement with Novartis in April 2011, we amended the collaboration with Novartis to provide that: a) Novartis retains the exclusive option to obtain rights to drug candidates developed by us so long as Novartis maintains ownership of at least 30% of our common

stock, rather than ownership of at least 40% as was the case prior to the amendment; b) we will use reasonable best efforts to nominate for election as directors at least two designees of Novartis so long as Novartis maintains ownership of at least 30% of our common stock, rather than ownership of at least 35% as was the case prior to the amendment; and c) Novartis' consent is required for the selection and appointment of our chief financial officer so long as Novartis owns at least 30% of our common stock, rather than ownership of at least 40% as was the case prior to the amendment.

### *Development and Commercialization Agreement*

#### Designation of Products

As part of the development and commercialization agreement with Novartis, Novartis has an option to license any of our development-stage drug candidates after demonstration of activity and safety in a proof-of-concept clinical trial so long as Novartis maintains at least 30% ownership of our common stock. The terms of these options, including license fees, milestone payments and payments in reimbursement of development expenses, vary according to the disease which the drug candidate treats, the stage of development of the drug candidate and the projected product valuation based on market research and sales forecasts.

In 2003, Novartis licensed telbivudine from us for the treatment of HBV. In September 2007, we entered into an amendment to the development and commercialization agreement, which we refer to as the 2007 amendment. Pursuant to the 2007 amendment, we transferred to Novartis worldwide development, commercialization and manufacturing rights and obligations pertaining to telbivudine (Tyzeka®/Sebivo®). Subsequently, we began receiving royalty payments equal to a percentage of net sales of Tyzeka®/Sebivo®. The royalty percentage varies based on the specified territory and the aggregate dollar amount of net sales.

In February 2009, Novartis waived its option to license any of our NNRTI compounds, including IDX899, which allowed us to enter into the ViiV license agreement. As part of the ViiV transaction, we amended the development and commercialization agreement with Novartis such that Novartis retained the exclusive option to license other drug candidates developed by us, or in some cases licensed to us, so long as Novartis maintained ownership of 40% of our voting stock rather than ownership of 51% of our voting stock, as was initially agreed to by the parties in 2003. The development and commercialization agreement was further amended in April 2011 to require Novartis to own at least 30% of our common stock to maintain these rights.

In October 2009, Novartis waived its option to license IDX184 and as a result, we retain the worldwide rights to develop, manufacture, commercialize and license IDX184. We may seek a partner who will assist in the future development and commercialization of this drug candidate.

#### Development of Products and Regulatory Activities

For the drug candidates Novartis chooses to license, Novartis will have the right to approve, in its reasonable discretion, the corresponding development budget. Each licensed product will be developed in accordance with a development plan approved by a joint steering committee, which is comprised of an equal number of representatives from Idenix and Novartis. Novartis will also be responsible for certain development expenses incurred in accordance with approved development budgets for the licensed products. The development and commercialization agreement has several joint committees in which we and Novartis participate. We participate in these committees as a means to govern or protect our interests. The committees span the period from early development through commercialization of drug candidates licensed by Novartis.

We have primary responsibility for preparing and filing regulatory submissions with respect to any licensed product in the United States and Novartis has primary responsibility in all other countries in the world. Under certain circumstances, primary responsibilities for all or certain regulatory tasks in a particular country may be switched from one party to the other.

## Product Sales Arrangement

In connection with the drug candidates that Novartis licenses from us, with the exception of Tyzeka<sup>®</sup>/Sebivo<sup>®</sup>, we have retained the right to co-promote or co-market in the United States, United Kingdom, France, Germany, Italy and Spain. In the United States, we would act as the lead commercial party, record revenue from product sales and share equally the resulting net benefit from co-promotion from the date of product launch. In the United Kingdom, France, Germany, Italy and Spain, Novartis would act as the lead commercial party, record revenue from product sales and would share with us the net benefit from co-promotion and co-marketing. The net benefit is defined as net product sales minus related cost of sales. In the United Kingdom, France, Germany, Italy and Spain, the net benefit that would be shared with us would increase incrementally during the first three years from the date of product launch, such that we would share equally with Novartis beginning in the third year from the date of product launch. In other countries, we would effectively sell products to Novartis for their further sale to third-parties. Novartis would pay us for such products at a price that is determined under the terms of our manufacturing and supply agreement with Novartis and we would receive a royalty payment from Novartis on net product sales.

Under the terms of the development and commercialization agreement, Novartis has the right to market, sell or promote any product that competes with the products that Novartis licenses from us.

## Indemnification

Under the development and commercialization agreement, we have agreed to indemnify Novartis and its affiliates against losses suffered as a result of our breach of representations and warranties in that agreement. We made numerous representations and warranties to Novartis regarding our HBV and HCV drug candidates, including representations regarding our ownership of the inventions and discoveries associated with such candidates. If one or more of the representations or warranties were not true at the time they were made to Novartis, we would be in breach of this agreement. In the event of a breach by us, Novartis has the right to seek indemnification from us for damages suffered as a result of such breach. The amounts for which we could be liable to Novartis could be substantial. For additional information on such indemnification rights, see “Stock Purchase Agreement”, “Risk Factors — Factors Related to Our Relationship with Novartis” and “Risk Factors — Factors Related to Patents and Licenses”.

## Termination

Novartis may terminate, in its sole discretion, the development and commercialization agreement with respect to a particular product, drug candidate or country by providing us with six months written notice. In addition, if either we or Novartis materially breach the development and commercialization agreement and do not cure such breach within 30 days, or under certain circumstances, 120 days, or if such breach is incurable, the non-breaching party may terminate the development and commercialization agreement with respect to: a) the particular product, drug candidate or country to which the breach relates; or b) in its entirety, if the material breach is not limited to a particular product, drug candidate or country.

Each party may also terminate the development and commercialization agreement in its entirety upon 30 days written notice if the other party files for bankruptcy, insolvency, reorganization or the like. If Novartis terminates the agreement for material breach by us or for bankruptcy, insolvency or reorganization on our part, then Novartis may elect to retain licenses to drug candidates or products, in which case it will remain obligated to make payments to us in amounts to be negotiated in good faith at the time of termination. If we terminate part or all of the agreement for material breach by Novartis or for bankruptcy, insolvency or reorganization on the part of Novartis, or if Novartis terminates the agreement unilaterally in the absence of a breach by us, we may be obligated to make payments to Novartis in amounts to be negotiated in good faith at the time of termination.

## *Manufacturing and Supply Agreement*

Under the master manufacturing and supply agreement, dated May 8, 2003, with Novartis, we appointed Novartis to manufacture or have manufactured the clinical supply of the API for each drug candidate licensed under

the development and commercialization agreement and certain other drug candidates. The cost of the clinical supply will be treated as a development expense, allocated between us and Novartis in accordance with the agreement. We have the ability to appoint Novartis or a third-party to manufacture the commercial supply of the API based on a competitive bid process under which Novartis has the right to match the best third-party bid. Novartis will perform the finishing and packaging of the API into the final form for sale.

#### *Stockholders' Agreement*

In connection with Novartis' purchase of our stock from our then existing stockholders, we and substantially all of our stockholders entered into the stockholders' agreement with Novartis, which was amended and restated in 2004 and in April 2011 in connection with our underwritten offering. Under the terms of the amended and restated stockholders' agreement, we have:

- granted Novartis, together with certain other holders of our common stock, rights to cause us to register, under the Securities Act of 1933, as amended, such shares of common stock;
- agreed to use our reasonable best efforts to nominate for election as directors at least two designees of Novartis for so long as Novartis and its affiliates own at least 30% of our voting stock and at least one designee of Novartis for so long as Novartis and its affiliates own at least 19.4% of our voting stock; and
- granted Novartis approval rights over a number of corporate actions that we or our subsidiaries may take as long as Novartis and its affiliates continue to own at least 19.4% of our voting stock.

#### *Novartis' Stock Subscription Rights*

Novartis has certain rights to acquire shares of our capital stock. Such rights are further described below under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies and Estimates".

#### *Stock Purchase Agreement*

On March 21, 2003, Novartis, substantially all holders of our capital stock as of May 8, 2003 and Idenix entered into the stock purchase agreement. Under the stock purchase agreement, Novartis purchased approximately 54% of our then outstanding capital stock from our stockholders for \$255.0 million in cash, with an additional aggregate amount of up to \$357.0 million contingently payable to these stockholders if we achieve predetermined development milestones with respect to specific HCV drug candidates. The future contingent payments are payable in cash or, under certain circumstances, Novartis AG American Depository Shares.

Under the stock purchase agreement, we agreed to indemnify Novartis and its affiliates against losses suffered as a result of our breach of representations and warranties in that agreement. In the stock purchase agreement, we and our stockholders who sold shares to Novartis, which include certain of our directors and officers, made numerous representations and warranties. The representations and warranties we made to Novartis regarding our HCV and HBV drug candidates and our ownership of related inventions and discoveries are substantially the same as the representations and warranties we made to Novartis in the development and commercialization agreement. If one or more of our representations or warranties were subsequently determined not to be true at the time we made them to Novartis, we would be in breach of this agreement. In the event of such a breach, Novartis has the right to seek indemnification for damages suffered by Novartis as a result of such breach, from us and, under certain circumstances, us and our stockholders who sold shares to Novartis. The amounts for which we could be liable to Novartis could be substantial. For additional information on such indemnification rights, see "Development and Commercialization Agreement", "Risk Factors — Factors Related to Our Relationship with Novartis" and "Risk Factors — Factors Related to Patents and Licenses".

### ***ViiV Healthcare Company and GlaxoSmithKline Collaboration***

In February 2009, we entered into the ViiV license agreement and granted ViiV an exclusive worldwide license to develop, manufacture and commercialize our NNRTI compounds, including IDX899, for the treatment of human diseases, including HIV/AIDS. In February 2009, we also entered into a stock purchase agreement, which we refer to as the GSK stock purchase agreement. Under this agreement, GSK purchased approximately 2.5 million shares of our common stock at an aggregate purchase price of \$17.0 million, or a per share price of \$6.87. These agreements became effective in March 2009.

In March 2009, we received a \$34.0 million payment related to this collaboration, which consisted of a \$17.0 million license fee payment under the ViiV license agreement and the \$17.0 million payment under the GSK stock purchase agreement described above. In 2010, we received a \$6.5 million milestone payment for the achievement of a preclinical operational milestone and a \$20.0 million milestone payment for the initiation of a phase IIb clinical study of '761. Pursuant to the ViiV license agreement, we were eligible to receive up to \$390.0 million in additional milestone payments as well as double-digit tiered royalties on worldwide product sales.

In February 2011, ViiV informed us that the FDA placed '761 on clinical hold. As a result of further evaluation, ViiV determined that it would not continue development of '761 or develop any other compound licensed under the ViiV license agreement. In December 2011, ViiV notified us that it would terminate the ViiV license agreement effective March 15, 2012. Upon termination, ViiV will relinquish all rights it has in the intellectual property licensed from us and grants us an exclusive, perpetual and irrevocable license to any intellectual property relating to the licensed products it may have developed during the term of the license agreement. As a result of this termination, we will not receive any additional milestone or royalty payments under the ViiV license agreement. We are not subject to early termination penalties under the ViiV license agreement.

Under the terms of the GSK stock purchase agreement, we have agreed to cooperate in one underwritten offering of the purchased shares, including the entry into an underwriting agreement with customary terms, provided that such underwritten offering occurs after the first anniversary of the closing date. The GSK stock purchase agreement may be terminated by mutual written agreement of the parties.

Under the ViiV license agreement and the GSK stock purchase agreement, we have agreed to indemnify ViiV as sublicensee, GSK and their affiliates against losses suffered as a result of our breach of representations and warranties in these agreements. We made numerous representations and warranties regarding our NNRTI program, including '761, including representations regarding our ownership of inventions and discoveries. If one or more of these representations or warranties were subsequently determined not to be true at the time we made them, we would be in breach of these agreements. In the event of such a breach, the parties have the right to seek indemnification from us for damages suffered as a result of such breach. The amounts for which we may be liable could be substantial.

As part of the collaboration with ViiV and GSK, Novartis waived certain rights under the development and commercialization agreement. Specifically, subject to certain retained rights, Novartis waived its rights to the intellectual property that covers the compounds licensed to ViiV. Novartis also agreed that the compounds licensed to ViiV are deemed rejected compounds under the development and commercialization agreement. In addition, we represented and warranted to Novartis that neither we nor our affiliates or licensees (or their successors and assigns) would assert infringement claims against Novartis or certain of its related entities (or their successors and assigns) if such entities exercise limited rights under a subset of the patent rights licensed to ViiV.

Pursuant to the amended and restated stockholders' agreement with Novartis, Novartis also executed a waiver and consent whereby Novartis:

- consented to the sale by us of approximately 2.5 million shares of our common stock to GSK;
- approved our entering into the ViiV license agreement;

- waived its rights to buy a pro rata portion of the shares of our common stock issued to GSK;
- approved our granting of registration rights to GSK and waived its rights to participate in such registration; and
- waived, until a certain time, its rights to request that we file a registration statement on Novartis' behalf or include shares of our common stock owned by Novartis in any such registration statement filed on behalf of GSK.

In January 2009, as part of the collaboration with ViiV, we amended the development and commercialization agreement to provide that Novartis retained the exclusive option to obtain rights to drug candidates developed by us, or in some cases licensed to us, for so long as Novartis maintained ownership of 40% of our common stock, rather than ownership of 51% of our common stock, as was the requirement prior to the execution of this amendment. The development and commercialization agreement was further amended in April 2011 to require Novartis to own at least 30% of our common stock to maintain these rights.

Additionally, in January 2009, as part of the collaboration with ViiV, we amended an agreement with Novartis providing that so long as Novartis and its affiliates owned at least 40% of our common stock, Novartis' consent is required for the selection and appointment of our chief financial officer. Prior to this amendment, the ownership requirement was 51%. If in Novartis' reasonable judgment our chief financial officer is not satisfactorily performing his or her duties, we are required to terminate his or her employment. The development and commercialization agreement was further amended in April 2011 to require Novartis to own at least 30% of our common stock to maintain these rights.

Lastly, as part of the transaction with ViiV, ViiV became a party to the cooperative research program and exclusive license agreement we have with the Università degli Studi di Cagliari, or the University of Cagliari, the co-owner of certain patents and patent applications licensed by us to ViiV under the ViiV license agreement. Under these arrangements, we are liable for certain payments to the University of Cagliari if we receive license fees or milestone payments with respect to such technology. We have made certain payments to the University of Cagliari based on the payments received from ViiV related to the development of '761. Although certain patent rights licensed to ViiV are owned solely by us and do not fall under the arrangements with the University of Cagliari, we have entered into an arrangement whereby if it is ever deemed that any patent owned solely by us and licensed to ViiV was co-developed by anyone on the faculty of the University of Cagliari, such co-development would fall within our existing arrangements with the University of Cagliari and no additional payments would be due by us. As a result of the termination of the ViiV license agreement, we will not receive any additional milestone or royalty payments under the ViiV license agreement and therefore do not expect to make future payments to the University of Cagliari for the patents and patent applications related to '761.

## **Cooperative Laboratory Agreement**

### ***University of Cagliari***

We have entered into two agreements with the University of Cagliari, the co-owner of the patent applications covering some of our HCV and certain HIV technology. One agreement covers our cooperative research program and the other agreement is an exclusive license under these patent applications to develop and sell jointly created drug candidates. In May 2003 and February 2009, Novartis and ViiV, respectively, became parties to each of these agreements. The cooperative research agreement includes provisions with respect to cost sharing, ownership and commercialization of the technology which is discovered or obtained as part of the collaboration. Under the terms of the cooperative research agreement, we made payments to the University of Cagliari for use of the facilities and for supplies consumed in connection with the research activities. This agreement terminated in December 2010.

Under the terms of the license agreement with the University of Cagliari, we have the exclusive worldwide right to make, use and sell certain HCV and HIV technologies and the right to sublicense any of those rights.

Under the terms of the agreement, we assume the costs and responsibility for filing, prosecuting, maintaining and defending the jointly owned patents. If we receive license fees or milestone payments with respect to technology licensed to us by the University of Cagliari, we must provide payments to the University of Cagliari. In addition, we will be liable to the University of Cagliari for a fixed royalty payment on worldwide sales of licensed drug products that derive from the specified patents. The license agreement terminates at the expiration of all royalty payment obligations, unless terminated earlier by us, by the mutual agreement of the parties or by a material breach of the terms of the agreement.

### **Research and Development Expenses**

Research and development expenses for the years ended December 31, 2011, 2010 and 2009 were \$41.3 million, \$44.5 million and \$41.9 million, respectively, and represented 68%, 61% and 62%, respectively, of our total operating expenses in such years.

### **Manufacturing**

We have internally developed the capacity to synthesize compounds in quantities ranging from milligrams to grams. Our medicinal chemists focus on small-scale synthesis that leads to the discovery of new compounds and the analysis of structure-activity relationships for each identified compound series. In addition, our development chemists aim to design efficient synthetic routes suitable for process chemistry scale up to levels of one kilogram batches of the lead molecule. This material supports key preclinical studies, including proof-of-principle studies in animal models, early pharmacokinetic assays, initial toxicology studies and formulation development. The process chemistry facility we maintain in Cambridge, Massachusetts allows us to accelerate these key studies. This facility also allows us to provide non-current good manufacturing practices materials in multi-kilogram quantities to support early toxicological studies and the initial development of formulations. Clinical materials are then manufactured using current good manufacturing practices, or cGMP, by third-parties.

To reduce costs and preserve manufacturing proprietary rights, we provide third-party manufacturers with only the required portion of the synthetic method and a sufficient quantity of the starting or intermediate material to prepare the quantity and quality of material necessary for the conduct of our clinical trials and related nonclinical toxicology studies. We currently rely upon a number of third-party manufacturers for the supply of our drug candidates in bulk quantities.

We have selected manufacturers that we believe comply with cGMP and other regulatory standards. We have established a quality control and quality assurance program, including a set of standard operating procedures, analytical methods and specifications, designed to ensure that our drug candidates are manufactured in accordance with cGMP and other domestic and foreign regulations.

### **Sales and Marketing**

In accordance with our development and commercialization agreement with Novartis, we have the right to co-promote or co-market with Novartis in the United States, United Kingdom, France, Germany, Italy and Spain any products that Novartis licenses from us. If we co-promote or co-market in the markets outside of the United States, Novartis will be primarily responsible for the marketing, distribution and sale of products which it licenses from us.

### **Patents and Licenses**

Our policy is to pursue patents and to otherwise protect our technology, inventions and improvements that are important to the development of our business. We also rely upon trade secrets that may be important to the development of our business.

### ***Hepatitis C Patent Portfolio***

Our HCV patent portfolio includes at least 25 issued U.S. patents, at least 10 pending U.S. patent applications, at least 40 granted foreign patents and at least 107 pending foreign patent applications. These patents are directed to treatment of HCV and/or other *Flaviviridae* infections.

The HCV patent portfolio includes nine issued U.S. patents that will expire in 2021, absent a patent term extension: U.S. Patent Nos. 6,812,219, 6,914,054, 7,105,493, 7,101,861, 7,148,206, 7,163,929, 7,169,766, 7,157,441 and 7,608,597. We co-own these nine patents with the University of Cagliari, which has exclusively licensed its interest in the patents to us under an agreement described under the heading “Cooperative Laboratory Agreement”. The HCV patent portfolio also includes the following 10 issued U.S. patents that will expire in 2023, absent a patent term extension: U.S. Patent Nos. 7,662,798, 7,456,155, 7,192,936, 7,384,924, 7,365,057, 7,547,704, 7,582,618, 7,608,600, 7,625,875 and 7,635,689. We co-own these 10 patents with the University of Cagliari, the Universite Montpellier II, or the University of Montpellier, and Le Centre National de la Recherche Scientifique, or CNRS, which have exclusively licensed their interest in the patents to us under an agreement described in the footnotes to the financial statements to this Annual Report on Form 10-K. In addition, the HCV patent portfolio includes U.S. Patent No. 7,138,376, which will expire in 2022, absent a patent term extension. We co-own this patent with CNRS, which has exclusively licensed its interest in the patent to us under an agreement described in the footnotes to the financial statements to this Annual Report on Form 10-K. The HCV patent portfolio further includes U.S. Patent No. 7,824,851, which will expire in 2023, absent a patent term extension. We co-own this patent with the University of Cagliari, which has exclusively licensed its interest in the patent to us under an agreement described under the heading “Cooperative Laboratory Agreement”. The HCV patent portfolio also includes U.S. Patent No. 7,598,373, which will expire in 2023, absent a patent term extension, and U.S. Patent No. 7,781,576 which will expire in 2029, each of which is owned exclusively by us. The HCV patent portfolio also includes U.S. Patent Nos. 7,902,202 and 7,951,789, each of which will expire in 2028, absent a patent term extension. We co-own these two patents with the University of Montpellier and CNRS, which have exclusively licensed their interest in the patents to us under an agreement as described in the footnotes to the financial statements to this Annual Report on Form 10-K.

### ***Hepatitis B Patent Portfolio and Licenses***

As a result of the transfer of all our development, commercialization and manufacturing rights to Novartis relating to telbivudine, we also assigned to Novartis certain patent rights relating to telbivudine.

Our HBV patent portfolio includes at least 12 issued U.S. patents, at least one pending U.S. patent application, at least 49 granted foreign patents and at least five pending foreign patent applications, including patents pertaining to telbivudine.

Five issued U.S. patents are directed to methods of using telbivudine for the treatment of HBV: U.S. Patent Nos. 6,395,716, 6,569,837, 6,444,652, 6,566,344 and 7,795,238. These five U.S. patents are co-owned by us, CNRS and the University of Montpellier. Under an agreement with these entities described in the footnotes to the financial statements to this Annual Report on Form 10-K, CNRS and the University of Montpellier have exclusively licensed their interest in the patents to us. The term of U.S. Patent No. 6,569,837 has been extended and will expire in 2020 and the other four patents will expire in 2019.

Two issued U.S. patents are directed to valtorcitabine, as well as pharmaceutical compositions that include valtorcitabine: U.S. Patent Nos. 6,875,751 and 7,585,851, each entitled “3’-Prodrugs of 2’-Deoxy-β-L-Nucleosides”. These patents will expire in 2021, absent a patent term extension.

Pursuant to the license agreement between us and the University of Alabama at Birmingham, or UAB, we were granted an exclusive license to the rights that the University of Alabama at Birmingham Research Foundation, or UABRF, an affiliate of UAB, Emory University and CNRS have to a 1995 U.S. patent application and progeny thereof and counterpart patent applications in Europe, Canada, Japan and Australia that cover the use of certain synthetic nucleosides for the treatment of HBV.

In July 2008, we entered into a settlement agreement with UAB, UABRF and Emory University relating to our telbivudine technology. Pursuant to this settlement agreement, all contractual disputes relating to patents covering the use of certain synthetic nucleosides for the treatment of HBV and all litigation matters relating to patents and patent applications related to the use of  $\beta$ -L-2'-deoxy-nucleosides for the treatment of HBV assigned to one or more of Idenix, CNRS and the University of Montpellier and which cover the use of telbivudine (Tyzeka<sup>®</sup>/Sebivo<sup>®</sup>) for the treatment of HBV have been resolved. Under the terms of the settlement agreement, we paid UABRF (on behalf of UAB and Emory University) a \$4.0 million upfront payment and will make additional payments to UABRF equal to 20% of all royalty payments received by us from Novartis from worldwide sales of telbivudine, subject to minimum payment obligations aggregating \$11.0 million. Our payment obligations under the settlement agreement expire on August 10, 2019. The settlement agreement was effective on June 1, 2008 and included mutual releases of all claims and covenants not to sue among the parties. It also included a release from a third-party scientist who had claimed to have inventorship rights in certain Idenix/CNRS/University of Montpellier patents.

### ***HIV Patent Portfolio***

Our HIV patent portfolio includes at least seven issued U.S. patents, one pending U.S. application, at least 58 granted foreign patents and at least 51 pending foreign patent applications.

Of these seven issued U.S. patents, U.S. Patent No. 6,635,636 will expire in 2019, absent a patent term extension, and is owned exclusively by us. Absent patent term extensions, U.S. Patent Nos. 6,545,007, 6,710,068 and 7,365,090 will expire in 2021, 2022 and 2023, respectively, and are co-owned by us with the University of Cagliari, which has exclusively licensed its rights to us under an agreement described under the heading "Cooperative Laboratory Agreement". Absent patent term extensions, U.S. Patent Nos. 7,534,809, 7,960,428 and 8,044,091 will expire in 2025, 2027 and 2025, respectively, and are owned exclusively by us.

### **Competition**

Our industry is highly competitive and subject to rapid technological changes. Significant competitive factors in our industry include product effectiveness, safety, timing and scope of regulatory approvals, price of products, availability of supply, patent protection and sales and marketing capabilities and resources.

Many of the companies competing against us have substantially greater financial, technical and other resources than we do. In addition, many of our competitors have significantly greater experience in testing pharmaceutical and other therapeutic drug candidates as well as obtaining FDA and other regulatory approvals of products in order to market and sell those products. Accordingly, our competitors may be more successful than we may be in obtaining regulatory approval for products and achieving widespread market acceptance. We also may compete with respect to manufacturing efficiency and marketing capabilities, areas in which we have substantially less experience than our competitors.

Tyzeka<sup>®</sup>/Sebivo<sup>®</sup>, and any future products that we successfully develop, will compete with existing and future therapies. The key competitive factors affecting the commercial success of our products are likely to be efficacy, safety profile, combinability with other drugs, convenience of dosing and price in comparison with available therapies.

Many organizations, including large pharmaceutical and biopharmaceutical companies as well as academic and research organizations and government agencies, are commercializing or pursuing novel drug therapies targeting the treatment of HCV and HBV. Companies we expect to compete with in the HCV market include Abbott Laboratories, Boehringer Ingelheim International GmbH, F. Hoffman-LaRoche & Co., Johnson & Johnson, Merck & Co., Inc., Bristol-Myers Squibb Company, Novartis, Gilead Sciences, Inc., Vertex Pharmaceuticals, Inc., Achillion Pharmaceuticals, Inc., Enanta Pharmaceuticals, Inc., and Presidio Pharmaceuticals, Inc.

For the treatment of HCV, Peg-IFN/RBV are approved by the FDA for commercial sale. Two drug products, Incivek (telaprevir) and Victrelis (boceprevir), were approved in 2011 by the FDA for the treatment of HCV in combination with Peg-IFN/RBV. Increased costs associated with the evolving standard of care treatment regimens and the cure rates of patients using either one of these approved drugs and future approved combinations of DAAs may be such that our development and discovery efforts in the area of HCV may be rendered noncompetitive. For the treatment of HBV, we are aware of six other drug products, specifically, lamivudine, entecavir, adefovir dipivoxil, tenofovir, pegylated interferon and interferon alpha, which are approved by the FDA and commercially available in the United States or in foreign jurisdictions. Five of these products have preceded Tyzeka®/Sebivo® into the marketplace and have gained acceptance with physicians and patients.

We believe that a significant number of clinical candidates are currently under development and will become available in the future for the treatment of HCV and HBV. We anticipate that we will face intense and increasing competition as new products enter the market and advanced technologies become available. Our competitors' products may be more effective, or more effectively marketed and sold, than any product we may commercialize. Competitive products may render our products obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our drug candidates. We are also aware that the development of a cure or new treatment methods for the diseases we are targeting could render our products non-competitive or obsolete.

### **Pharmaceutical Pricing and Reimbursement**

In both domestic and foreign markets, sales of our products will depend in part upon the availability of reimbursement from third-party payers. Third-party payers include government health agencies, managed care providers, private health insurers and other organizations. These third-party payers are increasingly challenging drug prices and are examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. We may need to conduct pharmacoeconomic studies to demonstrate the cost-effectiveness of our products. Any drug candidates we successfully develop may not be considered cost-effective. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. The United States and foreign governments continue to propose and pass legislation designed to reduce the cost of healthcare. Accordingly, legislation and regulations affecting the pricing of pharmaceutical products may change before our drug candidates are approved for marketing. Adoption of new legislation could further limit reimbursement for pharmaceutical products. Regulations that may be enacted are likely to affect access to and reimbursement for pharmaceutical products. It is unclear precisely how new regulations will impact the availability of new and emerging drug products, including any products we may develop, alone or with a collaboration partner.

The marketability of any products we successfully develop may suffer if the government and third-party payers fail to provide adequate coverage and reimbursement rates for such products. In addition, an increasing emphasis on managed care in the United States has and will continue to increase the pressure on pharmaceutical pricing.

### **Regulatory Matters**

In October 2006, we received approval from the FDA to market Tyzeka® in the United States. In 2007, Sebivo® was approved in more than 50 countries outside the United States, including major Asian countries and several countries included in the European Union. As previously mentioned, in October 2007, we transferred to Novartis our worldwide regulatory, development, commercialization and manufacturing rights and obligations related to telbivudine (Tyzeka®/Sebivo®) in exchange for royalty payments.

In June 2008, we submitted an IND with the FDA for IDX184, our lead nucleotide polymerase inhibitor drug candidate. In September 2009, we submitted a clinical trial application, or CTA, for IDX375, our lead

non-nucleoside polymerase inhibitor drug candidate. In December 2009, we submitted a CTA for IDX320, our lead protease inhibitor drug candidate. In December 2011, we submitted an IND for IDX719, our lead NS5A inhibitor drug candidate. In 2011, we elected not to devote significant resources to our protease inhibitor and non-nucleoside programs.

In September 2010, the FDA placed two of our HCV drug candidates, IDX184 and IDX320, on clinical hold. The hold was imposed due to three serious adverse events of elevated liver function tests that were detected during post drug exposure safety visits following a 14-day drug-drug interaction study of a combination of IDX184 and IDX320 in healthy volunteers. The liver function tests returned to normal levels in the three subjects during follow-up visits. We believe the hepatotoxicity observed in this drug-drug interaction study was caused by IDX320 and therefore discontinued the clinical development of this drug candidate. We filed a complete response to the FDA and in February 2011, the full clinical hold on IDX184 was removed. The program was placed on partial clinical hold, which allowed us to initiate a phase IIb 12-week clinical trial of IDX184 in July 2011 in combination with Peg-IFN/RBV with safety evaluations of the patients that will be shared with the FDA at certain intervals in the trial. We provided an interim analysis of the first 31 patients following 28 days of treatment to an independent DSMB and to the FDA. The DSMB reviewed the data for the first 31 patients and recommended the continuation of enrollment in the phase IIb IDX184 clinical trial. We submitted the interim data, along with the DSMB's recommendations, to the FDA and requested the continuation of this study and removal of the partial clinical hold for IDX184. In February 2012, the FDA removed the partial clinical hold on IDX184 and as a result we can continue enrollment of the phase IIb study of IDX184 and evaluate IDX184 in future interferon-free combination regimens with other DAAs. In addition, the FDA allowed us to truncate the phase IIb study from 100 patients, as in the original protocol, to a total of 60 patients, and to expand the enrollment criteria as recommended by the DSMB.

#### ***FDA Requirements for Approval of Drug Products***

The research, testing, manufacturing and marketing of drug products are extensively regulated by numerous governmental authorities in the United States and other countries. In the United States, drugs are subject to rigorous oversight by the FDA. The federal Food, Drug and Cosmetic Act and other federal and state statutes and regulations govern, among other things, the research, development, testing, manufacture, storage, record keeping, labeling, promotion, marketing and distribution of pharmaceutical products. If we fail to comply with applicable regulatory requirements, we may be subject to a variety of administrative or judicially imposed sanctions, including:

- product seizures;
- voluntary or mandatory recalls;
- voluntary or mandatory patient and physician notification;
- withdrawal of product approvals;
- prohibitions against or restrictions on the marketing of our products, if approved for commercial sale;
- fines;
- restrictions on importation of our products;
- injunctions;
- debarment;
- civil and criminal penalties; and
- suspension of review and/or refusal to approve pending applications.

The steps ordinarily required before a new pharmaceutical product may be marketed in the United States include preclinical studies, animal tests and formulation studies, the submission to the FDA of an IND, which must become effective before human clinical trials may commence in the United States, and adequate and well-controlled human clinical trials to establish the safety and effectiveness of the drug for each indication for which

it is being tested. Satisfaction of FDA pre-market approval requirements typically takes several years and the actual time required may vary substantially based upon the type, complexity and novelty of the drug candidate or disease. Government regulation may delay or prevent marketing of potential drug candidates for a considerable period of time and impose costly procedures upon a manufacturer's activities. Success in early stage clinical trials does not assure success in later stage clinical trials. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. Even if a product receives regulatory approval, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as *in vitro* and animal studies to assess the potential safety and efficacy of the drug candidate. The conduct of preclinical studies and formulation of compounds for testing must comply with federal regulations and requirements. The results of preclinical studies are submitted to the FDA, as part of the IND to justify the administration of the drug candidate to human subjects in the proposed clinical trial.

A 30-day waiting period after the filing of each IND is required prior to the commencement of clinical testing in humans. If the FDA has not commented on or questioned the IND within this 30-day period, the proposed clinical trial may begin. If the FDA has comments or questions, the questions must be answered to the satisfaction of the FDA before initial clinical testing can begin.

After the commencement of clinical trials, the FDA may, at any time, impose a clinical hold on ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials cannot commence or recommence without FDA authorization and then only under terms specified by the FDA. Additionally, if a clinical hold is imposed on an ongoing clinical trial, further administration of the investigational agent to patients would not be permitted unless specifically allowed by the FDA. In some instances, the IND process can result in substantial delay and expense. Clinical trials involve the administration of the drug candidate to healthy volunteers or patients under the supervision of a qualified principal investigator. Clinical trials must be conducted in compliance with federal regulations and requirements, under protocols detailing the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. The clinical trial protocol and informed consent information for patients to be enrolled in the clinical trial must also be approved by the institutional review board at each institution where the clinical trials will be conducted.

Clinical trials to support new drug applications, or NDAs, for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In phase I, the initial introduction of a drug candidate into healthy human subjects, a drug candidate is tested to assess metabolism, pharmacokinetics and pharmacological activity and safety, including side effects associated with increasing doses. Phase II usually involves clinical trials in a limited subset of the intended patient population to determine dosage tolerance and optimum dosage, identify possible adverse effects and safety risks and provide preliminary support for the efficacy of the drug candidate in the indication being studied. If a drug candidate demonstrates promising preliminary safety and efficacy profiles in phase II evaluations, phase III clinical trials are undertaken to further evaluate clinical efficacy and to further test for safety within an expanded patient population at geographically dispersed clinical trial sites. There can be no assurance that phase I, phase II or phase III testing of our drug candidates will be completed successfully within any specified time period, if at all.

After completion of the required clinical testing, generally an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include, among other things, the results of extensive clinical and preclinical studies and the compilation of data relating to the product's chemistry, pharmacology, manufacture, safety and effectiveness. The cost of an NDA is substantial, both in terms of studies required to generate and compile the requisite data, as well as the mandatory user fees submitted with the application.

The FDA has 60 days from its receipt of the NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that the NDA is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA may designate the submission for priority review. Priority review is granted to drug candidates that demonstrate a potential for significant improvement to approved products in terms of safety or efficacy in the treatment, diagnosis or prevention of serious or life-threatening conditions. The FDA's decision to grant priority review is driven solely by the data submitted and cannot be assured in advance. Under the Prescription Drug User Fee Act, drug candidates that are given a priority review designation have a six month FDA review timeline.

After a submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under federal law, the FDA has 180 days in which to review the application and respond to the applicant. The review timeline is often significantly extended by FDA requests for additional information or clarification regarding information already provided in the submission. The FDA may also refer the application to an appropriate advisory committee, typically a panel that includes clinicians, statisticians and other experts for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee.

If FDA evaluations of the NDA and the manufacturing facilities are favorable, the FDA may issue an approval letter. If the NDA will not be approved by the FDA in its current form, the FDA will issue a complete response letter describing the NDA deficiencies and the required actions needed for approval, if appropriate. When and if those conditions have been met to the FDA's satisfaction, the FDA may then issue an approval letter. The approval letter authorizes commercial marketing of the drug for specific indications. As a condition of the NDA approval, the FDA may require post-marketing testing and surveillance to monitor the drug's safety or efficacy, or impose other conditions. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems occur following initial marketing.

Once the NDA is approved, a product will be subject to certain post-approval requirements, including requirements for adverse event reporting and submission of periodic reports and/or supplemental new drug applications for approval of changes to the originally approved prescribing information, product formulation, and manufacturing and testing requirements. Following approval, drug products are required to be manufactured and tested for compliance with the NDA and/or compendial specifications prior to release for commercial distribution. The manufacture and testing must be performed in approved manufacturing and testing sites complying with cGMP requirements and subject to FDA inspection authority.

Approved drug products must be promoted in a manner which is consistent with their terms and conditions of approval. In addition, the FDA requires substantiation of any claims of superiority of one product over another including, in many cases, requirements that such claims be proven by adequate and well controlled head-to-head clinical trials. To the extent that market acceptance of our drug candidates may depend on their superiority over existing therapies, any restriction on our ability to advertise or otherwise promote claims of superiority, or requirements to conduct additional expensive clinical trials to provide proof of such claims, could negatively affect the sales of our products and/or our expenses.

From time to time, legislation is drafted and introduced that could significantly change the statutory provisions governing the approval, manufacturing and marketing of drug products. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA or the courts in ways that may significantly affect our business and our drug candidates. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be.

If the FDA's evaluation of the NDA submission or manufacturing facilities is not favorable, the FDA may decide that the application does not satisfy the regulatory criteria for approval.

### ***Foreign Regulation of Drug Product Approval in Europe***

In the European Union, investigational products are subject to extensive regulatory requirements. Prior to the initiation of clinical trials with investigational drug products, sponsor companies must file CTAs in the individual European Union countries in which subjects or patients will be enrolled. CTAs are similar to United States INDs and provide the local health authority and ethics committee with the study protocol, informed consent form, summaries of the manufacturing process as well as the preclinical animal toxicology results. Approval for the study can take from one to three months depending on the country, health authority and ethics committee.

As in the United States, the marketing of medicinal products is subject to the granting of marketing authorizations by relevant regulatory agencies. The granting of these marketing authorizations can involve additional testing as compared to the FDA requirements. Also, the time required may differ from that required for FDA approval. In the European Union, approval of new pharmaceutical products can be granted either through a mutual recognition procedure and decentralized approval or through a centralized procedure. Our drug candidates fall under the centralized procedure category.

#### ***Centralized Procedure***

The centralized procedure is currently mandatory for products developed by means of a biotechnological process and medicinal products which contain new active substances and for which the indication is treatment of AIDS, cancer, neurodegenerative disorder, diabetes, autoimmune diseases and other immune dysfunctions and viral diseases.

Under the centralized procedure, an application is submitted to the European Medicines Agency, or EMA. Two European Union member states are appointed to conduct an initial evaluation of each application, the so-called rapporteur and co-rapporteur countries. The regulatory authorities in both the rapporteur and co-rapporteur countries each prepare an assessment report. These reports become the basis of a scientific opinion of the Committee for Medicinal Products for Human Use. If this opinion is favorable, it is sent to the European Commission which drafts a decision. After consulting with the member states, the European Commission adopts a decision and grants a marketing authorization which is valid throughout the European Union and confers the same rights and obligations in each of the member states as a marketing authorization granted by that member state. Several other European countries outside the European Union, such as Norway and Iceland, accept European Union review and approval as a basis for their own national approval.

### ***Foreign Regulation of Drug Product Approval in Asia***

Until recently, submissions to regulatory authorities in Asia for marketing authorization have been primarily based on using prior approvals in either the United States or countries in the European Union as well as small, locally conducted studies. Recently an increasing number of companies are conducting phase III clinical trials in several major Asian countries such as Japan, China, Taiwan and South Korea. To conduct clinical trials in these regions, local clinical trial applications, equivalent to INDs, must be filed in the country. Upon completion of all clinical trials, marketing applications, similar to the United States NDA, need to be submitted to and approved by the appropriate regulatory authorities prior to commercialization.

#### ***Marketing Applications Format***

As part of the International Conference on Harmonization, or ICH, standardization initiatives spearheaded by the United States, European Union and Japan, future marketing applications in these regions will be submitted as a core global dossier known as the Common Technical Document, or CTD. While the FDA has not mandated that submissions be made in the CTD format, it has indicated that this is its preferable submission format. In the European Union and Japan, the CTD is the required submission format. Electronic CTDs are currently being used and are the manner of submission now preferred by the regulatory agencies requiring and recommending the CTD format. Non-ICH regions such as Eastern and Central Europe, Latin America and China have indicated that the CTD will be an acceptable submission format.

### ***Hazardous Materials***

Our research and development processes involve the controlled use of numerous hazardous materials, chemicals and radioactive materials and produce waste products. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposing of hazardous materials and waste products, including certain regulations promulgated by the U.S. Environmental Protection Agency, or EPA. The EPA regulations to which we are subject require that we register with the EPA as a generator of hazardous waste. We do not expect the cost of complying with these laws and regulations to be material. While we maintain insurance, it is possible that costs for which we may become liable as a result of any environmental liability or toxic tort claims that may be asserted against us in connection with our use or disposal of hazardous materials, chemicals and radioactive materials, may exceed or otherwise be excluded from such insurance coverage. Such amounts could be substantial.

### **Employees**

As of December 31, 2011, we had 105 full time employees. We had 81 employees engaged in research, development and manufacturing functions, 25 of whom hold Ph.D. degrees. We also had 24 employees engaged in administration and finance activities.

### **Available Information**

Our website address is *www.idenix.com*. We make available, free of charge, on or through our website our annual reports on Form 10-K, quarterly reports on Form 10-Q, periodic reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission, or SEC. We are not, however, including the information contained on our website, or information that may be accessed through links on our website, as part of, or incorporating it by reference into, this Annual Report on Form 10-K. In addition, copies of our reports filed electronically with the SEC may be accessed on the SEC's website at *www.sec.gov*. The public may also read and copy any materials filed with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330. We intend to disclose on our website any amendments to, or waivers from, our code of business conduct and ethics that are required to be disclosed pursuant to rules and regulations promulgated by the SEC.

### **Corporate Information**

We are a Delaware corporation. Our principal offices are located at 60 Hampshire Street, Cambridge, Massachusetts 02139. The telephone number of our principal executive offices is 617-995-9800. Idenix is one of our registered trademarks or service marks. All other trademarks, service marks or tradenames referenced in this Annual Report on Form 10-K are the property of their respective owners.

## **Item 1A. Risk Factors**

Our business faces many risks. The risks described below may not be the only risks we face. Additional risks we do not yet know of or which we currently believe are immaterial may also impair our business operations. If any of the events or circumstances described in the following risks actually occurs, our business, financial condition or results of operations could suffer and the trading price of our common stock could decline. The following risks should be considered, together with all of the other information in this Annual Report on Form 10-K for the year ended December 31, 2011, before deciding to invest in our securities.

### **Factors Related to Our Business**

***Our product candidates may exhibit undesirable side effects when used alone or in combination with other approved pharmaceutical products or investigational agents, which may delay or preclude their further development or regulatory approval, or limit their use if approved.***

Throughout the drug development process, we must continually demonstrate the safety and tolerability of our product candidates in order to obtain regulatory approval to advance their clinical development or to market them. Even if our product candidates demonstrate biologic activity and clinical efficacy, any unacceptable adverse side effects or toxicities, when administered alone or in the presence of other pharmaceutical products or investigational agents, which can arise at any stage of development, may outweigh their potential benefit. For instance, in September 2010, two of our drug candidates, IDX184 and IDX320, were placed on clinical hold by the FDA due to three serious adverse events of elevated liver function tests that were detected during post drug exposure safety visits following a 14-day drug-drug interaction study of a combination of IDX184 and IDX320 in healthy volunteers. In future preclinical studies and clinical trials our product candidates may demonstrate unacceptable safety profiles or unacceptable drug-drug interactions, which could result in the delay or termination of their development, prevent regulatory approval or limit their market acceptance if they are ultimately approved.

***We have a limited operating history and have incurred a cumulative loss since inception. If we do not generate significant revenues, we will not be profitable.***

We have incurred significant losses each year since our inception in May 1998. Telbivudine (Tyzeka®/Sebivo®), our only product to reach commercialization, is marketed by Novartis, and we receive royalty payments associated with sales of this product. There is risk in determining the potential future revenue associated with sales of this product or any other product that reaches commercialization. We will not be able to generate additional revenues from other product sales until we successfully complete clinical development and receive regulatory approval for one of our other drug candidates, and we or a collaboration partner successfully introduce such product commercially. We expect to incur annual operating losses over the next several years as we continue to expand our drug discovery and development efforts. We also expect that the net loss we will incur will fluctuate from quarter to quarter and such fluctuations may be substantial. To generate product revenue, regulatory approval for products we successfully develop must be obtained and we and/or one of our existing or future collaboration partners must effectively manufacture, market and sell such products. Even if we successfully commercialize drug candidates that receive regulatory approval, we may not be able to realize revenues at a level that would allow us to achieve or sustain profitability. Accordingly, we may never generate significant revenue and, even if we do generate significant revenue, we may never achieve profitability.

***We will need additional capital to fund our operations, including the development, manufacture and potential commercialization of our drug candidates. If we do not have or cannot raise additional capital when needed, we will be unable to develop and ultimately commercialize our drug candidates successfully.***

Our cash and cash equivalents balance was \$118.3 million at December 31, 2011. We believe that in addition to this balance the anticipated royalty payments associated with product sales of Tyzeka®/Sebivo® will be sufficient to sustain operations for at least the next 12 months from December 31, 2011. Our drug development programs and the potential commercialization of our drug candidates will require substantial cash to

fund expenses that we will incur in connection with preclinical studies and clinical trials, regulatory review and future manufacturing and sales and marketing efforts.

Our need for additional funding will depend in part on whether:

- with respect to our other drug candidates, Novartis exercises its option to license any such drug candidates, and we receive related license fees, milestone payments and development expense reimbursement payments from Novartis; with respect to any of our drug candidates not licensed by Novartis, we receive related license fees, milestone payments and development expense reimbursement payments from third-parties;
- with respect to Tyzeka®/Sebivo®, whether the level of royalty payments received from Novartis is significant; and
- the terms of a development and commercialization agreement, if any, that we enter into with respect to our drug candidate, IDX184, for the treatment of HCV.

In addition, although Novartis has agreed to pay for certain development expenses incurred under development plans it approves for products and drug candidates that it has licensed from us, Novartis has the right to terminate its license and the related funding obligations with respect to any such product or drug candidate by providing us with six months written notice.

Our future capital needs will also depend generally on many other factors, including:

- the amount of revenue that we may be able to realize from commercialization and sale of drug candidates, if any, which are approved by regulatory authorities;
- the scope and results of our preclinical studies and clinical trials;
- the progress of our current preclinical and clinical development programs for HCV;
- the cost of obtaining, maintaining and defending patents on our drug candidates and our processes;
- the cost, timing and outcome of regulatory reviews;
- any costs associated with changes in rules and regulations promulgated by the FDA related to the drug development process and/or clinical trials, including but not limited to increased costs associated with the evolving standard of care treatment regimens;
- the commercial potential of our drug candidates;
- the rate of technological advances in our markets;
- the cost of acquiring or in-licensing new discovery compounds, technologies, drug candidates or other business assets;
- the magnitude of our general and administrative expenses;
- any costs related to litigation in which we may be involved or related to any claims made against us;
- any costs we may incur under current and future licensing arrangements; and
- the costs of commercializing and launching other products, if any, which are successfully developed and approved for commercial sale by regulatory authorities.

We expect that we will incur significant costs to complete the clinical trials and other studies required to enable us to submit regulatory applications with the FDA and/or the EMA for our drug candidates as we continue development of each of our drug candidates. The time and cost to complete clinical development of our drug candidates may vary as a result of a number of factors.

We may seek additional capital through a combination of public and private equity offerings, debt financings and collaborative, strategic alliance and licensing arrangements. Such additional financing may not be available when we need it or may not be available on terms that are favorable to us. In October 2011, we filed a universal shelf registration statement with the SEC which will allow us to offer and sell from time to time up to a maximum of \$150.0 million of shares of common stock, at prices and terms to be determined at the time of sale. Any financing requiring the issuance of additional shares of capital stock must first be approved by Novartis so long as Novartis continues to own at least 19.4% of our voting stock. As of February 21, 2012, Novartis owned approximately 31% of our outstanding common stock.

If we raise additional capital through the sale of our common stock, existing stockholders, other than Novartis, which has the right to maintain a certain level of ownership, will experience dilution of their current level of ownership of our common stock and the terms of the financing may adversely affect the holdings or rights of our stockholders. If we are unable to obtain adequate financing on a timely basis, we could be required to delay, reduce or eliminate one or more of our drug development programs or to enter into new collaborative, strategic alliances or licensing arrangements that may not be favorable to us. More generally, if we are unable to obtain adequate funding, we may be required to scale back, suspend or terminate our business operations.

***Our research and development efforts may not result in additional drug candidates being discovered on anticipated timelines, which could limit our ability to generate revenues.***

Some of our research and development programs are at preclinical stages. Additional drug candidates that we may develop or acquire will require significant research, development, preclinical studies and clinical trials, regulatory approval and commitment of resources before any commercialization may occur. We cannot predict whether our research will lead to the discovery of any additional drug candidates that could generate revenues for us.

***Our failure to successfully acquire or develop and market additional drug candidates or approved drugs would impair our ability to grow.***

As part of our strategy, we intend to establish a franchise in the HCV market by developing multiple drug candidates for this therapeutic indication. The success of this strategy depends upon the development and commercialization of additional drug candidates that we successfully discover, license or otherwise acquire. In September 2010, the FDA placed two of our HCV drug candidates, IDX184 and IDX320, on clinical hold. The hold was imposed due to three serious adverse events of elevated liver function tests that were detected during post drug exposure safety visits following a 14-day drug-drug interaction study of a combination of IDX184 and IDX320 in healthy volunteers. We believe the hepatotoxicity observed in this drug-drug interaction study was caused by IDX320 and therefore discontinued the clinical development of this drug candidate. In February 2011, the full clinical hold on IDX184 was removed by the FDA and the program was placed on partial clinical hold. In February 2012, the FDA removed the partial clinical hold on IDX184 and as a result we are able to continue the development of IDX184.

Drug candidates we discover, license or acquire will require additional and likely substantial development, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All drug candidates are prone to the risks of failure which are inherent in pharmaceutical drug development, including the possibility that the drug candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities.

Proposing, negotiating and implementing the acquisition or in-license of drug candidates may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing and sales resources, may compete with us for the acquisition of drug candidates. We may not be able to acquire the rights to additional drug candidates on terms that we find acceptable.

***Our investments are subject to general credit, liquidity, market and interest rate risks.***

As of December 31, 2011, all of our cash and cash equivalents were invested in government agency and treasury money market instruments. Our investment policy seeks to manage these assets to achieve our goals of preserving principal and maintaining adequate liquidity. Should our investments cease paying or reduce the amount of interest paid to us, our interest income would suffer. In addition, general credit, liquidity, market and interest risks associated with our investment portfolio may have an adverse effect on our financial condition.

***The commercial markets which we intend to enter are subject to intense competition. If we are unable to compete effectively, our drug candidates may be rendered noncompetitive or obsolete.***

We are engaged in segments of the pharmaceutical industry that are highly competitive and rapidly changing. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations are commercializing or pursuing the development of products that target viral diseases, including the same diseases we are targeting.

We face intense competition from existing products and we expect to face increasing competition as new products enter the market and advanced technologies become available. For the treatment of HBV, we are aware of six other drug products, specifically, lamivudine, entecavir, adefovir dipivoxil, tenofovir, pegylated interferon and interferon alpha, which are approved by the FDA and commercially available in the United States or in foreign jurisdictions. Five of these products have preceded Tyzeka<sup>®</sup>/Sebivo<sup>®</sup> into the marketplace and have gained acceptance with physicians and patients. For the treatment of HCV, Peg-IFN/RBV are approved by the FDA for commercial sale. Two drug products, Incivek (telaprevir) and Victrelis (boceprevir), were approved in 2011 by the FDA for the treatment of HCV in combination with Peg-IFN/RBV. Increased costs associated with the evolving standard of care treatment regimens and the cure rates of patients using either one of these approved drugs and future approved combinations of DAAs may be such that our development and discovery efforts in the area of HCV may be rendered noncompetitive.

We believe that a significant number of drug candidates that are currently under development may become available in the future for the treatment of HBV and HCV. Our competitors' products may be more effective, have fewer side effects, have lower costs or be better marketed and sold than any of our products. Additionally, products that our competitors successfully develop for the treatment of HCV may be marketed prior to any HCV product we or our collaboration partners successfully develop. Many of our competitors have:

- significantly greater financial, technical and human resources than we have and may be better equipped to discover, develop, manufacture and commercialize products;
- more extensive experience in conducting preclinical studies and clinical trials, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products;
- products that have been approved or drug candidates that are in late-stage development; and
- collaborative arrangements in our target markets with leading companies and research institutions.

Novartis has the right to market and sell products that compete with the drug candidates and products that we license to them and any competition by Novartis could have a material adverse effect on our business.

Competitive products may render our products obsolete or noncompetitive before we can recover the expenses of developing and commercializing our drug candidates. Furthermore, the development of new treatment methods and/or the widespread adoption or increased utilization of vaccines for the diseases we are targeting could render our drug candidates noncompetitive, obsolete or uneconomical.

With respect to Tyzeka<sup>®</sup>/Sebivo<sup>®</sup> and other products, if any, we may successfully develop and obtain approval to commercialize, we will face competition based on the safety and effectiveness of our products, the timing and scope of regulatory approvals, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, price, patent position and other factors. Our competitors may develop or commercialize

more effective or more affordable products or obtain more effective patent protection than we do. Accordingly, our competitors may commercialize products more rapidly or effectively than we do, which could adversely affect our competitive position and business.

Biotechnology and related pharmaceutical technologies have undergone and continue to be subject to rapid and significant change. Our future will depend in large part on our ability to maintain a competitive position with respect to these technologies.

***If biopharmaceutical companies involved in HCV drug development continue to consolidate, competition may increase and our business may be harmed.***

In late 2011 and early 2012, several acquisitions of smaller biopharmaceutical companies by larger biopharmaceutical companies took place at substantial premiums over the market capitalizations of the target companies, including the acquisitions of Anadys Pharmaceuticals, Pharmasset, Inc. and Inhibitex Pharmaceuticals, by F. Hoffman-LaRoche & Co., Gilead Sciences, Inc. and Bristol-Myers Squibb Company, respectively. If such consolidation continues to take place, we may face competitive pressures to a far greater degree than had those consolidations not occurred, resulting from the greater resources the larger pharmaceutical companies can put toward their HCV development pipelines.

***If we are not able to attract and retain key management and scientific personnel and advisors, we may not successfully develop our drug candidates or achieve our other business objectives.***

The growth of our business and our success depends in large part on our ability to attract and retain key management and research and development personnel. Our key personnel include our senior officers, many of whom have very specialized scientific, medical or operational knowledge. The loss of the service of any of the key members of our senior management team may significantly delay or prevent our discovery of additional drug candidates, the development of our drug candidates and achievement of our other business objectives. Our ability to attract and retain qualified personnel, consultants and advisors is critical to our success.

We face intense competition for qualified individuals from numerous pharmaceutical and biotechnology companies, academic institutions, governmental entities and other research institutions. We may be unable to attract and retain these individuals and our failure to do so would have an adverse effect on our business.

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

Our business exposes us to significant potential product liability risks that are inherent in the development, manufacturing and marketing of human therapeutic products. Product liability claims could result in a recall of products or a change in the therapeutic indications for which such products may be used. In addition, product liability claims may distract our management and key personnel from our core business, require us to spend significant time and money in litigation or to pay significant damages, which could prevent or interfere with commercialization efforts and could adversely affect our business. Claims of this nature would also adversely affect our reputation, which could damage our position in the marketplace.

For Tyzeka<sup>®</sup>/Sebivo<sup>®</sup>, product liability claims could be made against us based on the use of our product prior to October 1, 2007, at which time we transferred to Novartis our worldwide development, commercialization and manufacturing rights and obligations related to Tyzeka<sup>®</sup>/Sebivo<sup>®</sup> in exchange for royalty payments equal to a percentage of net sales. For Tyzeka<sup>®</sup>/Sebivo<sup>®</sup> and our drug candidates, product liability claims could be made against us based on the use of our drug candidates in clinical trials. We have obtained product liability insurance for Tyzeka<sup>®</sup>/Sebivo<sup>®</sup> and maintain clinical trial insurance for our drug candidates in development. Such insurance may not provide adequate coverage against potential liabilities. In addition, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to maintain or increase current amounts of product liability and clinical trial insurance coverage, obtain product liability insurance for other products, if any, that we seek to commercialize, obtain additional clinical trial

insurance or obtain sufficient insurance at a reasonable cost. If we are unable to obtain or maintain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims, we may be unable to commercialize our products or conduct the clinical trials necessary to develop our drug candidates. A successful product liability claim brought against us in excess of our insurance coverage may require us to pay substantial amounts in damages. This could adversely affect our cash position and results of operations.

***Our insurance policies are expensive and protect us only from some business risks, which will leave us exposed to significant, uninsured liabilities.***

We do not carry insurance for all categories of risk that our business may encounter. We currently maintain general liability, property, workers' compensation, products liability, directors' and officers' and employment practices insurance policies. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

***If the estimates we make, and the assumptions on which we rely, in preparing our financial statements prove inaccurate, our actual results may vary from those reflected in our projections and accruals.***

Our financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses, the amounts of charges accrued by us and related disclosures of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. There can be no assurance, however, that our estimates, or the assumptions underlying them, will not change.

One of these estimates is our estimate of the development period over which we amortize non-refundable payments from Novartis, which we review on a quarterly basis. We estimate this period to be through May 2021 based on current judgments related to the product development timeline of our licensed drug candidates. When the estimated development period changes, we adjust periodic revenue that is being recognized and record the remaining unrecognized non-refundable payments over the remaining development period during which our performance obligations are completed. Significant judgments and estimates are involved in determining the estimated development period and different assumptions could yield materially different financial results. This, in turn, could adversely affect our stock price.

***If we fail to design and maintain an effective system of internal controls, we may not be able to accurately report our financial results or prevent fraud. As a result, current and potential stockholders could lose confidence in our financial reporting, which could harm our business and the trading price of our common stock.***

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report in Annual Reports on Form 10-K that contains an assessment by management of the effectiveness of the company's internal controls over financial reporting. In addition, the company's registered independent public accounting firm must attest to the effectiveness of our internal controls over financial reporting.

We have completed an assessment and will continue to review in the future our internal controls over financial reporting in an effort to ensure compliance with the Section 404 requirements. The manner by which companies implement, maintain and enhance these requirements including internal control reforms, if any, to comply with Section 404, and how registered independent public accounting firms apply these requirements and test companies' internal controls, is subject to change and will evolve over time. As a result, notwithstanding our efforts, it is possible that either our management or our independent registered public accounting firm may in the future determine that our internal controls over financial reporting are not effective.

A determination that our internal controls over financial reporting are ineffective could result in an adverse reaction in the financial marketplace due to a loss of investor confidence in the reliability of our financial statements, which ultimately could negatively impact the market price of our stock, increase the volatility of our stock price and adversely affect our ability to raise additional funding.

***Our business is subject to international economic, political and other risks that could negatively affect our results of operations or financial position.***

Our business is subject to risks associated with doing business internationally, including:

- changes in a specific country's or region's political or economic conditions, including Western Europe, in particular;
- potential negative consequences from changes in tax laws affecting our ability to repatriate profits;
- difficulty in staffing and managing operations overseas;
- unfavorable labor regulations applicable to our European operations;
- changes in foreign currency exchange rates; and
- the need to ensure compliance with the numerous regulatory and legal requirements applicable to our business in each of these jurisdictions and to maintain an effective compliance program to ensure compliance.

Our operating results may be impacted by the health of the North American and European economies. Our business and financial performance may be adversely affected by current and future economic conditions that cause a decline in business and consumer spending, including a reduction in the availability of credit, rising interest rates, financial market volatility and recession.

***We may be required to relocate one of our principal research facilities, which could interrupt our business activities and result in significant expense.***

We have been involved in a dispute with the City of Cambridge, Massachusetts and its License Commission pertaining to the level of noise emitted from certain rooftop equipment at our research facility located at 60 Hampshire Street in Cambridge. The License Commission has claimed that we are in violation of the local noise ordinance pertaining to sound emissions, based on a complaint from neighbors living adjacent to the property. We have contested this alleged violation before the License Commission, as well as the Middlesex County, Massachusetts, Superior Court. In July 2010, the License Commission granted us a special variance from the requirements of the local noise ordinance for a period of one-year, effective as of July 1, 2010. In August 2011, the License Commission granted an extension of the July 2010 variance until August 2012. We may, however, be required to cease certain activities at the building if: a) the noise emitted from certain rooftop equipment at our research facility exceeds the levels permitted by the special variance; b) the parties are unable to resolve this matter through negotiations and remedial action after August 2012; or c) any future legal challenge to the position of the City of Cambridge and the License Commission is unsuccessful. In any such event, we could be required to relocate to another facility which could interrupt some of our business activities and could be time consuming and costly.

#### **Factors Related to Development, Clinical Testing and Regulatory Approval of Our Drug Candidates**

***All of our drug candidates are in development. Our drug candidates remain subject to clinical testing and regulatory approval. If we are unable to develop our drug candidates, we will not be successful.***

To date, we have limited experience marketing, distributing and selling any products. The success of our business depends primarily upon Novartis' ability to commercialize Tyzeka®/Sebivo® and our ability, or that of any future collaboration partner, to successfully commercialize other products we may successfully develop. We received approval from the FDA in the fourth quarter of 2006 to market and sell Tyzeka® for the treatment of HBV in the United States. In April 2007, Sebivo® was approved in the European Union for the treatment of

patients with HBV. Effective October 1, 2007, we transferred to Novartis our worldwide development, commercialization and manufacturing rights and obligations related to telbivudine (Tyzeka®/Sebivo®) in exchange for royalty payments equal to a percentage of net sales. The royalty percentage varies based on the specified territory and the aggregate dollar amount of net sales.

Our other drug candidates are in various earlier stages of development. All of our drug candidates require regulatory review and approval prior to commercialization. Approval by regulatory authorities requires, among other things, that our drug candidates satisfy rigorous standards of safety, including efficacy and assessments of the toxicity and carcinogenicity of the drug candidates we are developing. To satisfy these standards, we must engage in expensive and lengthy testing. Notwithstanding the efforts to satisfy these regulatory standards, our drug candidates may not:

- offer therapeutic or other improvements over existing 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
- be successfully commercialized.

Commercial availability of our drug candidates is dependent upon successful clinical development and receipt of requisite regulatory approvals. Clinical data often are susceptible to varying interpretations. Many companies that have believed that their drug candidates performed satisfactorily in clinical trials in terms of both safety and efficacy have nonetheless failed to obtain regulatory approval for commercial sale. Furthermore, the FDA and other regulatory authorities may request additional information including data from additional clinical trials, which may significantly delay any approval and these regulatory agencies ultimately may not grant marketing approval for any of our drug candidates. For example, in September 2010, the FDA placed two of our HCV drug candidates, IDX184 and IDX320, on clinical hold. The hold was imposed due to three serious adverse events of elevated liver function tests that were detected during post drug exposure safety visits following a 14-day drug-drug interaction study of a combination of IDX184 and IDX320 in healthy volunteers. We believe the hepatotoxicity observed in this drug-drug interaction study was caused by IDX320 and therefore discontinued the clinical development of this drug candidate. In February 2011, the full clinical hold on IDX184 was removed. The program was placed on partial clinical hold, which allowed us to initiate a phase IIb 12-week clinical trial of IDX184 in July 2011 in combination with Peg-IFN/RBV. In February 2012, the FDA removed the partial clinical hold on IDX184 and as a result we are able to continue the development of IDX184.

***If our clinical trials are not successful, we will not obtain regulatory approval for the commercial sale of our drug candidates.***

To obtain regulatory approval for the commercial sale of our drug candidates, we will be required to demonstrate through preclinical studies and clinical trials that our drug candidates are safe and effective. Preclinical studies and clinical trials are lengthy and expensive and the historical rate of failure for drug candidates is high. The results from preclinical studies of a drug candidate may not predict the results that will be obtained in human clinical trials.

We, the FDA or other applicable regulatory authorities may prohibit the initiation or suspend clinical trials of a drug candidate at any time if we or they believe the persons participating in such clinical trials are being exposed to unacceptable health risks or for other reasons. The observation of adverse side effects in a clinical trial may result in the FDA or foreign regulatory authorities refusing to approve a particular drug candidate for any or all indications of use. Additionally, adverse or inconclusive clinical trial results concerning any of our drug candidates could require us to conduct additional clinical trials, result in increased costs, significantly delay the submission of applications seeking marketing approval for such drug candidates, result in a narrower indication than was originally sought or result in a decision to discontinue development of such drug candidates. Even if we successfully complete our clinical trials with respect to our drug candidates, we may not receive regulatory approval for such candidate.

Clinical trials require sufficient patient enrollment, which is a function of many 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 eligibility criteria for the clinical trial and other clinical trials evaluating other investigational agents for the same or similar uses, which may compete with us for patient enrollment. Delays in patient enrollment can result in increased costs and longer development times.

We cannot predict whether we will encounter additional problems with any of our completed, ongoing or planned clinical trials that will cause us or regulatory authorities to delay or suspend our clinical trials, delay or suspend patient enrollment into our clinical trials or delay the analysis of data from our completed or ongoing clinical trials. Delays in the development of our drug candidates would delay our ability to seek and potentially obtain regulatory approvals, increase expenses associated with clinical development and likely increase the volatility of the price of our common stock. Any of the following could suspend, terminate or delay the completion of our ongoing, or the initiation of our planned, clinical trials:

- discussions with the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- delays in obtaining, or the inability to obtain, required approvals from, or suspensions or termination by, institutional review boards or other governing entities at clinical sites selected for participation in our clinical trials;
- delays in enrolling participants into clinical trials;
- lower than anticipated retention of participants in clinical trials;
- insufficient supply or deficient quality of drug candidate materials or other materials necessary to conduct our clinical trials;
- serious or unexpected drug-related side effects experienced by participants in our clinical trials; or
- negative results of clinical trials.

If the results of our or our partner's ongoing or planned clinical trials for our drug candidates are not available when we expect or if we encounter any delay in the analysis of data from our preclinical studies and clinical trials:

- we may be unable to commence human clinical trials of any drug candidates;
- Novartis may choose not to license our drug candidates and we may not be able to enter into other collaborative arrangements for any of our other drug candidates; or
- we may not have the financial resources to continue the research and development of our drug candidates.

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

Each of our drug candidates is subject to extensive governmental regulations relating to development, clinical trials, manufacturing and commercialization. Rigorous preclinical studies and clinical trials and an extensive regulatory approval process are required in the United States and in many foreign jurisdictions prior to the commercial sale of any drug candidates. Before any drug candidate can be approved for sale, we, or other collaboration partners must demonstrate that it can be manufactured in accordance with the FDA's cGMP requirements. In addition, facilities where the principal commercial supply of a product is to be manufactured must pass FDA inspection prior to approval. 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 currently developing will obtain the appropriate regulatory approvals necessary to permit commercial distribution.

The time required for FDA review and other approvals is uncertain and typically takes a number of years, depending upon the complexity of the drug candidate. Analysis of data obtained from preclinical studies and clinical trials is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or

prevent regulatory approval. We or one of our partners may also encounter unanticipated delays or increased costs due to government regulation from future legislation or administrative action, changes in FDA policy during the period of product development, clinical trials and FDA regulatory review.

Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability or that of a partner to generate revenues from a particular drug candidate. For example, in September 2010, the FDA placed a clinical hold on IDX184 and IDX320, two of our drug candidates for the treatment of HCV. We discontinued the clinical development of IDX320 and in February 2011, the full clinical hold on IDX184 was removed by the FDA and the program was placed on partial clinical hold. Additionally, in February 2011, ViiV informed us that the FDA placed '761 on clinical hold. As a result of further evaluation, ViiV determined that it would not continue development of '761 or develop any other compound licensed under the ViiV license agreement. In December 2011, ViiV notified us that it would terminate the ViiV license agreement effective March 15, 2012. Furthermore, any regulatory approval to market a product may be subject to limitations on the indicated uses for which we or a partner may market the product. These restrictions may limit the size of the market for the product. Additionally, drug candidates we or our partners successfully develop could be subject to post market surveillance and testing.

We are also subject to numerous foreign regulatory requirements governing the conduct of clinical trials, and we, with our partners, are subject to numerous foreign regulatory requirements relating to manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval processes include all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Approval by any one regulatory authority does not assure approval by regulatory authorities in other jurisdictions. Many foreign regulatory authorities, including those in the European Union and in China, have different approval procedures than those required by the FDA and may impose additional testing requirements for our drug candidates. Any failure or delay in obtaining such marketing authorizations for our drug candidates would have a material adverse effect on our business.

***Our products will be subject to ongoing regulatory review even after approval to market such products is obtained. If we or our partners fail to comply with applicable United States and foreign regulations, we or our partners could lose approvals that we or our partners have been granted and our business would be seriously harmed.***

Even after approval, any drug product that we or our collaboration partners successfully develop will remain subject to continuing regulatory review, including the review of clinical results, which are reported after our product becomes commercially available. The marketing claims we or our collaboration partners are permitted to make in labeling or advertising regarding our marketed drugs in the United States will be limited to those specified in any FDA approval, and in other markets such as the European Union, to the corresponding regulatory approvals. Any manufacturer we or our collaboration partners use to make approved products will be subject to periodic review and inspection by the FDA or other similar regulatory authorities in the European Union and other jurisdictions. We and our collaboration partners are required to report any serious and unexpected adverse experiences and certain quality problems with our products and make other periodic reports to the FDA or other similar regulatory authorities in the European Union and other jurisdictions. The subsequent discovery of previously unknown problems with the drug, manufacturer or facility may result in restrictions on the drug manufacturer or facility, including withdrawal of the drug from the market. We do not have, and currently do not intend to develop, the ability to manufacture material at commercial scale or for our clinical trials. Our reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured products ourselves, including reliance on such manufacturers for regulatory compliance. Certain changes to an approved product, including the way it is manufactured or promoted, often require prior approval from regulatory authorities before the modified product may be marketed.

If we or our collaboration partners fail to comply with applicable continuing regulatory requirements, we or our collaboration partners may be subject to civil penalties, suspension or withdrawal of any regulatory approval obtained, product recalls and seizures, injunctions, operating restrictions and criminal prosecutions and penalties.

***If we or our partners fail to comply with ongoing regulatory requirements after receipt of approval to commercialize a product, we or our partners may be subject to significant sanctions imposed by the FDA, EMA or other United States and foreign regulatory authorities.***

The research, testing, manufacturing and marketing of drug candidates and products are subject to extensive regulation by numerous regulatory authorities in the United States and other countries. Failure to comply with these requirements may subject a company to administrative or judicially imposed sanctions. These enforcement actions may include, without limitation:

- warning letters and other regulatory authority communications objecting to matters such as promotional materials and requiring corrective action such as revised communications to healthcare practitioners;
- civil penalties;
- criminal penalties;
- injunctions;
- product seizure or detention;
- product recalls;
- total or partial suspension of manufacturing; and
- FDA refusal to review or approve pending new drug applications or supplements to new drug applications for previously approved products and/or similar rejections of marketing applications or supplements by foreign regulatory authorities.

The imposition of one or more of these sanctions on us or one of our partners could have a material adverse effect on 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 activities involve the controlled use of hazardous materials, chemicals and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by state and federal laws and regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials. Although we maintain workers' compensation insurance to cover us for costs we may incur due to injuries to our employees resulting from the use of these materials and environmental liability insurance to cover us for costs associated with environmental or toxic tort claims that may be asserted against us, this insurance may not provide adequate coverage against all potential liabilities. Additional federal, state, foreign and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with these laws or regulations. Additionally, we may incur substantial fines or penalties if we violate any of these laws or regulations.

***Growing availability of specialty pharmaceuticals may lead to increased focus of cost containment.***

Specialty pharmaceuticals refer to medicines that treat rare or life-threatening conditions that have smaller patient populations, such as certain types of cancer, multiple sclerosis, HBV, HCV and HIV. The growing availability and use of innovative specialty pharmaceuticals, combined with their relative higher cost as compared to other types of pharmaceutical products, is beginning to generate significant payer interest in developing cost containment strategies targeted to this sector. While the impact on our payers' efforts to control access and pricing of specialty pharmaceuticals has been limited to date, our portfolio of specialty products, combined with the increasing use of health technology assessment in markets around the world and the deteriorating finances of governments, may lead to a more significant adverse business impact in the future.

## **Factors Related to Our Relationship with Novartis**

### ***Novartis has substantial control over us and could delay or prevent a change in corporate control.***

As of February 21, 2012, Novartis owned approximately 31% of our outstanding common stock. For so long as Novartis owns 19.4% of our voting stock, Novartis has the ability to delay or prevent a change in control of Idenix that may be favored by other stockholders and otherwise exercise substantial control over all corporate actions requiring stockholder approval including:

- the election of our directors;
- any amendment of our restated certificate of incorporation or amended and restated by-laws;
- the approval of mergers and other significant corporate transactions, including a sale of substantially all of our assets; or
- the defeat of any non-negotiated takeover attempt that might otherwise benefit our other stockholders.

### ***Novartis has the right to exercise control over certain corporate actions, strategic direction, our research and development focus and other material decisions that may not otherwise require stockholder approval as long as it holds at least 19.4% of our voting stock.***

As long as Novartis and its affiliates own at least 19.4% of our voting stock, which we define below, we cannot take certain actions without the consent of Novartis. These actions include:

- the authorization or issuance of additional shares of our capital stock or the capital stock of our subsidiaries, except for a limited number of specified issuances;
- any change or modification to the structure of our board of directors or a similar governing body of any of our subsidiaries;
- any amendment or modification to any of our organizational documents or those of our subsidiaries;
- the adoption of a three-year strategic plan;
- the adoption of an annual operating plan and budget, if there is no approved strategic plan;
- any decision that would result in a variance of total annual expenditures, capital or expense, in excess of 20% from the approved three-year strategic plan;
- any decision that would result in a variance in excess of the greater of \$10.0 million or 20% of our profit or loss target in the strategic plan or annual operating plan;
- the acquisition of stock or assets of another entity that exceeds 10% of our consolidated net revenue, net income or net assets;
- the sale, lease, license or other disposition of any assets or business which exceeds 10% of our net revenue, net income or net assets;
- the incurrence of any indebtedness by us or our subsidiaries for borrowed money in excess of \$2.0 million;
- any material change in the nature of our business or that of any of our subsidiaries;
- any change in control of Idenix or any subsidiary; and
- any dissolution or liquidation of Idenix or any subsidiary, or the commencement by us or any subsidiary of any action under applicable bankruptcy, insolvency, reorganization or liquidation laws.

Pursuant to the stockholders' agreement among us, Novartis and certain of our stockholders, we are obligated to use our reasonable best efforts to nominate for election as directors at least two designees of Novartis for so long as Novartis and its affiliates own at least 30% of our voting stock and at least one designee of Novartis for so long as Novartis and its affiliates own at least 19.4% of our voting stock.

Under the stockholders' agreement, voting stock means our outstanding securities entitled to vote in the election of directors, but does not include securities issued in connection with our acquisition of all of the capital stock, or all or substantially all of the assets of another entity, and shares of common stock issued upon exercise of stock options or stock awards pursuant to compensation and equity incentive plans.

In April 2011, we amended the development and commercialization agreement to provide that Novartis retains the exclusive option to obtain rights to drug candidates developed by us, or in some cases licensed to us, so long as Novartis maintains ownership of at least 30% of our common stock, rather than ownership of at least 40%, as was the requirement prior to the execution of this amendment.

Additionally, in April 2011, we amended an agreement with Novartis providing that so long as Novartis and its affiliates own at least 30% of our common stock, Novartis' consent is required for the selection and appointment of our chief financial officer. Prior to this amendment, the ownership requirement was 40%. If in Novartis' reasonable judgment our chief financial officer is not satisfactorily performing his or her duties, we are required to terminate his or her employment.

Furthermore, under the terms of the stock purchase agreement, dated as of March 21, 2003 among us, Novartis and substantially all of our then existing stockholders, Novartis is required to make future contingent payments of up to \$357.0 million to these stockholders if we achieve predetermined development milestones with respect to specific HCV drug candidates. As a result, in making determinations as to our annual operating plan and budget for the development of our drug candidates, the interests of Novartis may be different than the interests of our other stockholders and Novartis could exercise its approval rights in a manner that may not be in the best interests of all of our stockholders.

***We currently depend on Novartis for a significant portion of our revenues, for the continuing commercialization of Tyzeka®/Sebivo® and for support in the development of drug candidates Novartis could license from us in the future. If our development and commercialization agreement with Novartis terminates, our business, in particular, the development of our drug candidates and the commercialization of any products that we successfully develop could be harmed.***

In May 2003, we received a \$75.0 million license fee from Novartis in connection with the license of our then HBV drug candidates, telbivudine and valtorcitabine. In April 2007, we received a \$10.0 million milestone payment for regulatory approval of Sebivo® in China and in June 2007, we received an additional \$10.0 million milestone payment for regulatory approval of Sebivo in the European Union. Pursuant to the development and commercialization agreement, as amended, Novartis also acquired options to license valopicitabine and additional drug candidates from us. In March 2006, Novartis exercised its option and acquired a license to valopicitabine and as a result, we received a \$25.0 million license fee. If Novartis exercises the option to license other drug candidates that we discover, or in some cases, acquire, we are entitled to receive license fees, milestone payments, reimbursement of expenses we incur in the development of such drug candidates in accordance with development plans mutually agreed with Novartis and proceeds in connection with the sales of such product if approved for commercialization.

Under the existing terms of the development and commercialization agreement, we have the right to co-promote and co-market with Novartis in the United States, United Kingdom, Germany, Italy, France and Spain any products licensed by Novartis, excluding Tyzeka®/Sebivo®. For Tyzeka /Sebivo®, we acted as the lead commercial party in the United States. Effective on October 1, 2007, we transferred to Novartis our worldwide development, commercialization and manufacturing rights and obligations related to telbivudine (Tyzeka®/Sebivo®). We receive royalty payments equal to a percentage of net sales of Tyzeka®/Sebivo®, with such percentage increasing according to specified tiers of net sales. The royalty percentage varies based on the specified territory and the aggregate dollar amount of net sales.

Novartis may terminate the development and commercialization agreement in any country or with respect to any product or drug candidate licensed under the development and commercialization agreement for any reason

with six months written notice. If the development and commercialization agreement is terminated in whole or in part and we are unable to enter similar arrangements with other collaborators or partners, our business would be materially adversely affected.

***Novartis has the option to license from us drug candidates we discover or, in some cases, acquire. If Novartis does not exercise its option or disputes the adequacy of the notice provided by us pertaining to the drug candidate, or after we provide notice, delays its decision to exercise such option with respect to a drug candidate, our development, manufacture and/or commercialization of such drug candidate may be substantially delayed or limited.***

Our drug development programs and potential commercialization of our drug candidates will require substantial additional funding. In addition to its license of Tyzeka®/Sebivo®, valtorcitabine and valopicitabine, Novartis has the option under the development and commercialization agreement to license our other drug candidates, except for IDX184.

Furthermore, under the development and commercialization agreement, we must provide Novartis with notice and a data package as part of Novartis' consideration to license a drug candidate from us. This notice includes information regarding the efficacy, safety and such other related material information from the final data set for the relevant clinical trial for the drug candidate, as well as a proposed development plan and proposed licensing terms. The development and commercialization agreement is not specific as to the exact content of the information required in such notice. If Novartis disputes the adequacy of the notice or data package, Novartis may argue that it is entitled to additional information or data, which would likely lead to a delay in its review of our drug candidate. Potential disputes over the adequacy of the notice and data package we provide Novartis may cause delays in our development programs in order to resolve any disputes with Novartis over the adequacy of such material. This could require substantial financial resources and could take a significant amount of time to complete.

If Novartis elects not to exercise such option, we may be required to seek other collaboration arrangements to provide funds necessary to enable us to develop such drug candidates. In October 2009, Novartis waived its option to license IDX184. As a result, we retain the worldwide rights to develop, manufacture, commercialize and license IDX184. We may seek a partner who will assist in the future development and commercialization of this drug candidate. We may not be successful in our efforts to enter into a collaboration arrangement with respect to a drug candidate not licensed by Novartis and we may not have sufficient funds to develop such drug candidate internally. As a result, our business would be adversely affected. In addition, the negotiation of a collaborative agreement is time consuming and could, even if successful, delay the development, manufacture and/or commercialization of a drug candidate and the terms of the collaboration agreements may not be favorable to us.

***If we breach any of the numerous representations and warranties we made to Novartis under the development and commercialization agreement or the stock purchase agreement, Novartis has the right to seek indemnification from us for damages it suffers as a result of such breach. These amounts could be substantial.***

We have agreed to indemnify Novartis and its affiliates against losses suffered as a result of our breach of representations and warranties in the development and commercialization agreement and the stock purchase agreement. Under the development and commercialization agreement and stock purchase agreement, we made numerous representations and warranties to Novartis regarding our HCV and HBV drug candidates, including representations regarding our ownership of and licensed rights to the inventions and discoveries relating to such drug candidates. If one or more of our representations or warranties were subsequently determined not to be true at the time we made them to Novartis, we would be in breach of these agreements. In the event of a breach by us, Novartis has the right to seek indemnification from us and, under certain circumstances, us and our stockholders who sold shares to Novartis, which include many of our directors and officers, for damages suffered by Novartis as a result of such breach. The amounts for which we could become liable to Novartis could be substantial.

In May 2004, we entered into a settlement agreement with UAB, relating to our ownership of our former chief executive officer's inventorship interest in certain of our patents and patent applications, including patent applications covering our HCV drug candidates. Under the terms of the settlement agreement, we agreed to make payments to UAB, including an initial payment made in 2004 in the amount of \$2.0 million, as well as regulatory milestone payments and payments relating to net sales of certain products. Novartis may seek to recover from us and, under certain circumstances, us and our stockholders who sold shares to Novartis, which include many of our officers and directors, the losses it suffers as a result of any breach of the representations and warranties we made relating to our HCV drug candidates and may assert that such losses include the settlement payments.

In July 2008, we, our former chief executive officer, in his individual capacity, the University of Montpellier and CNRS entered into a settlement agreement with UAB, UABRF, and Emory University. Pursuant to this settlement agreement, all contractual disputes relating to patents covering the use of certain synthetic nucleosides for the treatment of HBV and all litigation matters relating to patents and patent applications related to the use of  $\beta$ -L-2'-deoxy-nucleosides for the treatment of HBV assigned to one or more of Idenix, CNRS, and the University of Montpellier and which cover the use of telbivudine (Tyzeka<sup>®</sup>/Sebivo<sup>®</sup>) for the treatment of HBV have been resolved. Under the terms of the settlement, we paid UABRF (on behalf of UAB and Emory University) a \$4.0 million upfront payment and will make additional payments to UABRF equal to 20% of all royalty payments received by us from Novartis based on worldwide sales of telbivudine, subject to minimum payment obligations aggregating \$11.0 million. Novartis may seek to recover from us and, under certain circumstances, us and those of our officers, directors and other stockholders who sold shares to Novartis, such losses and other losses it suffers as a result of any breach of the representations and warranties we made relating to our HBV drug candidates and may assert that such losses include the settlement payments.

***If we materially breach our obligations or covenants arising under the development and commercialization agreement with Novartis, we may lose our rights to develop or commercialize our drug candidates.***

We have significant obligations to Novartis under the development and commercialization agreement. The obligations to which we are subject include the responsibility for developing and, in some countries, co-promoting or co-marketing the products licensed to Novartis in accordance with plans and budgets subject to Novartis' approval. The covenants and agreements we made when entering into the development and commercialization agreement include covenants relating to payments of our required portion of development expenses under the development and commercialization agreement, compliance with certain third-party license agreements, the conduct of our clinical studies and activities relating to the commercialization of any products that we successfully develop. If we materially breach this agreement and are unable within an agreed time period to cure such breach, the agreement may be terminated and we may be required to grant Novartis an exclusive license to develop, manufacture and/or sell such products. Although such a license would be subject to payment of a royalty by Novartis to be negotiated in good faith, we and Novartis have stipulated that no such payments would permit the breaching party to receive more than 90% of the net benefit it was entitled to receive before the agreement was terminated. Accordingly, if we materially breach our obligations under the development and commercialization agreement, we may lose our rights to develop our drug candidates or commercialize our successfully developed products and may receive lower payments from Novartis than we had anticipated.

***If we issue capital stock, in certain situations, Novartis will be able to purchase shares at par value to maintain its percentage ownership in Idenix and, if that occurs, this could cause dilution. In addition, Novartis has the right, under specified circumstances, to purchase a pro rata portion of other shares that we may issue.***

Under the terms of the stockholders' agreement, Novartis has the right to purchase, at par value of \$0.001 per share, such number of shares of our capital stock that would be required to maintain its percentage ownership of our voting stock if we issue shares of capital stock in connection with the acquisition or in-licensing of technology through the issuance of up to 5% of our stock in any 24-month period. If Novartis elects to maintain its percentage ownership of our voting stock under the rights described above, Novartis will be buying such

shares at a price that is substantially below market value, which would cause dilution. This right of Novartis will remain in effect until the earlier of:

- the date that Novartis and its affiliates own less than 19.4% of our voting stock; or
- the date that Novartis becomes obligated under the stock purchase agreement to make the additional future contingent payments of \$357.0 million to our stockholders who sold shares to Novartis in May 2003.

In addition to the right to purchase shares of our common stock at par value as described above, Novartis has the right, subject to limited exceptions noted below, to purchase a pro rata portion of shares of capital stock that we issue. The price that Novartis pays for these securities would be the price that we offer such securities to third-parties, including the price paid by persons who acquire shares of our capital stock pursuant to awards granted under stock compensation or equity incentive plans. Novartis' right to purchase a pro rata portion does not include:

- securities issuable in connection with any stock split, reverse stock split, stock dividend or recapitalization that we undertake that affects all holders of our common stock proportionately;
- shares that Novartis has the right to purchase at par value, as described above;
- shares of common stock issuable upon exercise of stock options and other awards pursuant to our 1998 equity incentive plan; and
- securities issuable in connection with our acquisition of all the capital stock or all or substantially all of the assets of another entity.

Novartis' right to purchase shares includes a right to purchase securities that are convertible into, or exchangeable for, our common stock, provided that Novartis' right to purchase stock in connection with options or other convertible securities issued to any of our directors, officers, employees or consultants pursuant to any stock compensation or equity incentive plan will not be triggered until the underlying equity security has been issued to the director, officer, employee or consultant. Novartis waived its right to purchase additional shares of our common stock as a result of the shares of common stock we issued to GSK in 2009. Additionally, Novartis did not purchase shares of our common stock pursuant to our underwritten offerings in August 2009, April 2010 or November 2011. We issued 1.8 million shares of our common stock to Novartis pursuant to a private placement agreement in conjunction with our underwritten offering in April 2011. Novartis' ownership was subsequently diluted from approximately 53% prior to the August 2009 offering to approximately 31% as of February 21, 2012.

***If Novartis terminates or fails to perform its obligations under the development and commercialization agreement, we may not be able to successfully commercialize our drug candidates licensed to Novartis and the development and commercialization of our other drug candidates could be delayed, curtailed or terminated.***

Under the amended development and commercialization agreement, Novartis is solely responsible for the worldwide development, commercialization and manufacturing rights to telbivudine. We expect to co-promote or co-market with Novartis other products, if any, that Novartis has licensed or will license from us which are successfully developed and approved for commercialization. As a result, we will depend upon the success of the efforts of Novartis to manufacture, market and sell Tyzeka®/Sebivo® and our other products, if any, that we successfully develop and license to Novartis. However, we have limited control over the resources that Novartis may devote to such manufacturing and commercialization efforts and, if Novartis does not devote sufficient time and resources to such efforts, we may not realize the commercial or financial benefits we anticipate, and our results of operations may be adversely affected.

In addition, Novartis has the right to terminate the development and commercialization agreement with respect to any product, drug candidate or country with six months written notice to us. If Novartis were to breach or terminate this agreement with us, the development or commercialization of the affected drug candidate or

product could be delayed, curtailed or terminated because we may not have sufficient resources or capabilities, financial or otherwise, to continue development and commercialization of the drug candidate, and we may not be successful in entering into a collaboration with another third-party.

***Novartis has the right to market and sell products that compete with the drug candidates and products that we license to it and any competition by Novartis could have a material adverse effect on our business.***

Novartis may market, sell, promote or license competitive products. Novartis has significantly greater financial, technical and human resources than we have and is better equipped to discover, develop, manufacture and commercialize products. In addition, Novartis has more extensive experience in preclinical studies and clinical trials, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products. In the event that Novartis competes with us, our business could be materially and adversely affected.

### **Factors Related to Our Dependence on Third-Parties Other Than Novartis**

***If we seek to enter into collaboration agreements for any drug candidates other than those licensed to Novartis and we are not successful in establishing such collaborations, we may not be able to continue development of those drug candidates.***

Our drug development programs and product commercialization efforts will require substantial additional cash to fund expenses to be incurred in connection with these activities. While we have entered into the development and commercialization agreement with Novartis in May 2003, we may seek to enter into additional collaboration agreements with other pharmaceutical companies to fund all or part of the costs of drug development and commercialization of drug candidates that Novartis does not license. We may seek a partner who will assist in the future development and commercialization of our drug candidate, IDX184, for the treatment of HCV. We may not be able to enter into collaboration agreements and the terms of any such collaboration agreements may not be favorable to us. If we are not successful in our efforts to enter into a collaboration arrangement with respect to a drug candidate, we may not have sufficient funds to develop such drug candidate or any other drug candidate internally.

If we do not have sufficient funds to develop our drug candidates, we will not be able to bring these drug candidates to market and generate revenue. As a result, our business will be adversely affected. In addition, the inability to enter into collaboration agreements could delay or preclude the development, manufacture and/or commercialization of a drug candidate and could have a material adverse effect on our financial condition and results of operations because:

- we may be required to expend our own funds to advance the drug candidate to commercialization;
- revenue from product sales could be delayed; or
- we may elect not to develop or commercialize the drug candidate.

***Our collaborations with outside scientists may be subject to restriction and change.***

We work with chemists and biologists at academic and other institutions that assist us in our research and development efforts. Many of our drug candidates were discovered with the research and development assistance of these chemists and biologists. Many of the scientists who have contributed to the discovery and development of our drug candidates are not our employees and may have other commitments that would limit their future availability to us. Although our scientific advisors and collaborators generally agree not to do competing work, if a conflict of interest between their work for us and their work for another entity arises, we may lose their services.

***We have depended on third-party manufacturers to manufacture products for us. If in the future we manufacture any of our products, we will be required to incur significant costs and devote significant efforts to establish these capabilities.***

We have relied upon third-parties to produce material for preclinical and clinical studies and may continue to do so in the future. Although we believe that we will not have any material supply issues, we cannot be certain that we will be able to obtain long-term supply arrangements of those materials on acceptable terms. We also expect to rely on third-parties to produce materials required for clinical trials and for the commercial production of certain of our products if we succeed in obtaining necessary regulatory approvals. If we are unable to arrange for third-party manufacturing, or to do so on commercially reasonable terms, we may not be able to complete development of our products or market them.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured products ourselves, including reliance on the third-party for regulatory compliance and quality assurance, the possibility of breach by the third-party of agreements related to supply because of factors beyond our control and the possibility of termination or nonrenewal of the agreement by the third-party, based on its own business priorities, at a time that is costly or damaging to us.

In addition, the FDA and other regulatory authorities require that our products be manufactured according to cGMP regulations. Any failure by us or our third-party manufacturers to comply with cGMPs and/or our failure to scale up our manufacturing processes could lead to a delay in, or failure to obtain, regulatory approval. In addition, such failure could be the basis for action by the FDA to withdraw approvals for drug candidates previously granted to us and for other regulatory action.

#### **Factors Related to Patents and Licenses**

***If we are unable to adequately protect our patents and licenses related to our drug candidates, or if we infringe the rights of others, it may not be possible to successfully commercialize products that we develop.***

Our success will depend in part on our ability to obtain and maintain patent protection both in the United States and in other countries for any products we successfully develop. The patents and patent applications in our patent portfolio are either owned by us, exclusively licensed to us, or co-owned by us and others and exclusively licensed to us. Our ability to protect any products we successfully develop from unauthorized or infringing use by third-parties depends substantially on our ability to obtain and maintain valid and enforceable patents. 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 obtain and enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any issued patents may not provide us with sufficient protection for any products we successfully develop or provide sufficient protection to afford us a commercial advantage against our competitors or their competitive products or processes. In addition, we cannot guarantee that any patents will be issued from any pending or future patent applications owned by or licensed to us. Even if patents have been issued or will be issued, we cannot guarantee that the claims of these patents are, or will be, valid or enforceable, or provide us with any significant protection against competitive products or otherwise be commercially valuable to us. The U.S. Congress recently passed the Leahy-Smith America Invents Act, or the America Invents Act, which was signed into law in September 2011. The America Invents Act reforms United States patent law in part by changing the standard for patent approval from a “first to invent” standard to a “first to file” standard and developing a post-grant review system. This new legislation changes United States patent law in a way that may weaken our ability to obtain or maintain patent protection for future inventions in the United States.

We may not have identified all patents, published applications or published literature that may affect our business, either by blocking our ability to commercialize our drug candidates, by preventing the patentability of our drug candidates by us, our licensors or co-owners, or by covering the same or similar technologies that may invalidate our patents, limiting the scope of our future patent claims or adversely affecting our ability to market

our drug candidates. For example, patent applications are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U.S. Patent and Trademark Office, which we refer to as the U.S. Patent Office, for the entire time prior to issuance of a U.S. patent. Patent applications filed in countries outside the United States are not typically published until at least 18 months from their first filing date. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we or our licensors or co-owners were the first to invent, or the first to file, patent applications on our product or drug candidates or for their uses. In the event that a third-party has also filed a U.S. patent application covering our product or drug candidates or a similar invention, we may have to participate in an adversarial proceeding, known as an interference, declared by the U.S. Patent Office to determine priority of invention in the United States. In late February 2012, an interference was declared by the U.S. Patent Office concerning patent application claims to certain nucleoside compounds useful in treating HCV. We cannot predict, whether we will prevail. The application at issue in the interference is not relevant to our compound IDX184 or any other compounds we currently have under development. An interference is based upon complex specialized U.S. patent law and we expect the interference proceeding could be expensive and time consuming, but we do not believe it will be relevant to any of our current clinical candidates, including IDX184.

The costs of these proceedings could be substantial and it is possible that our efforts could be unsuccessful, potentially resulting in a loss of our U.S. patent position. The laws of some 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 prospects could be substantially harmed.

Since our HBV product, telbivudine, was a known compound before the filing of our patent applications covering the use of this drug candidate to treat HBV, we cannot obtain patent protection on telbivudine itself. As a result, we have obtained and maintain patents granted on the method of using telbivudine as a medical therapy for the treatment of HBV.

In July 2008, we entered into a settlement agreement with UAB, UABRF and Emory University relating to our telbivudine technology. Pursuant to this settlement agreement, all contractual disputes relating to patents covering the use of certain synthetic nucleosides for the treatment of HBV and all litigation matters relating to patents and patent applications related to the use of  $\beta$ -L-2'-deoxy-nucleosides for the treatment of HBV assigned to one or more of Idenix, CNRS and the University of Montpellier and which cover the use of telbivudine (Tyzeka<sup>®</sup>/Sebivo<sup>®</sup>) for the treatment of HBV have been resolved. UAB also agreed to abandon certain continuation patent applications it filed in July 2005. Under the terms of the settlement, we paid UABRF (on behalf of UAB and Emory University) a \$4.0 million upfront payment and will make additional payments to UABRF equal to 20% of all royalty payments received by us from Novartis based on worldwide sales of telbivudine, subject to minimum payment obligations in the aggregate of \$11.0 million.

In accordance with our patent strategy, we are attempting to obtain patent protection for our HCV nucleoside/nucleotide polymerase inhibitor drug candidates, including IDX184. We have filed U.S. and foreign patent applications, and in some jurisdictions have obtained patent protection, related to IDX184 itself, as well as to methods of treating HCV with IDX184. Further, we are prosecuting U.S. and foreign patent applications, and have been granted U.S. and foreign patents, claiming methods of treating HCV with nucleoside/nucleotide polymerase inhibitors.

We are aware that a number of other companies have filed patent applications attempting to cover broad classes of compounds and their use to treat HCV or infection by any member of the Flaviviridae virus family to which HCV belongs. These classes of compounds might relate to nucleoside polymerase inhibitors associated with IDX184. The companies include Merck & Co., Inc., Isis Pharmaceuticals, Inc., Ribapharm, Inc. (a wholly-owned subsidiary of Valeant Pharmaceuticals International), Genelabs Technologies, Inc., Gilead Sciences, Inc.,

Britsol-Myers Squibb Company and Biota, Inc. (a subsidiary of Biota Holdings Ltd.). A foreign country may grant patent rights covering one or more of our drug candidates to one or more other companies. If that occurs, we may need to challenge the third-party patent rights, and if we do not challenge or are not successful with the challenge, we will need to obtain a license that might not be available to us on commercially reasonable terms or at all. The U.S. Patent Office may grant patent rights covering one or more of our drug candidates to one or more other companies. If that occurs, we may need to challenge the third-party patent rights, and if we do not challenge or are not successful with the challenge, we will need to obtain a license that might not be available at all or on commercially reasonable terms. Given the breadth of our patent portfolio to HCV nucleosides/nucleotides, we expect many competitors to challenge our patents in, for example, Europe or the United States at the appropriate time. We cannot predict whether these challenges will occur, or, if they do, exactly when they will occur. We also cannot predict the outcome of any of these challenges, and they may be expensive and time consuming.

A number of companies have filed patent applications and have obtained patents covering certain compositions and methods for the treatment, diagnosis and/or screening of HBV, HCV and HIV that could materially affect the ability to develop and commercialize Tyzeka<sup>®</sup>/Sebivo<sup>®</sup> and other drug candidates we may develop in the future. For example, we are aware that Apath, LLC has obtained broad patents covering HCV proteins, nucleic acids, diagnostics and drug screens. If we need to use these patented materials or methods to develop any of our HCV drug candidates and the materials or methods fall outside certain safe harbors in the laws governing patent infringement, we will need to buy these products from a licensee of the company authorized to sell such products or we will require a license from one or more companies, which may not be available to us on commercially reasonable terms or at all. This could materially affect or preclude our ability to develop and sell our HCV drug candidates.

If we find that any drug candidates we are developing should be used in combination with a product covered by a patent held by another company or institution, and that a labeling instruction is required in product packaging recommending that combination, we could be accused of, or held liable for, infringement or inducement of infringement of certain third-party patents claims covering the product recommended for co-administration with our product. In that case, we may be required to obtain a license from the other company or institution to provide the required or desired package labeling, which may not be available on commercially reasonable terms or at all.

Litigation and disputes related to intellectual property matters occur frequently in the biopharmaceutical industry. Litigation regarding patents, patent applications and other proprietary rights may be expensive and time consuming. If we are unsuccessful in litigation concerning patents or patent applications owned or co-owned by us or licensed to us, we may not be able to protect our products from competition or we may be precluded from selling our products. If we are involved in such litigation, it could cause delays in bringing drug candidates to market and harm our ability to operate. Such litigation could take place in the United States in a federal court or in the U.S. Patent Office. The litigation could also take place in a foreign country, in either the courts or the patent office of that country.

Our success will depend in part on our ability to uphold and enforce patents or patent applications owned or co-owned by us or licensed to us, which cover products we successfully develop. Proceedings involving our patents or patent applications could result in adverse decisions regarding:

- ownership of patents and patent applications;
- the patentability of our inventions relating to our products and drug candidates; and/or
- the enforceability, validity or scope of protection offered by our patents relating to our products and drug candidates.

Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us.

In May 2004, we and our former chief executive officer entered into a settlement agreement with UAB resolving a dispute regarding ownership of inventions and discoveries made by our former chief executive officer during the period from November 1999 to November 2002, at which time our former chief executive officer was on sabbatical and then unpaid leave from his position at UAB. The patent applications we filed with respect to such inventions and discoveries include the patent applications covering valopicitabine and IDX184.

Under the terms of the settlement agreement with UAB, we agreed to make a \$2.0 million initial payment to UAB, as well as other contingent payments based upon the commercial launch of other HCV products discovered or invented by our former chief executive officer during his sabbatical and unpaid leave. In addition, UAB and UABRF have each agreed that neither of them has any right, title or ownership interest in these inventions and discoveries. Under the development and commercialization agreement and stock purchase agreement, we made numerous representations and warranties to Novartis regarding our HCV program, including representations regarding our ownership of the inventions and discoveries. If one or more of our representations or warranties were subsequently determined not to be true at the time we made them to Novartis, we would be in breach of these agreements. In the event of a breach by us, Novartis has the right to seek indemnification from us and, under certain circumstances, us and our stockholders who sold shares to Novartis, which include many of our directors and officers, for damages suffered by Novartis as a result of such breach. The amounts for which we could be liable to Novartis could be substantial.

Our success will also depend in part on our ability to avoid infringement of the patent rights of others. If it is determined that we do infringe a patent right of another, we may be required to seek a license (which may not be available on commercially reasonable terms or at all), defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we are not successful in infringement litigation and we do not license or develop non-infringing technology, we may:

- incur substantial monetary damages;
- encounter significant delays in bringing our drug candidates to market; and/or
- be precluded from participating in the manufacture, use or sale of our drug candidates or methods of treatment requiring licenses.

***Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information.***

To protect our proprietary technology and processes, we also rely in part on confidentiality agreements with our corporate collaborators, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and confidential information and in such cases we could not assert any trade secret rights against such parties. Costly and time consuming litigation could be necessary to enforce and determine the scope of our proprietary rights and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

***If any of our agreements that grant us the exclusive right to make, use and sell our drug candidates are terminated, we and/or our collaboration partners may be unable to develop or commercialize our drug candidates.***

We, together with Novartis, entered into an amended and restated agreement with CNRS and the University of Montpellier, co-owners of the patents and patent applications covering Tyzeka®/Sebivo® and valtorcitabine. This agreement covers both the cooperative research program and the terms of our exclusive right to exploit the results of the cooperative research, including Tyzeka®/Sebivo® and valtorcitabine. The cooperative research program with CNRS and the University of Montpellier ended in December 2006 although many of the terms

remain in effect for the duration of the patent life of the affected products. We and Novartis have also entered into two agreements with the University of Cagliari, the co-owner of the patents and patent applications covering some of our HCV drug candidates and certain other drug candidates. One agreement with the University of Cagliari covers our cooperative research program and the other agreement is an exclusive license to develop and sell jointly created drug candidates. Under the amended and restated agreement with CNRS and the University of Montpellier and the license agreement, as amended, with the University of Cagliari, we obtained from our co-owners the exclusive right to exploit these drug candidates. Subject to certain rights afforded to Novartis as they relate to the license agreement with the University of Cagliari, these agreements can be terminated by either party in circumstances such as the occurrence of an uncured breach by the non-terminating party. The termination of our rights, including patent rights, under the agreement with CNRS and the University of Montpellier or the license agreement, as amended, with the University of Cagliari would have a material adverse effect on our business and could prevent us from developing a drug candidate or selling a product. In addition, these agreements provide that we pay certain costs of patent prosecution, maintenance and enforcement. These costs could be substantial. Our inability or failure to pay these costs could result in the termination of the agreements or certain rights under them.

Under our amended and restated agreement with CNRS and the University of Montpellier and our license agreement, as amended, with the University of Cagliari, we and Novartis have the right to exploit and license certain co-owned drug candidates. However, our agreements with CNRS and the University of Montpellier and with the University of Cagliari are currently governed by, and will be interpreted and enforced under, French and Italian law, respectively, which are different in substantial respects from United States law and which may be unfavorable to us in material respects. Under French law, co-owners of intellectual property cannot exploit, assign or license their individual rights without the permission of the co-owners. Similarly, under Italian law, co-owners of intellectual property cannot exploit or license their individual rights without the permission of the co-owners. Accordingly, if our agreements with the University of Cagliari terminate based on a breach, we may not be able to exploit, license or otherwise convey to Novartis or other third-parties our rights in certain products or drug candidates for a desired commercial purpose without the consent of the co-owner, which could materially affect our business and prevent us from developing certain drug candidates and selling our products.

Under United States law, a patent co-owner has the right to prevent another co-owner from suing infringers by refusing to join voluntarily in a suit to enforce a patent. Our amended and restated agreement with CNRS and the University of Montpellier and our license agreement, as amended, with the University of Cagliari provide that such parties will cooperate to enforce our jointly owned patents on our products or drug candidates. If these agreements terminate or the parties' cooperation is not given or is withdrawn, or they refuse to join in litigation that requires their participation, we may not be able to enforce these patent rights or protect our markets.

### **Factors Related to Our Common Stock**

#### ***Our common stock may have a volatile trading price.***

The market price of our common stock could be subject to significant fluctuations. Some of the factors that may cause the market price of our common stock to fluctuate include:

- realization of license fees and achievement of milestones under our development and commercialization agreement with Novartis;
- reductions in proceeds associated with Novartis' right to maintain its percentage ownership of our voting stock when we issue shares at a price below fair market value;
- adverse developments regarding the safety and efficacy of Tyzeka®/Sebivo® or our other drug candidates;
- the results of ongoing and planned clinical trials of our drug candidates;
- developments in the market with respect to competing products or more generally the treatment of HBV or HCV;

- the results of preclinical studies and planned clinical trials of our other discovery-stage programs;
- future sales of, and the trading volume in, our common stock;
- the timing and success of the launch of products, if any, we successfully develop;
- future royalty payments received by us associated with sales of Tyzeka<sup>®</sup>/Sebivo<sup>®</sup>;
- the entry into key agreements, including those related to the acquisition or in-licensing of new programs, or the termination of key agreements;
- the results and timing of regulatory actions relating to the approval of our drug candidates, including any decision by the regulatory authorities to place a clinical hold on our drug candidates;
- the initiation of, material developments in or conclusion of litigation to enforce or defend any of our intellectual property rights;
- the initiation of, material developments in or conclusion of litigation to defend products liability claims;
- the failure of any of our drug candidates, if approved, to achieve commercial success;
- the results of clinical trials conducted by others on drugs that would compete with our drug candidates;
- issues in manufacturing our drug candidates or any approved products;
- the loss of key employees;
- adverse publicity related to our company, our products or our product candidates;
- changes in estimates or recommendations by securities analysts who cover our common stock;
- future financings through the issuance of equity or debt securities or otherwise;
- changes in the structure of health care payment systems;
- our cash position and period-to-period fluctuations in our financial results;
- general and industry-specific economic conditions; and
- the decision by Novartis to license a drug candidate that has completed a proof-of-concept clinical trial.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock.

***We do not anticipate paying cash dividends, so you must rely on stock price appreciation for any return on your investment.***

We anticipate retaining any future earnings for reinvestment in our research and development programs. Therefore, we do not anticipate paying cash dividends in the future. As a result, only appreciation of the price of our common stock will provide a return to stockholders. Investors seeking cash dividends should not invest in our common stock.

***Sales of additional shares of our common stock could result in dilution to existing stockholders and cause the price of our common stock to decline.***

Sales of substantial amounts of our common stock in the public market or the availability of such shares for sale, could adversely affect the price of our common stock. In addition, the issuance of common stock upon exercise of outstanding options could be dilutive and may cause the market price for a share of our common stock to decline. As of February 21, 2012, we had 107,592,574 shares of common stock issued and outstanding, together with outstanding options to purchase approximately 7,080,909 shares of common stock with a weighted average exercise price of \$6.49 per share.

Novartis and other holders of shares of common stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders.

***An investment in our common stock may decline in value as a result of announcements of business developments by us or our competitors.***

The market price of our common stock is subject to substantial volatility as a result of announcements by us or other companies in our industry. As a result, purchasers of our common stock may not be able to sell their shares of common stock at or above the price at which they purchased such stock. Announcements which may subject the price of our common stock to substantial volatility include but are not limited to:

- our collaboration with Novartis;
- the termination of our collaboration with ViiV;
- the results of our clinical trials pertaining to any of our drug candidates;
- the results of discovery, preclinical studies and clinical trials by us or our competitors;
- the acquisition of technologies, drug candidates or products by us or our competitors;
- the development of new technologies, drug candidates or products by us or our competitors;
- regulatory actions with respect to our drug candidates or products or those of our competitors, including those relating to clinical trials, such as clinical holds imposed by regulatory authorities, marketing authorizations, pricing and reimbursement;
- the timing and success of launches of any product we successfully develop;
- future royalty payments received by us associated with sales of Tyzeka<sup>®</sup>/Sebivo<sup>®</sup>;
- the market acceptance of any products we successfully develop;
- significant changes to our existing business model;
- the initiation of, material developments in or conclusion of litigation to enforce or defend any of our intellectual property rights; and
- significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors.

In addition, if we fail to reach an important research, development or commercialization milestone or result by a publicly expected deadline, even if by only a small margin, there could be a significant impact on the market price of our common stock. Additionally, as we approach the announcement of important clinical data or other significant information and as we announce such results and information, we expect the price of our common stock to be particularly volatile and negative results would have a substantial negative impact on the price of our common stock.

***We could be subject to class action litigation due to stock price volatility, which, if such litigation occurs, will distract our management and could result in substantial costs or large judgments against us.***

The stock market frequently experiences extreme price and volume fluctuations. In September 2010, we experienced a significant decline in our stock price based on the FDA's decision to place a clinical hold on IDX184 and IDX320, two of our drug candidates for the treatment of HCV. In addition, the market prices of securities of companies in the biotechnology and pharmaceutical industry have been extremely volatile and have experienced fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. These fluctuations could adversely affect the market price of our common stock. In the past, securities class action litigation has often been brought against companies following periods of volatility in the market prices of their securities. Due to the volatility in our stock price, we may be the target of similar litigation in the future.

Securities litigation could result in substantial costs and divert our management's attention and resources, which could cause serious harm to our business, operating results and financial condition.

**Item 1B. Unresolved Staff Comments**

None.

**Item 2. Properties**

As of December 31, 2011, we leased approximately 74,000 square feet of office and laboratory space. Our major leased properties are described below:

<u>Property Location</u>	<u>Approximate Square Feet</u>	<u>Use</u>	<u>Lease Expiration Date</u>
Cambridge, MA	39,014 sq. ft.	Office Headquarters and Laboratory	December 2013
Montpellier, France	35,215 sq. ft.	Office and Laboratory	April 2017

In December 2011, we terminated our lease for additional office space in Cambridge, MA. Refer to the footnotes to the financial statements to this Annual Report on Form 10-K for more details.

**Item 3. Legal Proceedings**

None.

**Item 4. Mine Safety Disclosures**

Not applicable.

## PART II

### Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

#### Market Information

Our common stock has been traded on the NASDAQ Global Market under the symbol "IDIX". On February 21, 2012 the closing price of our common stock, as reported on the NASDAQ Global Market, was \$12.11 per share. The following table sets forth for the periods indicated the high and low sales prices per share of our common stock, as reported by the NASDAQ Global Market.

	<u>High</u>	<u>Low</u>
<b>2011</b>		
First quarter...	\$5.24	\$2.67
Second quarter .....	5.50	2.82
Third quarter .....	7.05	4.06
Fourth quarter .....	8.51	4.30
<b>2010</b>		
First quarter .....	\$3.15	\$2.12
Second quarter .....	5.34	2.80
Third quarter .....	6.11	2.57
Fourth quarter .....	5.37	3.07

#### Stockholders

On February 21, 2012, we had approximately 50 stockholders of record.

#### Dividends

We have never declared or paid cash dividends on our common stock. We currently intend to reinvest our future earnings, if any, for use in the business and do not expect to declare or pay cash dividends.

#### Repurchase of Securities

None.

## Item 6. Selected Consolidated Financial Data

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

	Years Ended December 31,				
	2011	2010	2009	2008	2007
	(In Thousands, Except per Share Data)				
<b>Consolidated Statements of Operations Data:</b>					
Total revenues	\$ 6,951	\$ 10,222	\$ 12,616	\$ 10,049	\$ 68,028
Operating expenses:					
Cost of revenues	2,324	2,765	2,210	1,745	2,001
Research and development	41,341	44,506	41,867	53,887	85,839
General and administrative	16,694	23,439	21,467	27,130	63,348
Restructuring and impairment charges	—	2,238	1,506	297	8,744
Total operating expenses	60,359	72,948	67,050	83,059	159,932
Loss from operations	(53,408)	(62,726)	(54,434)	(73,010)	(91,904)
Other income, net	1,368	1,131	1,266	2,848	6,135
Gain on sale of equity securities	—	—	—	—	3,500
Income tax benefit (expense)	61	40	(51)	(44)	(246)
Net loss	<u>\$ (51,979)</u>	<u>\$ (61,555)</u>	<u>\$ (53,219)</u>	<u>\$ (70,206)</u>	<u>\$ (82,515)</u>
Basic and diluted net loss per common share	\$ (0.57)	\$ (0.87)	\$ (0.87)	\$ (1.24)	\$ (1.47)
Shares used in computing basic and diluted net loss per common share	90,831	70,715	61,498	56,403	56,169
	December 31,				
	2011	2010	2009	2008	2007
	(In Thousands)				
<b>Consolidated Balance Sheets Data:</b>					
Cash and cash equivalents	\$ 118,271	\$ 46,115	\$ 46,519	\$ 41,509	\$ 48,260
Working capital	73,313	29,496	33,236	30,465	72,985
Total assets	141,044	69,884	76,650	79,780	160,540
Deferred revenue	36,068	2,623	1,025	—	—
Deferred revenue, related party	2,897	3,036	6,155	5,965	8,372
Deferred revenue, net of current portion	4,272	40,340	19,393	4,272	4,272
Deferred revenue, related party, net of current portion	24,382	28,588	30,776	35,790	41,861
Other long-term liabilities	10,640	12,058	13,590	12,789	14,835
Accumulated deficit	(675,715)	(623,736)	(562,181)	(508,962)	(438,756)
Total stockholders’ equity (deficit)	51,225	(31,096)	(5,453)	7,353	68,838

## Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

### Overview

Idenix Pharmaceuticals, Inc., which we refer to together with our wholly owned subsidiaries as Idenix, we, us or our, is a biopharmaceutical company engaged in the discovery and development of drugs for the treatment of human viral diseases with operations in the United States and Europe. Currently, our primary research and development focus is on the treatment of patients with hepatitis C virus, or HCV. Our HCV discovery program is focused on nucleoside/nucleotide polymerase inhibitors and NS5A inhibitors. Our strategic goal is to develop all oral combinations of direct-acting antiviral, or DAA, drug candidates that should eliminate the need for interferon and/or ribavirin with the current treatment for HCV. Our objective is to develop low dose, once- or twice-daily agents with broad genotypic activity that have low potential for drug-drug interaction, high tolerability and are designed for use in multiple combination regimens. We may seek to build a combination development strategy, both internally and with partners, to advance the future of HCV treatments. We believe that nucleosides/nucleotides will have a significant role in a combination DAA strategy for the treatment of HCV and therefore we are currently concentrating a substantial amount of our discovery efforts on this class of drugs. We believe we have strong nucleoside/nucleotide scientific expertise within our organization and should be able to leverage our intellectual patent portfolio to develop additional novel nucleoside/nucleotide drug candidates.

The following table summarizes key information regarding our pipeline of HCV drug candidates as well as Tyzeka<sup>®</sup>/Sebivo<sup>®</sup>:

<u>Indication</u>	<u>Product/Drug Candidates/Programs</u>	<u>Description</u>
HCV	Nucleoside/Nucleotide Polymerase Inhibitors (IDX184)	In the second quarter of 2011, we completed a one-month single dose bioavailability study in healthy volunteers of a new tablet formulation of IDX184. Using the new formulation, in July of 2011, we initiated the phase IIB clinical trial of IDX184 in treatment-naïve HCV genotype 1-infected patients under partial clinical hold, which is described in more detail below. The interim analysis of the first 31 patients following 28 days of treatment from this clinical trial demonstrated that the side effect profile of IDX184 was consistent with that seen with pegylated interferon and ribavirin, or Peg-IFN/RBV, and there were no serious adverse events. The interim data rapid virologic response, or RVR, findings demonstrated that 73% of patients in the 100 mg IDX184 arm and 63% in the 50 mg arm had undetectable virus (< 25 IU/ml) at 28 days. As of January 9, 2012, 87% of patients in the 100 mg arm and 94% in the 50 mg arm had undetectable virus at a median of 8 weeks of treatment. We provided an interim analysis of the first 31 patients following 28 days of treatment to an independent data safety monitoring board, or DSMB, and to the U.S. Food and Drug Administration, or FDA. The DSMB reviewed the data for the first 31 patients and recommended the continuation of enrollment in the phase IIB IDX184 clinical trial. We submitted the interim data, along with the DSMB's recommendations, to the FDA and requested the continuation of this study and removal of the partial clinical hold for IDX184. In February 2012, the FDA removed the partial clinical hold on IDX184 and as a result we can continue enrollment of the phase IIB study of IDX184 and evaluate IDX184 in future interferon-free combination regimens with other DAAs. In addition, the FDA allowed us to truncate the phase IIB study from 100 patients, as in the original protocol, to a total of 60 patients, and to expand the enrollment criteria as recommended by the DSMB.

<u>Indication</u>	<u>Product/Drug Candidates/Programs</u>	<u>Description</u>
	Nucleoside/Nucleotide Polymerase Inhibitors (IDX19368)	In 2011, we selected two additional nucleotide polymerase inhibitors, IDX19368 and IDX19370, to advance into preclinical testing. We selected IDX19368 as our lead candidate for our next generation nucleotide polymerase inhibitor program and we expect to submit an investigational new drug application, or IND, for this candidate in the middle of 2012. We are also evaluating other nucleotide prodrugs in preclinical testing.
	NS5A Inhibitors (IDX719)	In 2011, we selected IDX719 as our lead candidate for our NS5A program. In preclinical studies, IDX719 has shown potent and pan-genotypic activity. In December 2011, we filed an IND for IDX719 and in January 2012, we initiated a phase I clinical study in healthy volunteers. We expect to begin a proof-of-concept study in the second quarter of 2012.
HBV	Tyzeka®/Sebivo® (telbivudine) (L-nucleoside)	Novartis Pharma AG, or Novartis, has worldwide development, commercialization and manufacturing rights and obligations related to telbivudine (Tyzeka®/Sebivo®). We receive royalty payments equal to a percentage of net sales of Tyzeka®/Sebivo®.

In September 2010, the FDA placed two of our HCV drug candidates, IDX184 and IDX320, on clinical hold. The hold was imposed due to three serious adverse events of elevated liver function tests that were detected during post drug exposure safety visits following a 14-day drug-drug interaction study of a combination of IDX184 and IDX320 in 20 healthy volunteers. We believe the hepatotoxicity observed in this drug-drug interaction study was caused by IDX320 and therefore discontinued the clinical development of this drug candidate. In February 2011, the full clinical hold on IDX184 was removed. The program was placed on partial clinical hold, which allowed us to initiate a phase IIB 12-week clinical trial of IDX184 in HCV-infected patients in July 2011. We provided an interim analysis of the first 31 patients following 28 days of treatment to an independent DSMB and to the FDA. The DSMB reviewed the data for the first 31 patients and recommended the continuation of enrollment in the phase IIB IDX184 clinical trial. We submitted the interim data, along with the DSMB's recommendations, to the FDA and requested the continuation of this study and removal of the partial clinical hold for IDX184. In February 2012, the FDA removed the partial clinical hold on IDX184 and as a result we can continue enrollment of the phase IIB study of IDX184 and evaluate IDX184 in future interferon-free combination regimens with other DAAs. In addition, the FDA allowed us to truncate the phase IIB study from 100 patients, as in the original protocol, to a total of 60 patients, and to expand the enrollment criteria as recommended by the DSMB.

All of our drug candidates are currently in preclinical or clinical development. To commercialize any of our drug candidates, we will be required to obtain marketing authorization approvals after successfully completing preclinical studies and clinical trials of such drug candidates. We anticipate that we will incur significant additional third-party research and development expenses that range from \$200.0 million to \$500.0 million for each drug candidate prior to commercial launch. Our current estimates of additional third-party research and development expenses do not include the cost of phase IIIb/IV clinical trials and other clinical trials that are not required for regulatory approval. We use our employees and our infrastructure resources across several projects, including our product discovery efforts. We do not allocate our infrastructure costs on a project-by-project basis. As a result, we are unable to estimate the internal costs incurred to date for our drug candidates on a project-by-project basis.

Set forth below were the third-party research and development expenses incurred in connection with our significant preclinical studies and clinical trials:

Disease Indication	Product/Drug Candidate	Years Ended December 31,		
		2011	2010	2009
			(In Thousands)	
HCV	Nucleotide Polymerase Inhibitors	\$ 9,303	\$ 8,412	\$ 6,052
HCV	NS5A Inhibitors	5,479	5	—
HCV	Non-Nucleoside Polymerase Inhibitor	1,720	3,678	3,537
HCV	Protease Inhibitors	308	5,468	2,665
HCV	Preclinical discovery program and other	257	508	517
HCV	Combination drug-drug interaction study	6	747	—
HBV	Telbivudine (Tyzeka®/Sebivo®)	—	—	15
HIV	Non-Nucleoside Reverse Transcriptase Inhibitor	—	(26)	(325)
		<u>\$17,073</u>	<u>\$18,792</u>	<u>\$12,461</u>

As shown in the table above, in 2011, our focus continued to be on the development of our nucleotide polymerase inhibitors program. During 2011, we completed IND-enabling studies for our NS5A program and filed an IND in December 2011. We elected not to devote significant resources to our non-nucleoside and protease inhibitor programs and have reallocated these resources to the discovery and development of additional nucleoside/nucleotide polymerase inhibitors.

Novartis has the option to license our development-stage drug candidates after demonstration of activity and safety in a proof-of-concept clinical trial so long as Novartis maintains at least 30% ownership of our common stock pursuant to our development, license and commercialization agreement with Novartis, which we refer to as the development and commercialization agreement. If Novartis licenses any of our drug candidates, Novartis is obligated to fund development expenses that we incur in accordance with development plans agreed upon by us and Novartis. In October 2009, Novartis waived its option to license IDX184. As a result, we retain the worldwide rights to develop, manufacture, commercialize and license IDX184. We may seek a partner who will assist in the future development and commercialization of this drug candidate.

We have incurred significant losses each year since our inception in May 1998 and at December 31, 2011, we had an accumulated deficit of \$675.7 million. Historically, we have generated losses principally from costs associated with research and development activities, including clinical trial costs, and general and administrative activities. As a result of planned expenditures for future discovery and development activities, we expect to incur additional losses for the foreseeable future. We believe that our current cash, cash equivalents and the expected royalty payments associated with product sales of Tyzeka®/Sebivo® will be sufficient to sustain operations for at least the next 12 months from December 31, 2011.

#### ***Novartis Collaboration***

In May 2003, we entered into a collaboration with Novartis relating to the worldwide development and commercialization of our drug candidates. In May 2003, Novartis also purchased approximately 54% of our common stock. Since this date, Novartis has had the ability to exercise control over our strategic direction, research and development activities and other materials business decisions.

We derived the majority of our total revenues from Novartis in 2011, 2010 and 2009 through the recognition of license fees, milestone payments, research and development expense reimbursements and royalty payments. Under the collaboration, Novartis paid us \$117.2 million of non-refundable payments that have been recorded as deferred revenue. These deferred payments are being recognized over the development period of the licensed drug candidates, which represents the period of our continuing obligations. Additionally, we also receive royalty payments from Novartis based on net sales of Tyzeka®/Sebivo®.

We expect to continue to recognize revenue related to Novartis associated with the non-refundable payments as well as the royalty payments. We also anticipate recognizing additional revenues from our collaboration with Novartis, which may include license fees, development expense funding for our drug candidates that Novartis may elect to subsequently license from us, as well as, regulatory milestones and, if products are approved for sale, commercialization milestones and revenues derived from sales, by us or Novartis, of our licensed drug candidates.

***ViiV Healthcare Company and GlaxoSmithKline Collaboration***

In February 2009, we licensed our non-nucleoside reverse transcriptase inhibitor, or NNRTI, compounds to GlaxoSmithKline, or GSK. This agreement, which we refer to as the ViiV license agreement, was assigned to ViiV Healthcare Company, or ViiV, which is an affiliate of GSK. The ViiV license agreement granted ViiV an exclusive worldwide license to develop, manufacture and commercialize our NNRTI compounds, including IDX899, now known as ‘761, for the treatment of human diseases, including human immunodeficiency virus type-1, or HIV, and acquired immune deficiency syndrome, or AIDS. In February 2009, we also entered into a stock purchase agreement with GSK, which we refer to as the GSK stock purchase agreement. Under this agreement, GSK purchased approximately 2.5 million shares of our common stock at an aggregate purchase price of \$17.0 million, or a per share price of \$6.87. These agreements became effective in March 2009.

In March 2009, we received a \$34.0 million payment related to this agreement, which consisted of a \$17.0 million license fee payment under the ViiV license agreement and the \$17.0 million under the GSK stock purchase agreement described above. In 2010, we received a \$6.5 million milestone payment for the achievement of a preclinical operational milestone and a \$20.0 million milestone payment for the initiation of a phase IIb clinical study of ‘761.

In February 2011, ViiV informed us that the FDA placed ‘761 on clinical hold. As a result of further evaluation, ViiV determined that it would not continue development of ‘761 or develop any other compound licensed under the ViiV license agreement. In December 2011, ViiV notified us that it would terminate the ViiV license agreement effective March 15, 2012. Upon termination, we will have no future obligations pursuant to the license agreement and the deferred revenue balance of \$36.1 million at December 31, 2011 associated with the ViiV license agreement is expected to be recognized as other collaboration revenue in the first quarter of 2012.

**Results of Operations**

***Comparison of Years Ended December 31, 2011 and 2010***

*Revenues*

Revenues for the years ended December 31, 2011 and 2010 were as follows:

	<b>Years Ended December 31,</b>	
	<b>2011</b>	<b>2010</b>
	<b>(In Thousands)</b>	
Collaboration revenue—related party:		
License fee revenue . . . . .	\$ (183)	\$ 2,431
Royalty revenue . . . . .	<u>4,511</u>	<u>3,800</u>
	4,328	6,231
Other revenue:		
Collaboration revenue . . . . .	2,623	3,954
Government grants . . . . .	<u>—</u>	<u>37</u>
Total revenues . . . . .	<u>\$6,951</u>	<u>\$10,222</u>

Collaboration revenue — related party consisted of revenue associated with our collaboration with Novartis for the worldwide development and commercialization of our drug candidates. During the years ended December 31, 2011, 2010 and 2009, collaboration revenue — related party was comprised of the following:

- license and other fees received from Novartis for the license of hepatitis B virus, or HBV, and HCV drug candidates, net of reductions for Novartis stock subscription rights, which is being recognized over the development period of our licensed drug candidates;
- royalty payments associated with product sales of Tyzeka®/Sebivo® made by Novartis; and
- reimbursement by Novartis for expenses we incurred in connection with the development and registration of our licensed products and drug candidates, net of certain qualifying costs incurred by Novartis.

Collaboration revenue — related party was \$4.3 million in 2011 as compared to \$6.2 million in 2010. The \$2.6 million decrease in license fee revenue was primarily due to \$1.3 million related to the impact of Novartis' stock subscription rights and \$1.3 million due to adjusting the expected development period of our licensed drug candidates in 2010, which represents the period over which we recognize license fee revenue.

Collaboration revenue recognized under the ViiV license agreement was \$2.6 million in 2011 as compared to \$4.0 million in 2010. The decrease of \$1.4 million was primarily due to the recognition of additional revenue in 2010 related to the \$26.5 million milestone payments received under the ViiV license agreement. A cumulative catch-up of \$2.7 million was recognized in 2010 related to these milestone payments. There were no milestone payments received during 2011.

In December 2011, ViiV notified us they were terminating the license agreement effective March 15, 2012. Upon termination, we will have no future obligations pursuant to the license agreement and the deferred revenue balance of \$36.1 million at December 31, 2011 associated with the ViiV license agreement is expected to be recognized as other collaboration revenue in the first quarter of 2012.

#### *Cost of Revenues*

Cost of revenues were \$2.3 million in 2011 as compared to \$2.8 million in 2010. The decrease of \$0.5 million was primarily a result of lower royalty payments due by us to a third-party in 2011. In 2010, we paid royalties to a third-party associated with the \$26.5 million milestone payments received under the ViiV license agreement in 2010. There were no milestone payments received in 2011.

#### *Research and Development Expenses*

Research and development expenses were \$41.3 million in 2011 as compared to \$44.5 million in 2010. The decrease of \$3.2 million was primarily due to \$7.1 million of lower expenses related to devoting fewer resources to our protease inhibitor and non-nucleoside polymerase inhibitor programs in 2011. In addition, salaries and personnel related costs decreased \$1.0 million in 2011 compared to 2010 mainly due to a reduced headcount. These decreases were partially offset by a \$5.5 million increase in expenses related to our NS5A program.

We expect our research and development expenses for 2012 to be higher than the amount incurred in 2011 mainly due to the continued development of IDX184 and to the advancement of our other HCV drug candidates into clinical testing in 2012. We may seek a partner that will assist in the further development and commercialization of IDX184, which would reduce future costs associated with IDX184.

We will continue to devote substantial resources to our research and development activities, expand our research pipeline and engage in future development activities as we continue to advance our drug candidates and explore collaborations with other entities that we believe will create shareholder value.

### *General and Administrative Expenses*

General and administrative expenses were \$16.7 million in 2011 as compared to \$23.4 million in 2010. The decrease of \$6.7 million was primarily due to \$5.0 million of severance and share-based compensation expense related to the resignation of our former chief executive officer in 2010, for which there is no comparable expense in 2011.

We expect general and administrative expenses in 2012 to be consistent with the expenses incurred in 2011.

### *Restructuring Charges*

In 2010, we recorded restructuring charges of \$2.2 million for employee severance costs related to the restructuring of our Montpellier facility together with charges related to an earlier reduction of our United States workforce. All significant severance amounts were paid in 2010. There were no restructuring charges recorded in 2011.

### *Other Income, Net*

Other income, net was \$1.4 million in 2011 which was substantially unchanged as compared to 2010.

### *Income Tax Benefit (Expense)*

Income tax benefit was less than \$0.1 million in 2011 which was substantially unchanged as compared to 2010.

### ***Comparison of Years Ended December 31, 2010 and 2009***

#### *Revenues*

Revenues for the years ended December 31, 2010 and 2009 were as follows:

	<b>Years Ended December 31,</b>	
	<b>2010</b>	<b>2009</b>
	<b>(In Thousands)</b>	
Collaboration revenue—related party:		
License fee revenue .....	\$ 2,431	\$ 7,968
Royalty revenue .....	3,800	3,704
Reimbursement of research and development costs .....	—	45
	<u>6,231</u>	<u>11,717</u>
Other revenue:		
Collaboration revenue .....	3,954	854
Government grants .....	37	45
Total revenues .....	<u>\$10,222</u>	<u>\$12,616</u>

Collaboration revenue — related party was \$6.2 million in 2010 as compared to \$11.7 million in 2009. The \$5.5 million decrease in license fee revenue was primarily due to \$3.7 million related to the impact of Novartis' stock subscription rights and \$1.8 million due to adjusting the expected development period of our licensed drug candidates, which represents the period over which we recognize license fee revenue.

Collaboration revenue recognized under the ViiV license agreement was \$4.0 million in 2010 as compared to \$0.9 million in 2009. The increase of \$3.1 million was primarily due to the recognition of additional revenue related to the \$6.5 million and \$20.0 million milestone payments received under the ViiV license agreement in 2010. A cumulative catch-up of \$2.7 million was recognized related to the \$26.5 million milestone payments received in 2010.

### *Cost of Revenues*

Cost of revenues were \$2.8 million in 2010 as compared to \$2.2 million in 2009. The increase of \$0.6 million was primarily a result of higher royalty payments due by us to a third-party related to the \$6.5 million and \$20.0 million milestone payments received under the ViiV license agreement in 2010.

### *Research and Development Expenses*

Research and development expenses were \$44.5 million in 2010 as compared to \$41.9 million in 2009. The increase of \$2.6 million was primarily due to \$5.9 million of additional expenses in 2010 for a phase IIa clinical trial of IDX184, which was initiated in the fourth quarter of 2009, the phase I and proof-of-concept clinical studies of IDX320 and a combination drug-drug interaction study of IDX184 and IDX320, which were initiated in 2010. These costs were offset by \$2.4 million in lower salaries and personnel related costs, mainly related to reduced headcount as a result of the restructurings in the United States and Europe.

### *General and Administrative Expenses*

General and administrative expenses were \$23.4 million in 2010 as compared to \$21.5 million in 2009. The increase of \$1.9 million was primarily due to \$5.0 million of severance expense and share-based compensation expense related to the resignation of our former chief executive officer in October 2010. These costs were offset by \$2.8 million lower consulting fees, salaries and personnel related costs, mainly related to reduced headcount as a result of the restructuring in the United States.

### *Restructuring Charges*

Restructuring charges were \$2.2 million in 2010 as compared to \$1.5 million in 2009. During the first quarter of 2010, we initiated a plan to restructure our operations at our research facility in Montpellier, France to reduce its workforce by approximately 17 positions in connection with our ongoing cost saving initiatives. In the first quarter of 2010, we recorded charges of \$2.2 million for employee severance costs related to the restructuring of our Montpellier facility together with charges related to an earlier reduction of our United States workforce by 13 positions in January 2010. All significant severance amounts were paid in 2010.

In June 2009, we closed our lab facility in Cagliari, Italy and eliminated 18 employee positions as a result of continuing cost saving initiatives. The \$1.5 million restructuring charge recognized in 2009 consisted of \$1.2 million of employee severance costs and \$0.3 million contract termination costs associated with closing the lab facility. There was no remaining amount accrued related to this restructuring as of December 31, 2010.

### *Other Income, Net*

Other income, net was \$1.1 million in 2010 which was substantially unchanged as compared to 2009.

### *Income Tax Benefit (Expense)*

Income tax benefit was less than \$0.1 million in 2010 which was substantially unchanged as compared to 2009.

## **Liquidity and Capital Resources**

Since our inception in 1998, we have financed our operations with proceeds obtained in connection with license and development arrangements and equity financings. The proceeds include:

- license, milestone, royalty and other payments from Novartis;
- license, milestone and stock purchase payments from ViiV and GSK;

- reimbursements from Novartis for costs we have incurred subsequent to May 8, 2003 in connection with the development of Tyzeka®/Sebivo®, valtorcitabine and valopicitabine;
- sales of Tyzeka® in the United States through September 30, 2007;
- net proceeds from Sumitomo Pharmaceuticals Co., Ltd., or Sumitomo, for reimbursement of development costs;
- net proceeds from private placements of our convertible preferred stock in 1998, 1999 and 2001;
- net proceeds from public or underwritten offerings in July 2004, October 2005, August 2009, April 2010, April 2011 and November 2011;
- net proceeds from private placements of our common stock concurrent with our 2004, 2005 and April 2011 public offerings; and
- proceeds from the exercise of stock options granted pursuant to our equity compensation plans.

Any financing requiring the issuance of additional shares of capital stock must first be approved by Novartis for so long as Novartis continues to own at least 19.4% of our voting stock. We received Novartis' approval for the following offerings in 2009, 2010 and 2011:

- in May 2009, we received approval from Novartis to issue capital shares pursuant to financing transactions under a shelf registration statement filed in September 2008 with the Securities and Exchange Commission, or SEC, so long as the issuance of shares did not reduce Novartis' interest in Idenix below 43%. In August 2009, we issued approximately 7.3 million shares pursuant to an underwritten offering and received \$21.2 million in net proceeds. Additionally, pursuant to this shelf registration statement, in April 2010, we issued approximately 6.5 million shares of our common stock pursuant to an underwritten offering and received \$26.3 million in net proceeds. Novartis did not participate in these offerings;
- in April 2011, we received approval from Novartis to issue capital shares so long as the issuance of shares did not reduce Novartis' interest in Idenix below 30%. In April 2011, we issued approximately 21.1 million shares of our common stock pursuant to the September 2008 shelf registration statement and approximately 1.8 million shares of our common stock to Novartis pursuant to a private placement agreement. The net proceeds of both transactions were \$60.2 million. Upon completion of this offering, we fully utilized the shelf registration statement and Novartis owned approximately 35% of our outstanding common stock. In conjunction with the issuance of common stock in April 2011, we amended the collaboration with Novartis to provide that: a) Novartis retains the exclusive option to obtain rights to drug candidates developed by us so long as Novartis maintains ownership of at least 30% of our common stock, rather than ownership of at least 40% as was the case prior to the amendment; b) we will use reasonable best efforts to nominate for election as directors at least two designees of Novartis so long as Novartis maintains ownership of at least 30% of our common stock, rather than ownership of at least 35% as was the case prior to the amendment; and c) Novartis' consent is required for the selection and appointment of our chief financial officer so long as Novartis owns at least 30% of our common stock, rather than ownership of at least 40% as was the case prior to the amendment; and
- in November 2011, we received approval from Novartis to issue capital shares so long as the issuance of shares did not reduce Novartis' interest in Idenix below 31%. In October 2011, we filed a universal shelf registration statement with the SEC which will allow us to offer and sell from time to time up to a maximum of \$150.0 million of shares of common stock, at prices and terms to be determined at the time of sale. Pursuant to this shelf registration statement, in November 2011, we issued approximately 10.8 million shares of our common stock pursuant to an underwritten offering and received \$65.8 million in net proceeds. Novartis did not participate in this offering.

We have incurred losses in each year since our inception and at December 31, 2011, we had an accumulated deficit of \$675.7 million. We expect to incur losses over the next several years as we continue to expand our drug discovery and development efforts. As a result, we may seek additional funding through a combination of public or private financing, collaborative relationships or other arrangements and we may seek a partner who will assist in the future development and commercialization of IDX184. As previously noted, any financing requiring the issuance of additional shares of capital stock must first be approved by Novartis so long as Novartis continues to own at least 19.4% of our voting stock. As of February 21, 2012, Novartis owned approximately 31% of our outstanding common stock. Additional funding may not be available to us or, if available, may not be on terms favorable to us. Further, any additional equity financing may be dilutive to stockholders, other than Novartis, which has the right to maintain its current ownership level.

We believe that our current cash, cash equivalents and the expected royalty payments associated with product sales of Tyzeka®/Sebivo® will be sufficient to sustain operations for at least the next 12 months from December 31, 2011. If we are unable to obtain adequate financing on a timely basis, we could be required to delay, reduce or eliminate one or more of our drug development programs, enter into new collaborative, strategic alliances or licensing arrangements that may not be favorable to us and reduce the number of our employees. More generally, if we are unable to obtain adequate funding, we may be required to scale back, suspend or terminate our business operations.

We had total cash and cash equivalents of \$118.3 million and \$46.1 million as of December 31, 2011 and 2010, respectively. Our investment policy seeks to manage these assets to achieve our goals of preserving principal and maintaining adequate liquidity. As of December 31, 2011, all of our investments were in government agency and treasury money market instruments.

Net cash used in operating activities was \$54.5 million, \$28.1 million and \$36.0 million in 2011, 2010 and 2009, respectively. The increase in net cash used in operating activities of \$26.4 million in 2011 compared to 2010 was primarily due to the receipt of \$26.5 million in milestone payments under the ViiV license agreement during 2010. There were no milestone payments received in 2011. The decrease in net cash used in operating activities of \$7.9 million in 2010 compared to 2009 was primarily due to the receipt of payments under the ViiV license agreement of \$26.5 million in 2010 as compared to \$17.0 million in 2009.

Net cash used in investing activities was \$0.8 million in 2011, compared to net cash provided by investing activities of \$0.7 million and \$2.1 million in 2010 and 2009, respectively. The decrease of \$1.5 million in 2011 was due to the sale of a marketable security in 2010. The decrease in net cash provided by investing activities of \$1.4 million in 2010 was due primarily to lower net proceeds from sales and maturities of our marketable securities as compared to 2009. This was attributable to lower cash balances invested in marketable securities in 2010 due to the use of cash to fund operations.

Net cash provided by financing activities was \$127.7 million, \$26.9 million and \$38.3 million in 2011, 2010 and 2009, respectively. The increase in net cash provided by financing activities of \$100.8 million in 2011 compared to 2010 was primarily due to the receipt of proceeds related to the underwritten offerings in April 2011 and November 2011 of \$126.0 million as compared to the underwritten offering in April 2010 of \$26.3 million. The decrease in net cash provided by financing activities of \$11.4 million in 2010 compared to 2009 was primarily due to \$17.0 million received in proceeds related to the issuance of stock to GSK pursuant to the stock purchase agreement entered in March 2009. This amount was offset by \$5.1 million in additional net proceeds we received in 2010 as compared to 2009 from the issuance of our common stock pursuant to underwritten agreements.

### ***Contractual Obligations and Commitments***

Set forth below is a description of our contractual obligations as of December 31, 2011:

<u>Contractual Obligations</u>	<u>Payments Due by Period</u>				
	<u>Total</u>	<u>Less Than 1 Year</u>	<u>1-3 Years</u>	<u>4-5 Years</u>	<u>After 5 Years</u>
	(In Thousands)				
Operating leases . . . . .	\$ 6,468	\$2,349	\$2,649	\$1,307	\$ 163
Settlement payments and other agreements . . . . .	1,870	1,262	456	152	—
Long-term obligations . . . . .	7,613	—	287	—	7,326
Total contractual obligations . . . . .	<u>\$15,951</u>	<u>\$3,611</u>	<u>\$3,392</u>	<u>\$1,459</u>	<u>\$7,489</u>

Included in the table above is \$8.2 million related to a settlement agreement we entered into in July 2008 with the University of Alabama at Birmingham, or UAB, the University of Alabama at Birmingham Research Foundation, or UABRF, an affiliate of UAB, and Emory University relating to our telbivudine technology. Pursuant to this settlement agreement, all contractual disputes relating to patents covering the use of certain synthetic nucleosides for the treatment of HBV and all litigation matters relating to patents and patent applications related to the use of  $\beta$ -L-2'-deoxy-nucleosides for the treatment of HBV assigned to one or more of Idenix, Le Centre National de la Recherche Scientifique, or CNRS, and the Universite Montpellier II, or the University of Montpellier, and which cover the use of Tyzeka<sup>®</sup>/Sebivo<sup>®</sup> (telbivudine) for the treatment of HBV have been resolved. Under the terms of the settlement agreement, we paid UABRF (on behalf of UAB and Emory University) a \$4.0 million upfront payment and will make additional payments to UABRF equal to 20% of all royalty payments received by us from Novartis based on worldwide sales of telbivudine, subject to minimum payment obligations aggregating \$11.0 million. Our payment obligations under the settlement agreement will expire in August 2019. The settlement agreement was effective on June 1, 2008 and included mutual releases of all claims and covenants not to sue among the parties. It also included a release from a third-party scientist who had claimed to have inventorship rights in certain Idenix/CNRS/University of Montpellier patents.

In connection with certain of our operating leases, we have two letters of credit with a commercial bank totaling \$1.2 million which expire at varying dates through December 31, 2013. In December 2011, we terminated an operating lease for office space in Cambridge, MA. The letter of credit associated with this lease of \$0.4 million was terminated in the first quarter of 2012.

As of December 31, 2011, we had \$2.8 million of other long-term liabilities recorded. These liabilities and certain potential payment obligations relating to our HBV and HCV product and drug candidates that are described below are excluded from the contractual obligations table above as we cannot make a reliable estimate of the period in which the cash payments may be made.

In May 2004, we entered into a settlement agreement with UAB which provides for a milestone payment of \$1.0 million to UAB upon receipt of regulatory approval in the United States to market and sell certain HCV products invented or discovered by our former chief executive officer during the period from November 1, 1999 to November 1, 2000. This settlement agreement also provides that we will pay UAB an amount equal to 0.5% of worldwide net sales of such HCV products with a minimum sales-based payment equal to \$12.0 million. Currently, there are no such HCV products approved and therefore there was no related liability recorded as of December 31, 2011.

We have potential payment obligations under the license agreement with the Università degli Studi di Cagliari, or the University of Cagliari, pursuant to which we have the exclusive worldwide right to make, use and sell certain HCV and other technologies. We made certain payments to the University of Cagliari under these arrangements based on the payments we received from ViiV under the ViiV license agreement. We are also

liable for certain payments to the University of Cagliari if we receive license fees or milestone payments with respect to such technology from Novartis or another collaborator. As a result of the termination of the ViiV license agreement, we will not receive any additional milestone or royalty payments under the ViiV license agreement and therefore do not expect to make future payments to the University of Cagliari for the patent and patent applications related to '761.

In May 2003, we and Novartis entered into an amended and restated agreement with CNRS and the University of Montpellier pursuant to which we worked in collaboration with scientists from CNRS and the University of Montpellier to discover and develop technologies relating to antiviral substances, including telbivudine. This cooperative agreement expired in December 2006, but we retain rights to exploit the patents derived from the collaboration. Under the cooperative agreement, we are obligated to make royalty payments for products derived from such patents.

In March 2003, we entered into a final settlement agreement with Sumitomo under which the rights to develop and commercialize telbivudine in Japan, China, South Korea and Taiwan previously granted to Sumitomo were returned to us. This agreement with Sumitomo became effective upon consummation of our collaboration with Novartis in May 2003. The settlement agreement which we entered into with Sumitomo provides for a \$5.0 million milestone payment to Sumitomo if and when the first commercial sale of telbivudine occurs in Japan. As part of the development and commercialization agreement, Novartis will reimburse us for any such payment made to Sumitomo.

In December 2001, we retained the services of Clariant (subsequently acquired by Archimica Group), a provider of manufacturing services in the specialty chemicals industry, in the form of a multiproject development and supply agreement. Under the terms of the agreement with Clariant, we would, on an "as needed" basis, utilize the Clariant process development and manufacture services in the development of certain of our drug candidates, including telbivudine. After reviewing respective bids from each of Novartis and Clariant, the joint manufacturing committee of Idenix and Novartis decided to proceed with Novartis as the primary manufacturer of telbivudine. In late 2007, we transferred full responsibility to Novartis for the development, commercialization and manufacturing of telbivudine. As a result, in January 2008, we exercised our right under the agreement with Clariant to terminate the relationship effective July 2008. In February 2008, Clariant asserted that they should have been able to participate in the manufacturing process for telbivudine as a non-primary supplier and therefore are due an unspecified amount. We do not agree with Clariant's assertion and since no estimate of a potential loss can be made, we have not recorded a liability associated with this potential contingent matter. Clariant has not initiated legal proceedings. If legal proceedings are initiated, we intend to vigorously defend against such lawsuit.

#### **Off-Balance Sheet Transactions**

We currently have no off-balance sheet transactions.

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

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States of America, or GAAP. The preparation of the financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition, accrued expenses and share-based compensation. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are more fully described in Note 2 to our consolidated financial statements included in this Annual Report on Form 10-K for the year ended December 31, 2011. However, we believe that the following critical accounting policies are important to the understanding and evaluating of our reported financial results.

### ***Revenue Recognition***

Revenue is recognized in accordance with SEC Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*, or SAB No. 101, as amended by SEC Staff Accounting Bulletin No. 104, *Revenue Recognition*, and, for revenue arrangements entered into after June 30, 2003, in accordance with the revenue recognition guidance of the Financial Accounting Standards Board, or FASB. For multiple-element arrangements entered into or materially modified after January 1, 2011, we recognize revenue under Accounting Standard Update No. 2009-13, *Multiple-Deliverable Revenue Arrangements*, or ASU No. 2009-13. We record revenue provided that there is persuasive evidence that an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collectability is reasonably assured.

Our revenues are generated primarily through collaborative research, development and/or commercialization agreements. The terms of these agreements typically include payments to us for non-refundable license fees, milestones, collaborative research and development funding and royalties received from our collaboration partners.

### ***Non-Refundable License Fee Payments***

Where we have continuing performance obligations under the terms of a collaborative arrangement, non-refundable license fees are recognized as revenue over the expected development period as we complete our performance obligations. When our level of effort is relatively constant over the performance period or no other performance pattern is evident, the revenue is recognized on a straight-line basis. The determination of the performance period involves judgment on the part of management. Payments received from collaboration partners for research and development efforts by us are recognized as revenue over the contract term as the related costs are incurred, net of any amounts due to the collaboration partner for costs incurred during the period for shared development costs.

Where we have no continuing involvement or obligations under a collaborative arrangement, we record non-refundable license fee revenue when we have a contractual right to receive the payment, in accordance with the terms of the license agreement.

### ***Milestone Payments***

Revenue is recognized for payments that are contingent upon the achievement of a milestone in its entirety, in the period in which the milestone is achieved, only if the milestone is substantive and meets all of the following criteria: a) performance consideration earned by achieving the milestone be commensurate with either performance to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from performance to achieve the milestone; b) it relates to past performance; and c) the payment is reasonable relative to all deliverables and payment terms in the arrangement.

### ***Collaboration Revenue — Related Party***

We entered into a collaboration with Novartis relating to the worldwide development and commercialization of our drug candidates in May 2003, which we refer to as the development and commercialization agreement. Under this arrangement, we have received non-refundable license fees, milestones, collaborative research and development funding and royalty payments. This agreement has several joint committees in which we and Novartis participate. We participate in these committees as a means to govern or protect our interests. The

committees span the period from early development through commercialization of drug candidates licensed by Novartis. As a result of applying the provisions of SAB No. 101, which was the applicable revenue guidance at the time the collaboration was entered into, our revenue recognition policy attributes revenue to the development period of the drug candidates licensed under the development and commercialization agreement. We have not attributed revenue to our involvement in the committees following the commercialization of the licensed products as we have determined that our participation on the committees, as such participation relates to the commercialization of drug candidates, is protective. Our determination is based in part on the fact that our expertise is, and has been, the discovery and development of drugs for the treatment of human viral diseases. Novartis, on the other hand, has the considerable commercialization expertise and infrastructure necessary for the commercialization of such drug candidates. Accordingly, we believe our obligation post commercialization is inconsequential.

We recognize non-refundable payments received from Novartis over the performance period of our continuing obligations. In the second quarter of 2010, we adjusted the period over which we amortize the deferred payments to be through May 2021 based on current judgments related to the product development timeline of our licensed drug candidates. We review our assessment and judgment on a quarterly basis with respect to the expected duration of the development period of our licensed drug candidates. If the estimated performance period changes, we will adjust the periodic revenue that is being recognized and will record the remaining unrecognized non-refundable payments over the remaining development period during which our performance obligations will be completed. Significant judgments and estimates are involved in determining the estimated development period and different assumptions could yield materially different results.

Upon the grant of options and stock awards under stock incentive plans, with the exception of the 1998 equity incentive plan, the fair value of our common stock that would be issuable to Novartis, less the exercise price, is recorded as a reduction of the non-refundable payments associated with the Novartis collaboration. The amount is attributed proportionately between cumulative revenue recognized through the current date and the remaining amount of deferred revenue. These amounts will be adjusted through the date that Novartis elects to purchase the shares to maintain its percentage ownership based upon changes in the value of our common stock and in Novartis' percentage ownership. As of December 31, 2011, the aggregate impact of Novartis' stock subscription rights has reduced the non-refundable payments by \$22.8 million, which has been recorded as additional paid-in capital. Of this amount, \$5.8 million has been recorded as a reduction of deferred revenue with the remaining amount of \$17.0 million as a reduction of license fee revenue. For the year ended December 31, 2011, the impact of Novartis' stock subscription rights has increased additional paid-in capital by \$4.5 million, decreased deferred revenue by \$1.2 million and decreased license fee revenue by \$3.3 million.

Royalty revenue consists of revenue earned under our license agreement with Novartis for sales of Tyzeka<sup>®</sup>/Sebivo<sup>®</sup>, which is recognized when reported from Novartis. Royalty revenue is equal to a percentage of Tyzeka<sup>®</sup>/Sebivo<sup>®</sup> net sales, with such percentage increasing according to specified tiers of net sales. The royalty percentage varies based on the specified territory and the aggregate dollar amount of net sales.

#### *Other Revenue*

In February 2009, we entered into the ViiV license agreement. Under the ViiV license agreement, we granted ViiV an exclusive worldwide license to develop, manufacture and commercialize our NNRTI compounds, including IDX899, now known as '761, for the treatment of human diseases, including HIV/AIDS. This agreement had performance obligations, including joint committee participation and ViiV's right to license other NNRTI compounds that we may develop in the future, that we had assessed under the FASB guidance related to multiple element arrangements, prior to the implementation of ASU No. 2009-13. We concluded that this arrangement should be accounted for as a single unit of accounting and recognized as revenue using the contingency adjusted performance method. Under this agreement, we received a non-refundable license fee payment and milestone payments from ViiV. These milestone payments did not meet our revenue recognition criteria for immediate recognition. The non-refundable license fee payment and milestone payments received

from ViiV were recorded as deferred revenue and were being recognized as revenue over the life of the agreement, which was estimated to be 17 years. A cumulative catch-up was recognized for the period from the execution of the license agreement in March 2009 through the period in which the milestone payments were received.

In February 2011, ViiV informed us that the FDA placed '761 on clinical hold. As a result of further evaluation, ViiV determined that it would not continue development of '761 or develop any other compound licensed under the ViiV license agreement. In December 2011, ViiV notified us that it would terminate the ViiV license agreement effective March 15, 2012. Upon termination, ViiV will relinquish all rights it has in the intellectual property licensed from us and grants us an exclusive, perpetual and irrevocable license to any intellectual property relating to the licensed products it may have developed during the term of the license agreement. As a result of the termination of the ViiV license agreement, we will not receive any additional milestone or royalty payments under the ViiV license agreement. Upon termination, we will have no future obligations pursuant to the license agreement and the deferred revenue balance of \$36.1 million at December 31, 2011 associated with the ViiV license agreement is expected to be recognized as other collaboration revenue in the first quarter of 2012.

Government research grants that provide for payments to us for work performed are recognized as revenue when the related expense is incurred and we have obtained governmental approval to use the grant funds for these expenses.

#### *Deferred Revenue*

In March 2003, we entered into a final settlement agreement with Sumitomo under which the rights to develop and commercialize telbivudine in Japan, China, South Korea and Taiwan previously granted to Sumitomo were returned to us. This agreement with Sumitomo became effective upon consummation of our collaboration with Novartis in May 2003. We repurchased these product rights for \$5.0 million. The repurchase of these rights resulted in a \$4.6 million reversal of revenue that we previously recognized under our original arrangements with Sumitomo. We recorded the remaining amount of \$0.4 million as a reduction of deferred revenue. We have also included \$4.3 million as deferred revenue, net of current portion in our consolidated balance sheets at December 31, 2011 and 2010 representing amounts received from Sumitomo that we have not included in our revenue to date. We are required to pay an additional \$5.0 million to Sumitomo if and when the first commercial sale of telbivudine occurs in Japan. This payment will be recorded first as a reduction of the remaining \$4.3 million of deferred revenue, with the excess recorded as an expense. As part of the development and commercialization agreement, Novartis will reimburse us for any such payment made to Sumitomo. If regulatory approval is not received for telbivudine in Japan, we would have no further obligations under the settlement agreement with Sumitomo and, therefore, the \$4.3 million of remaining deferred revenue would be recognized as revenue at that time.

#### *Accrued Expenses*

As part of the process of preparing our financial statements, we are required to estimate expenses we have incurred for which we have not been invoiced. This process involves estimating the level of service performed by third-parties on our behalf and the associated cost incurred for these services as of each balance sheet date in our financial statements. Examples of estimated accrued expenses in which subjective judgments may be required include services provided by contract organizations for preclinical development, clinical trials and manufacturing of clinical materials. Accruals for amounts due to clinical research organizations are among our most significant estimates. In connection with these service fees, our estimates are most affected by our understanding of the status and timing of services provided relative to the actual level of services incurred by the service providers. The date on which certain services commence, the level of services performed on or before a given date and the cost of services is often subject to our judgment. We make these judgments based upon the facts and circumstances known to us. In the event that we do not identify certain costs that have been incurred or we

underestimate or overestimate the level of services or the costs of such services, our reported expenses for a reporting period could be overstated or understated. To date, our estimates have not differed significantly from the actual costs incurred.

### ***Share-Based Compensation***

We account for share-based compensation for employees and directors using a fair value based method that results in expense being recognized in our financial statements. We make assumptions related to the expected volatility of our stock and the expected term of the awards granted in order to value and expense our share-based compensation. The expected option term and expected volatility are determined by examining the expected option term and volatility of our own stock as well as those of similarly sized biotechnology companies. We review these assumptions periodically. The amounts recognized for share-based compensation expense could vary depending upon changes in these assumptions.

Share-based compensation expense is recognized based on awards ultimately expected to vest and should be reduced for estimated forfeitures. During 2011, 2010 and 2009, because substantially all of our stock option grants vest monthly, no forfeiture assumption was applied.

For purposes of our consolidated statements of operations, we allocate share-based compensation to expense categories based on the nature of the service provided by the recipients of the stock option grants. We expect to continue to grant options to purchase common stock in the future.

### **Recent Accounting Pronouncements**

In June, 2011, the FASB issued Accounting Standard Update No. 2011-5, *Presentation of Comprehensive Income*. The objective of this amendment is to improve the comparability, consistency and transparency of financial reporting and to increase the prominence of items reported in other comprehensive income. This guidance is effective for fiscal years beginning after December 15, 2011 and requires retrospective application to all periods presented. We do not expect that this guidance will have any material effect on our consolidated financial statements.

## **Item 7A. Quantitative and Qualitative Disclosure About Market Risk**

### **Interest Rate Risk**

Changes in interest rates may impact our financial position, operating results or cash flows. The primary objective of our investment activities is to preserve capital while maintaining liquidity until it is required to fund operations. To minimize risk, we maintain our operating cash in commercial bank accounts. We invest our cash in high quality financial instruments, primarily government agency and treasury money market instruments. Due to the nature of these instruments, we do not believe that we have a material exposure to interest rate risk.

### **Foreign Currency Exchange Rate Risk**

Our foreign currency transactions include agreements denominated, wholly or partly, in foreign currencies, European subsidiaries that are denominated in foreign currencies and royalties earned based on worldwide product sales of Sebivo® by Novartis. As a result of these foreign currency transactions, our financial position, results of operations and cash flows can be affected by market fluctuations in foreign currency exchange rates. We have not entered into any derivative financial instruments to reduce the risk of fluctuations in currency exchange rates.

## **Item 8. Financial Statements and Supplementary Data**

The financial statements required by this item are incorporated by reference to the financial statements listed in Item 15(a) of Part IV of this Annual Report on Form 10-K.

## **Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure**

None.

### **Item 9A. Controls and Procedures**

#### **Disclosure Controls and Procedures**

##### ***Evaluation of Disclosure Controls and Procedures***

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2011. The term “disclosure controls and procedures”, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2011, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

##### ***Management’s Annual Report on Internal Control Over Financial Reporting***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive officer and principal financial officer and effected by our 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 GAAP and 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 our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our 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. 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.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2011. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control-Integrated Framework*.

Based on our assessment, management concluded that, as of December 31, 2011, our internal control over financial reporting was effective based on those criteria.

The effectiveness of our internal control over financial reporting as of December 31, 2011 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which is included herein.

***Changes in Internal Control Over Financial Reporting***

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the quarter ended December 31, 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information**

None.

## PART III

Certain information required by Part III of this Form 10-K is omitted because we plan to file a definitive proxy statement pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and certain information to be included therein is incorporated herein by reference.

### **Item 10. Directors, Executive Officers and Corporate Governance**

The response to this Item is incorporated herein by reference to our Proxy Statement for our 2012 Annual Meeting of Stockholders (the “2012 Proxy Statement”) under the captions “Proposal 1 — Election of Directors”, “Corporate Governance”, “Director Compensation” and “Security Ownership of Certain Beneficial Owners and Management”.

### **Codes of Business Conduct**

We have adopted a Code of Business Conduct and Ethics that applies to all of our directors, officers and employees, including our principal executive officer, principal financial officer, and principal accounting officer or controller, and persons performing similar functions. The Code of Business Conduct and Ethics is posted on our website, [www.idenix.com](http://www.idenix.com), and is available in print to any shareholder upon request to the General Counsel at our headquarter offices at 617-995-9800. Information regarding any amendments to the Code of Business Conduct and Ethics will also be posted on our website.

### **Item 11. Executive Compensation**

The response to this Item is incorporated herein by reference to our 2012 Proxy Statement under the captions “Executive Compensation”, “Compensation Committee Interlocks and Insider Participation” and “Compensation Committee Report”.

The “Compensation Committee Report” contained in the Proxy Statement shall not be deemed “soliciting material” or “filed” with the SEC or otherwise subject to the liabilities of Section 18 of the Exchange Act nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Act, or the Exchange Act, except to the extent we specifically request that such information be treated as soliciting material or specifically incorporate such information by reference into a document filed under the Securities Act or the Exchange Act.

### **Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

The response to this Item is incorporated herein by reference to our 2012 Proxy Statement under the captions “Security Ownership of Certain Beneficial Owners and Management” and “Executive Compensation — Equity Compensation Plan Information”.

### **Item 13. Certain Relationships, Related Transactions and Director Independence**

The response to this Item is incorporated herein by reference to our 2012 Proxy Statement under the captions “Certain Relationships and Related Person Transactions”, “Employment Agreements” and “Corporate Governance — Director Independence”.

### **Item 14. Principal Accountant Fees and Services**

The response to this Item is incorporated herein by reference to our 2012 Proxy Statement under the captions “Principal Accounting Fees and Services” and “Pre-Approval Policies and Procedures”.

**PART IV**

**Item 15. Exhibits and Financial Statement Schedules**

(a)(1) *Financial Statements*: The financial statements required to be filed as part of this Annual Report on Form 10-K are as follows:

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Report of Independent Registered Public Accounting Firm .....	71
Consolidated Balance Sheets at December 31, 2011 and 2010 .....	72
Consolidated Statements of Operations for the Years Ended December 31, 2011, 2010 and 2009 .....	73
Consolidated Statements of Stockholders' Equity (Deficit) and Comprehensive Loss for the Years Ended December 31, 2011, 2010 and 2009 .....	74
Consolidated Statements of Cash Flows for the Years Ended December 31, 2011, 2010 and 2009 .....	75
Notes to the Consolidated Financial Statements .....	76

(a)(2) *Financial Statement Schedules*. The financial statement schedules have been omitted as the information required is not applicable or the information is presented in the consolidated financial statements or the related notes.

(a)(3) *Exhibits*. The Exhibits have been listed in the Exhibit Index immediately preceding the Exhibits filed as part of this Annual Report on Form 10-K and incorporated herein by reference.

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Idenix Pharmaceuticals, Inc.:

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of stockholders' equity (deficit) and comprehensive loss and of cash flows present fairly, in all material respects, the financial position of Idenix Pharmaceuticals, Inc. and its subsidiaries at December 31, 2011 and 2010, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2011 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective 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 (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Annual Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated 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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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 (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) 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 (iii) 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.

/s/ PRICEWATERHOUSECOOPERS LLP  
Boston, Massachusetts  
March 6, 2012

**IDENIX PHARMACEUTICALS, INC.**  
**CONSOLIDATED BALANCE SHEETS**  
**(IN THOUSANDS, EXCEPT SHARE DATA)**

	December 31,	
	2011	2010
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 118,271	46,115
Restricted cash	411	411
Receivables from related party	1,157	840
Other current assets	3,999	2,124
Total current assets	123,838	49,490
Intangible asset, net	8,708	9,843
Property and equipment, net	4,696	7,179
Restricted cash	750	750
Other assets	3,052	2,622
Total assets	\$ 141,044	\$ 69,884
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable	\$ 2,886	\$ 2,558
Accrued expenses	8,413	11,472
Deferred revenue	36,068	2,623
Deferred revenue, related party	2,897	3,036
Other current liabilities	261	305
Total current liabilities	50,525	19,994
Other long-term liabilities	10,640	12,058
Deferred revenue, net of current portion	4,272	40,340
Deferred revenue, related party, net of current portion	24,382	28,588
Total liabilities	89,819	100,980
Commitments and contingencies (Note 15)		
Stockholders' equity (deficit):		
Common stock, \$0.001 par value; 200,000,000 and 125,000,000 shares authorized at December 31, 2011 and 2010, respectively; 107,218,463 and 73,091,514 shares issued and outstanding at December 31, 2011 and 2010, respectively	107	73
Additional paid-in capital	726,468	591,884
Accumulated other comprehensive income	365	683
Accumulated deficit	(675,715)	(623,736)
Total stockholders' equity (deficit)	51,225	(31,096)
Total liabilities and stockholders' equity (deficit)	\$ 141,044	\$ 69,884

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

**IDENIX PHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(IN THOUSANDS, EXCEPT PER SHARE DATA)**

	<u>Years Ended December 31,</u>		
	<u>2011</u>	<u>2010</u>	<u>2009</u>
Revenues:			
Collaboration revenue—related party .....	\$ 4,328	\$ 6,231	\$ 11,717
Other revenue .....	<u>2,623</u>	<u>3,991</u>	<u>899</u>
Total revenues .....	6,951	10,222	12,616
Operating expenses:			
Cost of revenues .....	2,324	2,765	2,210
Research and development .....	41,341	44,506	41,867
General and administrative .....	16,694	23,439	21,467
Restructuring charges .....	<u>—</u>	<u>2,238</u>	<u>1,506</u>
Total operating expenses .....	60,359	72,948	67,050
Loss from operations .....	(53,408)	(62,726)	(54,434)
Other income, net .....	<u>1,368</u>	<u>1,131</u>	<u>1,266</u>
Loss before income taxes .....	(52,040)	(61,595)	(53,168)
Income tax benefit (expense) .....	<u>61</u>	<u>40</u>	<u>(51)</u>
Net loss .....	<u>\$(51,979)</u>	<u>\$(61,555)</u>	<u>\$(53,219)</u>
Basic and diluted net loss per common share .....	\$ (0.57)	\$ (0.87)	\$ (0.87)
Shares used in computing basic and diluted net loss per common share .....	90,831	70,715	61,498

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

**IDENIX PHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) AND COMPREHENSIVE LOSS**  
**DECEMBER 31, 2011, 2010 and 2009**  
**(IN THOUSANDS, EXCEPT SHARE DATA)**

	<u>Common Stock</u>		<u>Additional</u>	<u>Accumulated</u>	<u>Accumulated</u>	<u>Total</u>	<u>Comprehensive</u>
	<u>Shares</u>	<u>Amount</u>	<u>Paid-in</u>	<u>Other</u>	<u>Deficit</u>	<u>Stockholders'</u>	<u>Loss</u>
			<u>Capital</u>	<u>Comprehensive</u>		<u>Equity (Deficit)</u>	
				<u>Income</u>			
Balance at December 31, 2008	56,538,859	\$ 57	\$515,883	\$ 375	\$(508,962)	\$ 7,353	
Issuance of common stock upon exercise of stock options	90,987	—	150	—	—	150	—
Issuance of common stock with related party	11,466	—	28	—	—	28	—
Issuance of common stock to GlaxoSmithKline	2,475,728	2	16,998	—	—	17,000	—
Issuance of common stock, net of offering costs	7,248,936	7	21,163	—	—	21,170	—
Share-based compensation	—	—	4,614	—	—	4,614	—
Antidilution shares contingently issuable to related party	—	—	(3,144)	—	—	(3,144)	—
Net loss	—	—	—	—	(53,219)	(53,219)	\$(53,219)
Net change in unrealized holding loss on marketable securities, net of tax	—	—	—	31	—	31	31
Cumulative translation adjustment	—	—	—	564	—	564	564
Comprehensive loss	—	—	—	—	—	—	\$(52,624)
Balance at December 31, 2009	66,365,976	\$ 66	\$555,692	\$ 970	\$(562,181)	\$ (5,453)	
Issuance of common stock upon exercise of stock options	207,346	—	494	—	—	494	—
Issuance of common stock with related party	57,520	—	145	—	—	145	—
Issuance of common stock, net of offering costs	6,460,672	7	26,259	—	—	26,266	—
Share-based compensation	—	—	6,417	—	—	6,417	—
Antidilution shares contingently issuable to related party	—	—	2,877	—	—	2,877	—
Net loss	—	—	—	—	(61,555)	(61,555)	\$(61,555)
Cumulative translation adjustment	—	—	—	(287)	—	(287)	(287)
Comprehensive loss	—	—	—	—	—	—	\$(61,842)
Balance at December 31, 2010	73,091,514	\$ 73	\$591,884	\$ 683	\$(623,736)	\$(31,096)	
Issuance of common stock upon exercise of stock options	410,723	—	1,398	—	—	1,398	—
Issuance of common stock with related party	1,857,297	2	5,260	—	—	5,262	—
Issuance of common stock, net of offering costs	31,858,929	32	120,974	—	—	121,006	—
Share-based compensation	—	—	2,423	—	—	2,423	—
Antidilution shares contingently issuable to related party	—	—	4,529	—	—	4,529	—
Net loss	—	—	—	—	(51,979)	(51,979)	\$(51,979)
Cumulative translation adjustment	—	—	—	(318)	—	(318)	(318)
Comprehensive loss	—	—	—	—	—	—	\$(52,297)
Balance at December 31, 2011	107,218,463	\$107	\$726,468	\$ 365	\$(675,715)	\$ 51,225	

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

**IDENIX PHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(IN THOUSANDS)**

	<u>Years Ended December 31,</u>		
	<u>2011</u>	<u>2010</u>	<u>2009</u>
<b>Cash flows from operating activities:</b>			
Net loss .....	\$(51,979)	\$(61,555)	\$(53,219)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization .....	4,199	4,576	5,186
Share-based compensation expense .....	2,423	6,417	4,614
Revenue adjustment for contingently issuable shares .....	3,308	1,956	(1,813)
Other .....	235	161	295
Changes in operating assets and liabilities:			
Receivables from related party .....	(317)	209	(155)
Other assets .....	(2,437)	419	2,836
Accounts payable .....	320	620	(1,927)
Accrued expenses and other current liabilities .....	(3,119)	2,581	(980)
Deferred revenue .....	(2,623)	22,545	16,146
Deferred revenue, related party .....	(3,124)	(4,387)	(6,155)
Other liabilities .....	(1,407)	(1,593)	(788)
Net cash used in operating activities .....	<u>(54,521)</u>	<u>(28,051)</u>	<u>(35,960)</u>
<b>Cash flows from investing activities:</b>			
Purchases of property and equipment .....	(837)	(727)	(671)
Sales and maturities of marketable securities .....	—	1,476	2,722
Net cash provided by (used in) investing activities .....	<u>(837)</u>	<u>749</u>	<u>2,051</u>
<b>Cash flows from financing activities:</b>			
Proceeds from exercise of common stock options .....	1,398	494	150
Proceeds from issuance of common stock to related party .....	5,262	145	28
Proceeds from issuance of common stock, net of offering costs .....	121,006	26,266	38,170
Net cash provided by financing activities .....	<u>127,666</u>	<u>26,905</u>	<u>38,348</u>
Effect of changes in exchange rates on cash and cash equivalents .....	(152)	(7)	571
Net increase (decrease) in cash and cash equivalents .....	72,156	(404)	5,010
Cash and cash equivalents at beginning of year .....	46,115	46,519	41,509
Cash and cash equivalents at end of year .....	<u>\$118,271</u>	<u>\$ 46,115</u>	<u>\$ 46,519</u>
<b>Supplemental disclosure of cash flow information:</b>			
Taxes paid .....	\$ 20	\$ 25	\$ 57
<b>Supplemental disclosure of non-cash investing and financing activities:</b>			
Change in value of shares of common stock contingently issuable or issued to related party .....	4,529	2,877	(3,144)

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

**IDENIX PHARMACEUTICALS, INC.**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**1. Business**

Idenix Pharmaceuticals, Inc., which we refer to together with our wholly owned subsidiaries as Idenix, we, us or our, is a biopharmaceutical company engaged in the discovery and development of drugs for the treatment of human viral diseases with operations in the United States and Europe. Currently, our primary research and development focus is on the treatment of patients with hepatitis C virus, or HCV, using nucleoside/nucleotide polymerase inhibitors and NS5A inhibitors.

We have incurred losses in each year since our inception and at December 31, 2011, we had an accumulated deficit of \$675.7 million. We expect to incur losses over the next several years as we continue to expand our drug discovery and development efforts. As a result of continuing losses, we may seek additional funding through a combination of public or private financing, collaborative relationships or other arrangements and we may seek a partner who will assist in the future development and commercialization of IDX184. In April 2011, we issued approximately 21.1 million shares of our common stock pursuant to the September 2008 shelf registration statement and approximately 1.8 million shares of our common stock to Novartis Pharma AG, or Novartis, pursuant to a private placement agreement. The net proceeds of both transactions were \$60.2 million. In October 2011, we filed a universal shelf registration statement with the Securities and Exchange Commission, or SEC, which will allow us to offer and sell from time to time up to a maximum of \$150.0 million of shares of common stock, at prices and terms to be determined at the time of sale. Pursuant to this shelf registration statement, in November 2011, we issued approximately 10.8 million shares of our common stock pursuant to an underwritten offering and received \$65.8 million in net proceeds. Any financing requiring the issuance of additional shares of capital stock must first be approved by Novartis so long as Novartis continues to own at least 19.4% of our voting stock. Additional funding may not be available to us or, if available, may not be on terms favorable to us. Further, any additional equity financing may be dilutive to stockholders, other than Novartis, which has the right to maintain its current ownership level. As of February 21, 2012, Novartis owned approximately 31% of our outstanding common stock.

We believe that our current cash, cash equivalents and the expected royalty payments associated with product sales of Tyzeka<sup>®</sup>/Sebivo<sup>®</sup> will be sufficient to sustain operations for at least the next 12 months from December 31, 2011. If we are unable to obtain adequate financing on a timely basis, we could be required to delay, reduce or eliminate one or more of our drug development programs, enter into new collaborative, strategic alliances or licensing arrangements that may not be favorable to us and reduce the number of our employees. More generally, if we are unable to obtain adequate funding, we may be required to scale back, suspend or terminate our business operations.

We are subject to risks common to companies in the biopharmaceutical industry including, but not limited to, the successful development of products, clinical trial uncertainty, regulatory approval, fluctuations in operating results and financial risks, potential need for additional funding, protection of proprietary technology and patent risks, compliance with government regulations, dependence on key personnel and collaboration partners, competition, technological and medical risks and management of growth.

**2. Summary of Significant Accounting Policies**

Significant accounting policies applied by us in the preparation of our consolidated financial statements were as follows:

***Principles of Consolidation***

The accompanying consolidated financial statements reflect the operations of Idenix Pharmaceuticals, Inc. and our wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

**IDENIX PHARMACEUTICALS, INC.**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED**

***Recent Accounting Pronouncements***

In June, 2011, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update No. 2011-5, *Presentation of Comprehensive Income*. The objective of this amendment is to improve the comparability, consistency and transparency of financial reporting and to increase the prominence of items reported in other comprehensive income. This guidance is effective for fiscal years beginning after December 15, 2011 and requires retrospective application to all periods presented. We do not expect that this guidance will have any material effect on our consolidated financial statements.

***Use of Estimates and Assumptions***

The preparation of consolidated financial statements in accordance with generally accepted accounting principles requires management to make estimates and judgments that may affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, judgments and methodologies, including those related to revenue recognition, our collaborative relationships, clinical trial expenses, impairment and amortization of long-lived assets including intangible assets, share-based compensation, income taxes including the valuation allowance for deferred tax assets, contingencies, litigation and restructuring charges. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions.

***Cash and Cash Equivalents***

We consider all highly liquid investments purchased with a maturity date of 90 days or less at the date of purchase to be cash equivalents.

In connection with certain of our operating lease commitments (Note 15), we issued letters of credit collateralized by cash deposits that are classified as restricted cash on the consolidated balance sheets. Restricted cash amounts have been classified as current or non-current based on the expected or contractual release date of the restrictions.

***Concentration of Credit Risk***

Financial instruments that potentially subject us to concentrations of credit risk primarily consist of cash and cash equivalents, marketable securities and receivables from related party. We invest our excess cash, cash equivalents and marketable securities in interest bearing accounts at major United States financial institutions. Management mitigates credit risk by limiting the investment type and maturity to securities that preserve capital, maintain liquidity and have a high credit quality.

At December 31, 2011 and 2010, all of our receivables from related party were due from Novartis. The receivables from related party balances were royalties associated with the sales of Tyzeka<sup>®</sup>/Sebivo<sup>®</sup> under the collaborative agreement with Novartis in the normal course of business. Revenue from Novartis represented the majority of our revenues for the years ended December 31, 2011, 2010 and 2009.

***Marketable Securities***

We classify our marketable securities with remaining final maturities of 12 months or less based on the purchase date as current marketable securities, exclusive of those categorized as cash equivalents. We classify our marketable securities with remaining final maturities greater than 12 months as non-current marketable securities to the extent we do not expect to be required to liquidate them before maturity. We classify all of our marketable debt securities as available-for-sale. We report available-for-sale investments at fair value as of each balance sheet date and include any unrealized gains and, to the extent deemed temporary, unrealized losses in other comprehensive loss. Realized gains and losses are determined using the specific identification method and are included in other income, net in our consolidated financial statements.

**IDENIX PHARMACEUTICALS, INC.**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED**

Investments are considered to be impaired when a decline in fair value below cost basis is determined to be other-than-temporary. We evaluate whether a decline in fair value below cost basis is other-than-temporary using available evidence regarding our investments. In the event that the cost basis of a security significantly exceeds its fair value, we evaluate, among other factors, the duration of the period that, and extent to which, the fair value is less than cost basis, the financial health of and business outlook for the issuer, including industry and sector performance, and operational and financing cash flow factors, overall market conditions and trends, our intent to sell the investment and if it is more likely than not that we would be required to sell the investment before its anticipated recovery. Once a decline in fair value is determined to be other-than-temporary, a write-down is recorded in the consolidated statement of operations and a new cost basis in the security is established.

***Fair Value Measurements***

Our financial statements include assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2011 and 2010. Fair values determined by Level 1 inputs utilize observable data such as quoted prices in active markets. Fair values determined by Level 2 inputs utilize data points other than quoted prices in active markets that are observable either directly or indirectly. Fair values determined by Level 3 inputs utilize unobservable data points in which there is little or no market data, which require the reporting entity to develop its own assumptions.

As of December 31, 2011 and 2010, all of our investments were in government agency and treasury money market instruments. Our money market investments have calculated net asset values and are therefore classified as Level 2. There were no level 3 assets held at fair value at December 31, 2011 or 2010 and there were no gross unrealized gains or losses for the years ended December 31, 2011 and 2010.

***Intangible Asset***

Our intangible asset relates to a settlement agreement entered into by and among us along with our former chief executive officer in his individual capacity, the Universite Montpellier II, or the University of Montpellier, Le Centre National de la Recherche Scientifique, or CNRS, the Board of Trustees of the University of Alabama on behalf of the University of Alabama at Birmingham, or UAB, the University of Alabama at Birmingham Research Foundation, or UABRF, and Emory University as described more fully in Note 15. The settlement agreement, entered into in July 2008 and effective as of June 1, 2008, includes a full release of all claims, contractual or otherwise, by the parties.

Pursuant to the settlement agreement, we paid UABRF (on behalf of UAB and Emory University) a \$4.0 million upfront payment and will make additional payments to UABRF equal to 20% of all royalty payments received by us from Novartis based on worldwide sales of telbivudine, subject to minimum payment obligations aggregating \$11.0 million. We are amortizing \$15.0 million related to this settlement payment to UAB and related entities over the life of the agreement, or August 2019.

The following table is a rollforward of our intangible asset as shown in our consolidated balance sheets:

	<b>December 31,</b>	
	<b>2011</b>	<b>2010</b>
	<b>(In Thousands)</b>	
Beginning balance .....	\$ 9,843	\$ 11,069
Amortization expense .....	(1,135)	(1,226)
Ending balance .....	<b>\$ 8,708</b>	<b>\$ 9,843</b>

**IDENIX PHARMACEUTICALS, INC.**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED**

As of December 31, 2011, accumulated amortization was \$6.3 million. Amortization expense for this asset is anticipated to be \$1.1 million per year through December 31, 2016 and \$3.2 million through the remaining life of the agreement.

***Property and Equipment***

Property and equipment are recorded at cost. Depreciation is calculated using the straight-line method over the estimated useful life of each of the assets, except for leasehold improvements which are amortized using the straight-line method over the shorter of the asset life or the related lease term. Upon disposal of property and equipment, the related cost and accumulated depreciation is removed from the asset accounts and any resulting gain or loss is included in the consolidated statements of operations. Repair and maintenance costs are expensed as incurred.

***Impairment of Long-Lived Assets***

We evaluate the recoverability of our property and equipment and other long-lived assets when circumstances indicate that an event of impairment may have occurred in accordance with FASB guidance. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written-down to their estimated fair values. Long-lived assets and certain identifiable intangible assets to be disposed of are reported at the lower of carrying amount or fair value less cost to sell.

No significant impairment charges were recognized for the years ended December 31, 2011, 2010 and 2009.

***Revenue Recognition***

Revenue is recognized in accordance with the SEC Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*, or SAB No. 101, as amended by SEC Staff Accounting Bulletin No. 104, *Revenue Recognition*, and, for revenue arrangements entered into after June 30, 2003, in accordance with the revenue recognition guidance of the FASB. For multiple-element arrangements entered into or materially modified after January 1, 2011, we recognize revenue under Accounting Standard Update No. 2009-13, *Multiple-Deliverable Revenue Arrangements*, or ASU No. 2009-13. We record revenue provided that there is persuasive evidence that an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collectability is reasonably assured.

Our revenues are generated primarily through collaborative research, development and/or commercialization agreements. The terms of these agreements typically include payments to us for non-refundable license fees, milestones, collaborative research and development funding and royalties received from our collaboration partners.

***Non-Refundable License Fee Payments***

Where we have continuing performance obligations under the terms of a collaborative arrangement, non-refundable license fees are recognized as revenue over the expected development period as we complete our performance obligations. When our level of effort is relatively constant over the performance period or no other performance pattern is evident, the revenue is recognized on a straight-line basis. The determination of the performance period involves judgment on the part of management. Payments received from collaboration partners for research and development efforts by us are recognized as revenue over the contract term as the related costs are incurred, net of any amounts due to the collaboration partner for costs incurred during the period for shared development costs.

**IDENIX PHARMACEUTICALS, INC.**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED**

Where we have no continuing involvement or obligations under a collaborative arrangement, we record non-refundable license fee revenue when we have a contractual right to receive the payment, in accordance with the terms of the license agreement.

*Milestone Payments*

Revenue is recognized for payments that are contingent upon the achievement of a milestone in its entirety, in the period in which the milestone is achieved, only if the milestone is substantive and meets all of the following criteria: a) performance consideration earned by achieving the milestone be commensurate with either performance to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from performance to achieve the milestone; b) it relates to past performance; and c) the payment is reasonable relative to all deliverables and payment terms in the arrangement.

*Collaboration Revenue — Related Party*

We entered into a collaboration with Novartis relating to the worldwide development and commercialization of our drug candidates in May 2003, which we refer to as the development and commercialization agreement. Under this arrangement, we have received non-refundable license fees, milestones, collaborative research and development funding and royalties. This arrangement has several joint committees in which we and Novartis participate. We participate in these committees as a means to govern or protect our interests. The committees span the period from early development through commercialization of drug candidates licensed by Novartis. As a result of applying the provisions of SAB No. 101, which was the applicable revenue guidance at the time the collaboration was entered into, our revenue recognition policy attributes revenue to the development period of the drug candidates licensed under the development and commercialization agreement. We have not attributed revenue to our involvement in the committees following the commercialization of the licensed products as we have determined that our participation on the committees, as such participation relates to the commercialization of drug candidates, is protective. Our determination is based in part on the fact that our expertise is, and has been, the discovery and development of drugs for the treatment of human viral diseases. Novartis, on the other hand, has the considerable commercialization expertise and infrastructure necessary for the commercialization of such drug candidates. Accordingly, we believe our obligation post commercialization is inconsequential.

We recognize non-refundable payments over the performance period of our continuing obligations. This period is estimated based on current judgments related to the product development timeline of our licensed drug candidates and is currently estimated to be through May 2021. This policy is described more fully in Note 3.

Upon the grant of options and stock awards under stock incentive plans, with the exception of the 1998 equity incentive plan, as amended, or the 1998 plan, the fair value of our common stock that would be issuable to Novartis, less the exercise price, is recorded as a reduction of the non-refundable payments associated with the Novartis collaboration. The amount is attributed proportionately between cumulative revenue recognized through the current date and the remaining amount of deferred revenue. These amounts will be adjusted through the date that Novartis elects to purchase the shares to maintain its percentage ownership based upon changes in the value of our common stock and in Novartis' percentage ownership. This policy is described more fully in Note 3.

Royalty revenue consists of revenue earned under our license agreement with Novartis for sales of Tyzeka®/Sebivo®, which is recognized when reported from Novartis. Royalty revenue is equal to a percentage of Tyzeka®/Sebivo® net sales, with such percentage increasing according to specified tiers of net sales. The royalty percentage varies based on the specified territory and the aggregate dollar amount of net sales.

**IDENIX PHARMACEUTICALS, INC.**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED**

*Other Revenue*

In February 2009, we entered into a license agreement with ViiV Healthcare Company, or ViiV, which we refer to as the ViiV license agreement. Under the ViiV license agreement, we granted ViiV an exclusive worldwide license to develop, manufacture and commercialize our non-nucleoside reverse transcriptase inhibitor, or NNRTI, compounds, including IDX899, now known as '761, for the treatment of human diseases, including human immunodeficiency virus type-1, or HIV, and acquired immune deficiency syndrome, or AIDS. This agreement had performance obligations, including joint committee participation and ViiV's right to license other NNRTI compounds that we may develop in the future, that we have assessed under the FASB guidance related to multiple element arrangements, prior to the implantation of ASU No. 2009-13. We concluded that this arrangement should be accounted for as a single unit of accounting and recognized as revenue using the contingency adjusted performance method. Under this agreement, we received a non-refundable license fee payment and milestone payments from ViiV. These milestone payments did not meet our revenue recognition criteria for immediate recognition. The non-refundable license fee payment and milestone payments received under the ViiV license agreement were recorded as deferred revenue and were being recognized as revenue over the life of the agreement, which was estimated to be 17 years. A cumulative catch-up was recognized for the period from the execution of the license agreement in March 2009 through the period in which the milestone payments were received.

In February 2011, ViiV informed us that the FDA placed '761 on clinical hold. As a result of further evaluation, ViiV determined that it would not continue development of '761 or develop any other compound licensed under the ViiV license agreement. In December 2011, ViiV notified us that it would terminate the ViiV license agreement effective March 15, 2012. Upon termination, ViiV will relinquish all rights it has in the intellectual property licensed from us and grants us an exclusive, perpetual and irrevocable license to any intellectual property relating to the licensed products it may have developed during the term of the license agreement. As a result of the termination of the ViiV license agreement, we will not receive any additional milestone or royalty payments under the ViiV license agreement. Upon termination, we will have no future obligations pursuant to the license agreement and the deferred revenue balance of \$36.1 million at December 31, 2011 associated with the ViiV license agreement is expected to be recognized as other collaboration revenue in the first quarter of 2012.

Government research grants that provide for payments to us for work performed are recognized as revenue when the related expense is incurred and we have obtained governmental approval to use the grant funds for these expenses.

*Deferred Revenue*

In March 2003, we entered into a final settlement agreement with Sumitomo Pharmaceuticals Co., Ltd., or Sumitomo, under which the rights to develop and commercialize telbivudine in Japan, China, South Korea and Taiwan previously granted to Sumitomo were returned to us. This agreement with Sumitomo became effective upon consummation of our collaboration with Novartis in May 2003. We repurchased these product rights for \$5.0 million. The repurchase of these rights resulted in a \$4.6 million reversal of revenue that we previously recognized under our original arrangements with Sumitomo. We recorded the remaining amount of \$0.4 million as a reduction of deferred revenue. We have also included \$4.3 million as deferred revenue, net of current portion in our consolidated balance sheets at December 31, 2011 and 2010 representing amounts received from Sumitomo that we have not included in our revenue to date. We are required to pay an additional \$5.0 million to Sumitomo if and when the first commercial sale of telbivudine occurs in Japan. This payment will be recorded first as a reduction of the remaining \$4.3 million of deferred revenue, with the excess recorded as an expense. As part of the development and commercialization agreement, Novartis will reimburse us for any such payment made to Sumitomo. If regulatory approval is not received for telbivudine in Japan, we would have no further obligations under the settlement agreement with Sumitomo and, therefore, the \$4.3 million of remaining deferred revenue would be recognized as revenue at that time.

**IDENIX PHARMACEUTICALS, INC.**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED**

***Deferred Expenses***

We have entered into cooperative agreements in which we have co-developed or acquired licenses for certain of our antiviral technology from third-parties. These cooperative agreements generally require royalty or other payments to be paid by us to the co-developers or licensors when we out-license rights to or commercialize these certain technologies to our collaboration partners. These payments to the co-developers or licensors are deferred and are recognized as expense over the same period that we recognize the related revenue under our collaborative arrangements. These amounts are recognized as other assets in our consolidated balance sheets.

***Research and Development Expenses***

All costs associated with internal research and development and external research and development services, including preclinical and clinical trial studies are expensed as incurred. Research and development expenses include costs for salaries, employee benefits, subcontractors, facility related expenses, depreciation, license fees and share-based compensation.

***Patents***

All costs to secure and defend patents are expensed as incurred.

***Share-Based Compensation***

We account for share-based compensation for employees and directors using a fair value based method that results in expense being recognized in our financial statements. We make assumptions related to the expected volatility of our stock and the expected term of the awards granted in order to value and expense our share-based compensation. The expected option term and expected volatility are determined by examining the expected option term and volatility of our own stock as well as those of similarly sized biotechnology companies. We review these assumptions periodically. The amounts recognized for share-based compensation expense could vary depending upon changes in these assumptions.

Share-based compensation expense is recognized based on awards ultimately expected to vest and should be reduced for estimated forfeitures. During 2011, 2010 and 2009, because substantially all of our stock option grants vest monthly, no forfeiture assumption was applied.

For purposes of our consolidated statements of operations, we allocate share-based compensation to expense categories based on the nature of the service provided by the recipients of the stock option grants. We expect to continue to grant options to purchase common stock in the future.

***Foreign Currency***

The functional currencies of our foreign subsidiaries are the local currency or the U.S. dollar. When the functional currency of the foreign subsidiary is the local currency, assets and liabilities of the foreign subsidiary are translated into U.S. dollars at the rates of exchange in effect at the end of the accounting period. Income and expense items are translated at the average exchange rates for the period. Net gains and losses resulting from foreign currency translation are included in other comprehensive loss which is a separate component of stockholders' equity (deficit).

When the functional currency of the foreign subsidiary is the U.S. dollar, a combination of current and historical exchange rates are used in remeasuring the local currency transactions of the foreign subsidiary. Nonmonetary assets and liabilities, including equity, are remeasured using historical exchange rates. Monetary

**IDENIX PHARMACEUTICALS, INC.**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED**

assets and liabilities are remeasured at current exchange rates. Income and expense amounts are remeasured using the average exchange rate for the period. Net realized gains and losses from foreign currency transactions are included in the consolidated statements of operations. Gains and losses resulting from foreign currency remeasurements are included in the consolidated statements of operations.

***Income Taxes***

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

For uncertain tax positions that meet “a more likely than not” threshold, we recognize the benefit of uncertain tax positions in our consolidated financial statements.

***Comprehensive Loss***

Comprehensive loss is comprised of net loss and certain changes in stockholders’ equity (deficit) that are excluded from net loss. We include foreign currency translation adjustments for subsidiaries in which the functional currency is the local currency and unrealized gains and losses on marketable securities in other comprehensive loss. The consolidated statements of stockholders’ equity (deficit) and comprehensive loss reflect total comprehensive loss for the years ended December 31, 2011, 2010 and 2009.

***Net Loss per Common Share***

Basic net loss per common share is computed by dividing net loss available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted net loss per common share is computed by dividing net loss available to common stockholders by the weighted average number of common shares and other potential common shares then outstanding. Potential common shares consist of common shares issuable upon the assumed exercise of outstanding stock options (using the treasury stock method), issuance of contingently issuable shares subject to Novartis’ stock subscription rights (Note 3) and restricted stock awards.

***Segment Reporting***

Our management, which uses consolidated financial information in determining how to allocate resources and assess performance, has determined that it operates in only one reportable segment.

**3. Novartis Relationship**

***Overview***

In May 2003, we entered into a collaboration with Novartis relating to the worldwide development and commercialization of our drug candidates. In May 2003, Novartis also purchased approximately 54% of our common stock. Since this date, Novartis has had the ability to exercise control over our strategic direction, research and development activities and other material business decisions. As a result of our collaboration with Novartis, transactions between us and Novartis are considered related party transactions.

Pursuant to the development and commercialization agreement, we have granted Novartis the option to license any of our development-stage drug candidates, so long as Novartis maintains at least 30% ownership of

**IDENIX PHARMACEUTICALS, INC.**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED**

our common stock. If Novartis exercises this option, financial terms will be based upon certain contractual obligations and future negotiations. Novartis may exercise this option generally after demonstration of activity and safety in a proof-of-concept clinical trial. If Novartis licenses a drug candidate, it is obligated to fund a portion of the development expenses that we incur in accordance with development plans agreed upon by us and Novartis. Under the development and commercialization agreement, we have granted Novartis an exclusive worldwide license to market and sell drug candidates that Novartis chooses to license from us. The commercialization rights under the development and commercialization agreement also include our right to co-promote or co-market all licensed products in the United States, United Kingdom, France, Germany, Italy and Spain. Under the development and commercialization agreement, we granted Novartis an exclusive worldwide license to market and sell Tyzeka<sup>®</sup>/Sebivo<sup>®</sup>, valtorcitabine and valopicitabine.

In 2003, Novartis licensed telbivudine from us under the development and commercialization agreement and we co-developed and co-launched Tyzeka<sup>®</sup>/Sebivo<sup>®</sup> for the treatment of HBV. In September 2007, we amended the development and commercialization agreement and we transferred to Novartis our worldwide development, commercialization, manufacturing rights and obligations pertaining to telbivudine in exchange for royalties based on net product sales of Tyzeka<sup>®</sup>/Sebivo<sup>®</sup> from Novartis. The royalty percentage increases according to specified tiers of net sales and the percentage varies based on specified territories and the aggregate dollar amounts of net sales. We recognized \$4.5 million, \$3.8 million and \$3.7 million as royalty revenue from Novartis' sales of Tyzeka<sup>®</sup>/Sebivo<sup>®</sup> during the years ended December 31, 2011, 2010 and 2009, respectively.

In October 2009, Novartis waived its right to license IDX184, a nucleotide prodrug for the treatment of HCV. As a result, we retain the worldwide rights to develop, manufacture, commercialize and license IDX184. We may seek a partner who will assist in the future development and commercialization of this drug candidate.

To date, we have received \$117.2 million of non-refundable payments from Novartis under the development and commercialization agreement that have been recorded as deferred revenue. The \$117.2 million received from Novartis consisted of a \$25.0 million license fee for valopicitabine, a \$75.0 million license fee for telbivudine (Tyzeka<sup>®</sup>/Sebivo<sup>®</sup>) and valtorcitabine, offset by \$0.1 million in interest costs, a \$5.0 million reimbursement for reacquiring product rights from Sumitomo to develop and commercialize Sebivo<sup>®</sup> in certain markets in Asia, \$2.3 million in reimbursement costs associated with the development of valopicitabine prior to Novartis licensing valopicitabine and a \$10.0 million milestone payment for the regulatory approval of Sebivo<sup>®</sup> in the European Union. These payments are being recognized over the development period of the licensed drug candidates, which represents the period of our continuing obligations. In the second quarter of 2010, we adjusted the period over which we amortize the deferred payments to be through May 2021 based on current judgments related to the product development timeline of our licensed drug candidates. We review our assessment and judgment on a quarterly basis with respect to the expected duration of the development period of our licensed drug candidates. If the estimated performance period changes, we will adjust the periodic revenue that is being recognized and will record the remaining unrecognized non-refundable payments over the remaining development period during which our performance obligations will be completed. Significant judgments and estimates are involved in determining the estimated development period and different assumptions could yield materially different results. Related to the deferred revenue, we recognized \$3.1 million, \$4.4 million and \$6.2 million as revenue during the years ended December 31, 2011, 2010 and 2009, respectively. These amounts are impacted by Novartis' stock subscription rights described below.

As mentioned above, in addition to the collaboration, in May 2003, Novartis purchased approximately 54% of our then outstanding capital stock from our stockholders. The stockholders received \$255.0 million in cash from Novartis with an additional aggregate amount of up to \$357.0 million contingently payable to these stockholders if we achieve predetermined development milestones relating to specific HCV drug candidates. As of February 21, 2012, Novartis owned approximately 31% of our outstanding stock.

**IDENIX PHARMACEUTICALS, INC.**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED**

***Stockholders' Agreement***

In connection with Novartis' purchase of stock from our stockholders, we, Novartis and substantially all of our stockholders at that time entered into a stockholders' agreement, which we refer to as the stockholders' agreement. The stockholders' agreement was amended and restated in 2004 and in April 2011 in connection with our underwritten offerings of our common stock. The stockholders' agreement, as amended, provides, among other things, that we will use our reasonable best efforts to nominate for election as a director at least two designees of Novartis for so long as Novartis and its affiliates own at least 30% of our voting stock and that we will use our reasonable best efforts to nominate for election at least one designee of Novartis for so long as Novartis and its affiliates own at least 19.4% of our voting stock. As long as Novartis and its affiliates continue to own at least 19.4% of our voting stock, Novartis will have approval rights over a number of corporate actions that we may take, including the authorization or issuance of additional shares of capital stock and significant acquisitions and dispositions.

***Novartis' Stock Subscription Rights***

Under our stock purchase agreement with Novartis, which we refer to as the stock purchase agreement, Novartis has the right to purchase, at par value of \$0.001 per share, such number of shares as is required to maintain its percentage ownership of our voting stock if we issue shares of capital stock in connection with the acquisition or in-licensing of technology through the issuance of up to 5% of our stock in any 24-month period. These purchase rights of Novartis remain in effect until the earlier of: a) the date that Novartis and its affiliates own less than 19.4% of our voting stock; or b) the date that Novartis becomes obligated to make the additional contingent payments of \$357.0 million to holders of our stock who sold shares to Novartis on May 8, 2003.

In addition to the right to purchase shares of our stock at par value as described above, if we issue any shares of our capital stock, other than in certain situations, Novartis has the right to purchase such number of shares required to maintain its percentage ownership of our voting stock for the same consideration per share paid by others acquiring our stock. Any financing requiring the issuance of additional shares of capital stock must first be approved by Novartis so long as Novartis continues to own at least 19.4% of our voting stock. We received Novartis' approval for the following offerings in 2009, 2010 and 2011:

- in May 2009, we received approval from Novartis to issue capital shares pursuant to financing transactions under a shelf registration statement filed in September 2008 with the SEC so long as the issuance of shares did not reduce Novartis' interest in Idenix below 43%. In August 2009, we issued approximately 7.3 million shares pursuant to an underwritten offering and received \$21.2 million in net proceeds. Additionally, pursuant to this shelf registration statement, in April 2010, we issued approximately 6.5 million shares of our common stock pursuant to an underwritten offering and received \$26.3 million in net proceeds. Novartis did not participate in these offerings;
- in April 2011, we received approval from Novartis to issue capital shares so long as the issuance of shares did not reduce Novartis' interest in Idenix below 30%. In April 2011, we issued approximately 21.1 million shares of our common stock pursuant to the September 2008 shelf registration statement and approximately 1.8 million shares of our common stock to Novartis pursuant to a private placement agreement. The net proceeds of both transactions were \$60.2 million. Upon completion of this offering, we fully utilized the shelf registration statement and Novartis owned approximately 35% of our outstanding common stock. In conjunction with the issuance of common stock in April 2011, we amended the collaboration with Novartis to provide that: a) Novartis retains the exclusive option to obtain rights to drug candidates developed by us so long as Novartis maintains ownership of at least 30% of our common stock, rather than ownership of at least 40% as was the case prior to the amendment; b) we will use reasonable best efforts to nominate for election as directors at least two

**IDENIX PHARMACEUTICALS, INC.**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED**

designees of Novartis so long as Novartis maintains ownership of at least 30% of our common stock, rather than ownership of at least 35% as was the case prior to the amendment; and c) Novartis' consent is required for the selection and appointment of our chief financial officer so long as Novartis owns at least 30% of our common stock, rather than ownership of at least 40% as was the case prior to the amendment; and

- in November 2011, we received approval from Novartis to issue capital shares so long as the issuance of shares did not reduce Novartis' interest in Idenix below 31%. In October 2011, we filed a universal shelf registration statement with the SEC which will allow us to offer and sell from time to time up to a maximum of \$150.0 million of shares of common stock, at prices and terms to be determined at the time of sale. Pursuant to this shelf registration statement, in November 2011, we issued approximately 10.8 million shares of our common stock pursuant to an underwritten offering and received \$65.8 million in net proceeds. Novartis did not participate in this offering. As of February 21, 2012, Novartis owned approximately 31% of our outstanding common stock.

Upon the grant of options and stock awards under stock incentive plans, with the exception of the 1998 plan, the fair value of our common stock that would be issuable to Novartis, less the exercise price, is recorded as a reduction of the non-refundable payments associated with the Novartis collaboration. The amount is attributed proportionately between cumulative revenue recognized through the current date and the remaining amount of deferred revenue. These amounts will be adjusted through the date that Novartis elects to purchase the shares to maintain its percentage ownership based upon changes in the value of our common stock and in Novartis' percentage ownership.

In connection with the closing of our initial public offering in July 2004, Novartis terminated a common stock subscription right with respect to approximately 1.4 million shares of common stock issuable by us as a result of the exercise of stock options granted after May 8, 2003 pursuant to the 1998 plan. In exchange for Novartis' termination of such right, we issued 1.1 million shares of common stock to Novartis for a purchase price of \$0.001 per share. The fair value of these shares was determined to be \$15.4 million at the time of issuance. As a result of the issuance of these shares, Novartis' rights to purchase additional shares as a result of future option grants and stock issuances under the 1998 plan were terminated and no additional adjustments to revenue and deferred revenue will be required. Prior to the termination of the stock subscription rights under the 1998 plan, as we granted options that were subject to this stock subscription right, the fair value of our common stock that would be issuable to Novartis, less par value, was recorded as an adjustment of the non-refundable payments received from Novartis. We remain subject to potential revenue adjustments with respect to grants of options and stock awards under our stock incentive plans other than the 1998 plan.

As of December 31, 2011, the aggregate impact of Novartis' stock subscription rights has reduced the non-refundable payments by \$22.8 million, which has been recorded as additional paid-in capital. Of this amount, \$5.8 million has been recorded as a reduction of deferred revenue with the remaining amount of \$17.0 million as a reduction of license fee revenue. For the year ended December 31, 2011, the impact of Novartis' stock subscription rights increased additional paid-in capital by \$4.5 million, decreased deferred revenue by \$1.2 million and decreased license fee revenue by \$3.3 million. For the year ended December 31, 2010, the impact of Novartis' stock subscription rights increased additional paid-in capital by \$2.9 million, decreased deferred revenue by \$0.9 million and decreased license fee revenue by \$2.0 million. For the year ended December 31, 2009, the impact of Novartis' stock subscription rights reduced additional paid-in capital by \$3.1 million, increased deferred revenue by \$1.3 million and increased license fee revenue by \$1.8 million.

**IDENIX PHARMACEUTICALS, INC.**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED**

***Manufacturing and Supply Agreement***

Under the master manufacturing and supply agreement, dated May 8, 2003, with Novartis, which we refer to as the manufacturing and supply agreement, we appointed Novartis to manufacture or have manufactured the clinical supply of the active pharmaceutical ingredient, or API, for each drug candidate licensed under the development and commercialization agreement and certain other drug candidates. The cost of the clinical supply will be treated as a development expense, allocated between us and Novartis in accordance with the agreement. We have the ability to appoint Novartis or a third-party to manufacture the commercial supply of the API based on a competitive bid process under which Novartis has the right to match the best third-party bid. Novartis will perform the finishing and packaging of the API into the final form for sale.

***Product Sales Arrangement***

In connection with the drug candidates that Novartis licenses from us, with the exception of Tyzeka®/Sebivo®, we have retained the right to co-promote or co-market in the United States, United Kingdom, France, Germany, Italy and Spain. In the United States, we would act as the lead commercial party and record revenue from product sales and share equally the net benefit from co-promotion from the date of product launch. In the United Kingdom, France, Germany, Italy and Spain, Novartis would act as the lead commercial party, record revenue from product sales and would share with us the net benefit from co-promotion and co-marketing. The net benefit is defined as net product sales minus related cost of sales. The amount of the net benefit that would be shared with us would start at 15% for the first 12-month period following the date of launch, increasing to 30% for the second 12-month period following the date of launch and 50% thereafter. In other countries, we would effectively sell products to Novartis for their further sale to third-parties. Novartis would pay us for such products at a price that is determined under the terms of our manufacturing and supply agreement with Novartis and we would receive a royalty payment from Novartis on net product sales.

**4. Net Loss per Common Share**

The following sets forth the computation of basic and diluted net loss per common share:

	Years Ended December 31,		
	2011	2010	2009
	(In Thousands, Except per Share Data)		
Basic and diluted net loss per common share:			
Net loss . . . . .	\$(51,979)	\$(61,555)	\$(53,219)
Basic and diluted weighted average number of common shares outstanding . . . . .	90,831	70,715	61,498
Basic and diluted net loss per common share . . . . .	\$ (0.57)	\$ (0.87)	\$ (0.87)

The following common shares were excluded from the calculation of diluted net loss per common share because their effect was antidilutive:

	Years Ended December 31,		
	2011	2010	2009
	(In Thousands)		
Options . . . . .	7,579	7,032	5,560
Contingently issuable shares to related party . . . . .	2,377	1,735	—

**IDENIX PHARMACEUTICALS, INC.**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED**

**5. Marketable Securities and Fair Value Measurements**

At December 31, 2011 and December 31, 2010, we had \$102.6 million and \$17.7 million, respectively, in money market funds that were classified as Level 2 fair value and included as part of cash and cash equivalents in our condensed consolidated balance sheets. There were no gross unrealized gains or losses for the years ended December 31, 2011 or 2010.

The following table is a rollforward of our auction rate investments (described below) whose fair value was determined on a recurring basis using significant unobservable inputs (Level 3) at December 31, 2010 (no Level 3 assets were held at December 31, 2011):

	<b>December 31, 2010</b>
	<b>(In Thousands)</b>
Beginning balance .....	\$ 1,584
Purchases, sales and settlements .....	(1,476)
Total realized/unrealized losses recognized in earnings .....	(108)
Ending balance .....	\$ —

In 2010, we held one investment in an auction rate security with an estimated value of \$1.6 million, which did not actively trade and therefore was classified as Level 3. We determined the fair value of this security based on a cash flow model which incorporated a three-year discount period, a 1.97% per annum coupon rate, a 0.519% per coupon payment discount rate (which integrated a liquidity discount rate, 3-year swap forward rate and credit spread), as well as coupon history. We also considered in determining the fair value that our holding in the auction rate security was backed by the United States government and that the security was rated A3 during 2010. During 2010, we sold the security for proceeds of \$1.5 million and recognized a realized loss of \$0.1 million.

**6. Property and Equipment, Net**

Property and equipment consisted of the following:

	<b>Estimated Useful Life (Years)</b>	<b>December 31,</b>	
		<b>2011</b>	<b>2010</b>
<b>(In Thousands)</b>			
Scientific equipment .....	7	\$ 6,584	\$ 6,740
Computer equipment and software .....	2	3,662	4,021
Enterprise software .....	5	2,599	2,599
Office furniture and equipment .....	5 -7	727	1,386
Leasehold improvements .....	*	7,994	10,287
Construction-in-progress .....		—	94
		21,566	25,127
Less—accumulated depreciation .....		(16,870)	(17,948)
		\$ 4,696	\$ 7,179

\* Shorter of asset life or lease term

**IDENIX PHARMACEUTICALS, INC.**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED**

Depreciation and amortization expense related to property and equipment for the years ended December 31, 2011, 2010 and 2009 was \$3.1 million, \$3.4 million and \$3.9 million, respectively.

The decrease of \$2.3 million in leasehold improvements in the table above was related to the disposal of assets resulting from the termination of an operating lease for office space in Cambridge, MA during 2011. There were no significant charges related to the termination of this lease.

**7. Accrued Expenses**

Accrued expenses consisted of the following:

	December 31,	
	2011	2010
	(In Thousands)	
Research and development contract costs . . . . .	\$2,425	\$ 1,948
Payroll and benefits . . . . .	3,267	3,232
Professional fees . . . . .	592	797
Short-term portion of accrued settlement payment . . . . .	874	1,086
Severance payments . . . . .	—	2,297
Other . . . . .	1,255	2,112
	\$8,413	\$11,472

On October 28, 2010, our former chief executive officer resigned from his positions as chairman of the board of directors, president and chief executive officer and received severance payments of approximately \$2.3 million, which were paid in 2011.

**8. Restructuring Charges**

During the first quarter of 2010, we restructured our operations at our research facility in Montpellier, France to reduce its workforce by approximately 17 positions in connection with our ongoing cost saving initiatives. In the first quarter of 2010, we recorded charges of \$2.2 million for employee severance costs related to the restructuring of our Montpellier facility together with charges related to an earlier reduction of our United States workforce by 13 positions in January 2010. All significant severance amounts were paid in 2010. There were no restructuring charges in 2011.

**9. Equity Incentive Plans and Share-Based Compensation**

In May 1998, we adopted the 1998 plan, which provides for the grant of incentive stock options, nonqualified stock options, stock awards and stock appreciation rights. We initially reserved approximately 1.5 million shares of common stock for issuance pursuant to the 1998 plan. We subsequently amended the 1998 plan and reserved an additional 3.6 million shares of common stock for issuance under the 1998 plan. No stock options, stock awards or stock appreciation rights may be granted under the 1998 plan after June 29, 2008.

In July 2004, we adopted the 2004 stock incentive plan, or the 2004 plan. The 2004 plan provided for the grant of incentive stock options, non-qualified stock options, stock appreciation rights, performance share awards and restricted and unrestricted stock awards for the purchase of an aggregate of 0.8 million shares of common stock.

**IDENIX PHARMACEUTICALS, INC.**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED**

In June 2005, we adopted the 2005 stock incentive plan, or the 2005 plan. The 2005 plan allows for the granting of incentive stock options, non-qualified stock options, stock appreciation rights, performance share awards and restricted stock awards, or awards. The 2005 plan, as approved by our stockholders, provided for the authorization of awards covering an aggregate of 2.2 million shares of common stock plus 0.8 million shares previously authorized for issuance under the 2004 plan. In connection with our public offering in October 2005, our board of directors reduced the number of shares of common stock reserved for issuance under the 2005 plan to 1.4 million shares. In March 2006, our board of directors authorized the restoration of the reserve of 1.6 million shares for issuance under the 2005 plan. In May 2007, our stockholders approved an amendment to the 2005 plan increasing the number of shares of common stock from 3.0 million to 6.0 million shares. In June 2010, our stockholders approved an amendment to the 2005 plan increasing the number of shares of common stock from 6.0 million to 9.0 million shares.

The equity incentive plans are administered by the compensation committee of the board of directors. The compensation committee determines the type and term of each award, the award exercise or purchase price, if applicable, the number of shares underlying each award granted and the rate at which each award becomes vested or exercisable. Incentive stock options may be granted only to our employees at an exercise price per share of not less than the fair market value per share of common stock as determined by the board of directors on the date of grant (not less than 110% of the fair market value in the case of holders of more than 10% of our voting common stock) and with a term not to exceed ten years from date of grant (five years for incentive stock options granted to holders of more than 10% of our voting common stock). Nonqualified stock options may be granted to any officer, employee, director, consultant or advisor at a per share exercise price in such amount as the compensation committee may determine. The compensation committee may also grant restricted stock and other share-based awards on such terms and conditions as it may determine.

The following table shows share-based compensation expense as included in our consolidated statements of operations:

	<u>Years Ended December 31,</u>		
	<u>2011</u>	<u>2010</u>	<u>2009</u>
	(In Thousands)		
Research and development . . . . .	\$1,066	\$1,214	\$1,546
General and administrative . . . . .	1,357	5,203	3,068
Total share-based compensation expense . . . . .	<u>\$2,423</u>	<u>\$6,417</u>	<u>\$4,614</u>

Share-based compensation expense is based on awards ultimately expected to vest. During the years ended December 31, 2011, 2010 and 2009, because substantially all of our stock option grants vest monthly, share-based employee compensation expense included the actual impact of forfeitures.

The table below illustrates the fair value per share and Black-Scholes option pricing model with the following assumptions used for grants issued:

	<u>Years Ended December 31,</u>		
	<u>2011</u>	<u>2010</u>	<u>2009</u>
Weighted average fair value of options . . . . .	\$2.15	\$2.03	\$3.12
Risk-free interest rate . . . . .	2.07%	1.97%	1.94%
Expected dividend yield . . . . .	0%	0%	0%
Expected option term (in years) . . . . .	5.2	5.1	5.1
Expected volatility . . . . .	75.0%	70.9%	70.2%

**IDENIX PHARMACEUTICALS, INC.**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED**

No dividend yield was assumed as we do not pay dividends on our common stock. The risk-free interest rate is based on the yield of United States Treasury securities consistent with the expected term of the option. The expected option term and expected volatility were determined by examining the expected option term and expected volatilities of similarly sized biotechnology companies as well as expected term and expected volatility of our stock.

The following table summarizes option activity under the equity incentive plans:

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price per Share</u>	<u>Weighted Average Remaining Contractual Term</u>	<u>Aggregate Intrinsic Value</u>
				(In Thousands)
Options outstanding at December 31, 2010 . . . . .	7,031,736	\$6.61		
Granted . . . . .	1,281,800	\$3.42		
Cancelled . . . . .	(324,201)	\$6.28		
Exercised . . . . .	(410,723)	\$3.40		
Options outstanding at December 31, 2011 . . . . .	<u>7,578,612</u>	\$6.25	4.95	\$19,164
Options exercisable at December 31, 2011 . . . . .	5,911,502	\$6.99	3.88	\$12,817
Options vested and expected to vest at December 31, 2011 . . . . .	7,578,612	\$6.25	4.95	\$19,164

The aggregate intrinsic value in the table above represents the total pre-tax amount, net of exercise price, which would have been received by option holders if all option holders had exercised all options with an exercise price lower than the market price on December 31, 2011, based on the closing price of our common stock of \$7.45 on that date.

The total intrinsic value of stock options exercised, which represents the amount by which the fair market value exceeded the exercise price, during 2011, 2010 and 2009 was \$1.2 million, \$0.5 million and \$0.2 million, respectively.

On October 28, 2010, our former chief executive officer, resigned from his positions as chairman of the board of directors, president and chief executive officer. In connection with his resignation, he was granted approximately 0.3 million options and acceleration of all unvested options. The related share-based compensation expense recognized in 2010 was \$2.7 million.

We had an aggregate of \$3.8 million of share-based compensation expense as of December 31, 2011 remaining to be amortized over a weighted average expected term of 2.54 years.

**10. Income Taxes**

Our effective income tax rate differs from the statutory federal income tax rate was as follows:

	<u>Years Ended December 31,</u>		
	<u>2011</u>	<u>2010</u>	<u>2009</u>
Federal statutory rate benefit . . . . .	(34)%	(34)%	(34)%
State tax benefit, net of federal expense (benefit) . . . . .	3	(2)	2
Permanent items . . . . .	1	1	(1)
Other . . . . .	1	1	(3)
Valuation allowance . . . . .	<u>29</u>	<u>34</u>	<u>36</u>
Effective income tax rate . . . . .	<u>0%</u>	<u>0%</u>	<u>0%</u>

**IDENIX PHARMACEUTICALS, INC.**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED**

The components of our net deferred taxes were as follows:

	December 31,	
	2011	2010
	(In Thousands)	
Depreciation . . . . .	\$ 1,667	\$ 1,672
Development contracts . . . . .	1,065	1,233
Nonqualified stock options . . . . .	7,628	7,202
Deferred licensing income . . . . .	23,917	16,916
Accrued expenses and other . . . . .	3,425	2,669
Capitalized research costs . . . . .	64,185	58,661
Research and development credits . . . . .	10,532	9,632
Foreign tax credit carryforward . . . . .	877	877
Net operating carryforwards . . . . .	91,605	90,656
Valuation allowance . . . . .	<u>(204,901)</u>	<u>(189,518)</u>
Deferred tax asset . . . . .	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2011, we had United States federal and state net operating loss carryforwards of \$256.9 million and \$79.2 million, respectively, which may be available to offset future federal and state income tax liabilities. The federal net operating loss carryforwards begin to expire in 2022 and the state net operating loss carryforwards begin to expire in 2012. Approximately \$9.0 million of the net operating loss carryforwards available for federal and state income tax purposes relate to exercises of employee stock options, the tax benefit of which, if realized, will be credited to additional paid-in capital. We have federal and state research and development credits of \$8.3 million and \$3.3 million, respectively. The federal research and development credits begin to expire in 2022 and the state credits begin to expire in 2021. We also have foreign credit carryforwards of \$0.9 million, which begin to expire in 2016.

Ownership changes, as defined in the Internal Revenue Code, may limit the amount of net operating loss carryforwards that can be utilized annually to offset future taxable income. Subsequent ownership changes could further affect the limitation in future years.

Our management has evaluated the positive and negative evidence bearing upon the realization of our deferred tax assets, which are comprised principally of net operating loss carryforwards, deferred licensing income, capitalized research costs and research and development credit carryforwards. Management has determined that it is more likely than not that we will not realize the benefits of federal, state and foreign deferred tax assets and, as a result, a valuation allowance of \$204.9 million has been established at December 31, 2011.

There were no significant changes to the balance of unrecognized tax benefits in 2011 or 2010 as compared to 2007 when we adopted FASB guidance related to unrecognized tax benefits. The total amount of unrecognized tax benefits was \$1.4 million at December 31, 2011. Of this amount, \$0.3 million will impact the effective tax rate if ultimately realized and \$1.1 million would be offset by an increase in the valuation allowance on deferred tax assets.

Our policy is to classify interest and penalties associated with uncertain tax positions as other income, net in our consolidated statements of operations. As of December 31, 2011, we have accrued \$0.4 million related to interest and penalties for uncertain tax positions. Of this amount, less than \$0.1 million and \$0.2 million was included in other income, net for the years ended December 31, 2010 and 2009, respectively. There were no amounts included in other income, net for the year ended December 31, 2011.

The open tax years by major jurisdiction are: a) the years ended December 31, 2008 through 2010 for the United States; and b) the years ended December 31, 2009 and 2010 for France.

**IDENIX PHARMACEUTICALS, INC.**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED**

**11. Employee Benefit Plans**

We maintain a retirement savings plan under Section 401(k) of the Internal Revenue Code, or the 401(k) plan. The 401(k) plan allows participants to defer a portion of their annual compensation on a pre-tax basis and covers substantially all of our United States employees who meet minimum age and service requirements.

We match 25% of employee contributions up to 6% of participants' annual compensation. We made contributions to the 401(k) plan of \$0.1 million in each of the years ended December 31, 2011, 2010 and 2009.

We are required by statute to maintain a defined benefit plan for our employees in France. We have recorded \$0.3 million in other long-term liabilities related to this benefit plan as of December 31, 2011 and 2010.

**12. Related Party Transactions**

In connection with the development and commercialization agreement, we have generated revenues from Novartis related to royalty revenue associated with the sale of Tyzeka<sup>®</sup>/Sebivo<sup>®</sup>, license payments and reimbursements of certain research and development expenses in the amount of \$4.3 million, \$6.2 million and \$11.7 million for the years ended December 31, 2011, 2010 and 2009, respectively. All amounts included in receivables from related party at December 31, 2011 and 2010 are due from Novartis. We also included \$27.3 million and \$31.6 million as deferred revenue, related party, as of December 31, 2011 and 2010, respectively, relating to non-refundable payments received from Novartis.

**13. Segment Reporting**

We operate in a single segment, we have no organizational structure dictated by product lines, geography or customer type and all significant revenues are generated from operations in the United States. The following table presents total long-lived assets by geographic area:

	<b>December 31,</b>	
	<b>2011</b>	<b>2010</b>
	<b>(In Thousands)</b>	
United States .....	\$3,389	\$5,301
France .....	<u>1,307</u>	<u>1,878</u>
	<u>\$4,696</u>	<u>\$7,179</u>

**14. Collaborative Agreements and License Agreements**

Our collaborative agreement with Novartis is fully described in Note 3 to the consolidated financial statements.

***ViiV Healthcare Company and GlaxoSmithKline Collaboration***

In February 2009, we entered into the ViiV license agreement which granted ViiV an exclusive worldwide license to develop, manufacture and commercialize our NNRTI compounds, including IDX899, now known as '761, for the treatment of human diseases, including HIV/AIDS. We also entered into a stock purchase agreement with GSK in February 2009, which we refer to as the GSK stock purchase agreement. Under this agreement, GSK purchased approximately 2.5 million shares of our common stock at an aggregate purchase price of \$17.0 million, or a per share price of \$6.87. These agreements became effective in March 2009.

**IDENIX PHARMACEUTICALS, INC.**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED**

In March 2009, we received \$34.0 million related to this collaboration, which consisted of a \$17.0 million license fee payment under the ViiV license agreement and \$17.0 million under the GSK stock purchase agreement described above. In 2010, we received a \$6.5 million milestone payment related to the achievement of a preclinical operational milestone and a \$20.0 million milestone payment for the initiation of a phase IIb clinical study of '761. Pursuant to the ViiV license agreement, we were eligible to receive up to \$390.0 million in additional milestone payments as well as double-digit tiered royalties on worldwide product sales.

The ViiV license agreement had performance obligations, including joint committee participation and ViiV's right to license other NNRTI compounds that we may develop in the future, that we have assessed under the FASB guidance related to multiple element arrangements, prior to the implementation of ASU No. 2009-13. We concluded that this arrangement should be accounted for as a single unit of accounting and recognized using the contingency adjusted performance method. The milestone payments did not meet our revenue recognition criteria for immediate recognition and are being recognized over the life of the agreement, which was estimated to be 17 years. The parties have agreed that if ViiV, its affiliates or its sublicenses desire to develop '761 for an indication other than HIV, or if ViiV intends to develop any other licensed compound for any indication, the parties will mutually agree on a separate schedule of milestone and royalty payments prior to the start of development. We recognized \$2.6 million, \$4.0 million and \$0.9 million of collaboration revenue for the years ended December 31, 2011, 2010 and 2009, respectively. We recorded \$36.1 million and \$38.7 million of deferred revenue as of December 31, 2011 and 2010, respectively, related to payments received from ViiV.

In February 2011, ViiV informed us that the FDA placed '761 on clinical hold. As a result of further evaluation, ViiV determined that it would not continue development of '761 or develop any other compound licensed under the ViiV license agreement. In December 2011, ViiV notified us it would terminate the ViiV license agreement effective March 15, 2012. Upon termination, ViiV will relinquish all rights it has in the intellectual property licensed from us and grants us an exclusive, perpetual and irrevocable license to any intellectual property relating to the licensed products it may have developed during the term of the license agreement. As a result of the termination of the ViiV license agreement, we will not receive any additional milestone or royalty payments under the ViiV license agreement. Upon termination, we will have no future obligations pursuant to the license agreement and the deferred revenue balance as of December 31, 2011 of \$36.1 million is expected to be recognized as other collaboration revenue in the first quarter of 2012.

Under the terms of the GSK stock purchase agreement, in June 2009, we filed a registration statement with the SEC covering the shares GSK purchased from us. We have also agreed to cooperate in one underwritten offering of the purchased shares, including the entry into an underwriting agreement with customary terms, provided that such underwritten offering occurs after the first anniversary of the closing date. The GSK stock purchase agreement may be terminated by mutual agreement of the parties.

ViiV has also become a party to the cooperative research program and exclusive license agreement we have with the Università degli Studi di Cagliari, or the University of Cagliari, which is more fully described below under the "University of Cagliari" heading.

In connection with the ViiV license agreement and GSK stock purchase agreement, Novartis waived and amended certain rights under the development and commercialization agreement and amended a letter agreement related to the selection and appointment of our chief financial officer. Novartis also executed a waiver and consent under the amended and restated stockholders' agreement. These waivers and amendments are more fully described in Part I. Item 1 of this Annual Report on Form 10-K under the heading "ViiV Healthcare Company and GlaxoSmithKline Collaboration".

**IDENIX PHARMACEUTICALS, INC.**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED**

***University of Cagliari***

In January 1999, we entered into a cooperative antiviral research activity agreement, as amended with the Dipartimento di Biologia Sperimentale “Bernardo Loddo” dell’Universita di Cagliari pursuant to which we acquired an exclusive license to certain antiviral technology. We are required to make royalty payments to the University of Cagliari upon commercialization of any products resulting from the licensed technology. We were also required to make payments to the University of Cagliari for use of the facilities and for supplies consumed in connection with the research activities. This agreement terminated in December 2010. We incurred expenses of approximately \$0.1 million for the year ended December 31, 2009 in connection with this agreement. There were no significant expenses incurred during 2010.

In December 2000, we and the University of Cagliari also entered into a license agreement pursuant to which we were granted an exclusive license under certain patent rights resulting from specified research activities. In May 2003, we, the University of Cagliari and Novartis entered into an amendment of these agreements, pursuant to which Novartis was granted the right, under certain circumstances, to prosecute and enforce patents resulting from the research activities, and to assume our rights under the agreement if the agreement terminates due to an uncured breach of the agreement by us. In October 2005, we and the University of Cagliari amended such agreements in a manner that will require certain payments to the University of Cagliari if we receive license fees or milestone payments in connection with a sublicense by us of technology covered by the agreements between the University of Cagliari and us.

In March 2009, ViiV became a party to the cooperative research program and exclusive license agreement we have with the University of Cagliari, the co-owner of certain patents and patent applications licensed by us to ViiV under the ViiV license agreement. Under these arrangements, we are liable for certain payments to the University of Cagliari if we receive license fees or milestone payments with respect to such technology. We have made certain payments to the University of Cagliari based on the payments we received from ViiV. Although certain patent rights licensed to ViiV are owned solely by us and do not fall under the arrangements with the University of Cagliari, we have entered into an arrangement whereby if it is ever deemed that any patent owned solely by us and licensed to ViiV was co-developed by anyone on the faculty of the University of Cagliari, such co-development will fall within the existing arrangements with the University of Cagliari and no additional payments would be due by us. As a result of the termination of the ViiV license agreement, we will not receive any additional milestone or royalty payments under the ViiV license agreement and therefore do not expect to make future payments to the University of Cagliari for the patent and patent applications related to ‘761.

***Sumitomo Pharmaceuticals Co., Ltd.***

We entered into collaborative agreements with Sumitomo in 2001, in connection with the development and commercialization in Japan, China, Taiwan, and South Korea of telbivudine, a drug for the treatment of HBV. In connection with this arrangement, we and Sumitomo agreed to share certain direct third-party expenses of development of telbivudine.

In March 2003, we entered into a final settlement agreement with Sumitomo under which the rights to develop and commercialize telbivudine in Japan, China, South Korea and Taiwan previously granted to Sumitomo were returned to us. This agreement with Sumitomo became effective upon consummation of our collaboration with Novartis in May 2003. We repurchased these product rights for \$5.0 million and as a result of this payment, we reversed approximately \$4.6 million of revenue previously recognized in original arrangements with Sumitomo with the remaining amount recorded as a reduction of deferred revenue.

We also have recorded \$4.3 million included as deferred revenue, net of current portion in our consolidated balance sheets at each of December 31, 2011 and 2010 representing amounts received from Sumitomo that have

**IDENIX PHARMACEUTICALS, INC.**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED**

not been included in revenue to date. We are required to pay an additional \$5.0 million to Sumitomo if and when the first commercial sale of telbivudine occurs in Japan. This payment will be recorded first as a reduction of the remaining \$4.3 million of deferred revenue, with the excess recorded as an expense. As part of the development and commercialization agreement, we will be reimbursed by Novartis for any such payment made to Sumitomo. If regulatory approval is not received for telbivudine in Japan, we would have no further obligations under the settlement agreement with Sumitomo and therefore, the \$4.3 million of remaining deferred revenue would be recognized as revenue at that time.

**15. Commitments and Contingencies**

***Lease Arrangements***

We lease our facilities and certain equipment under operating leases. Our lease arrangements have terms through the year 2017. Total rent expense under operating leases was approximately \$3.4 million, \$3.3 million and \$3.0 million for the years ended December 31, 2011, 2010 and 2009, respectively. Future minimum payments under lease arrangements at December 31, 2011 were as follows:

<u>Years Ending December 31,</u>	<u>Operating Leases (In Thousands)</u>
2012 .....	\$2,349
2013 .....	1,940
2014 .....	709
2015 .....	655
2016 .....	652
2017 and thereafter .....	<u>163</u>
Total .....	<u><u>\$6,468</u></u>

In October 2003, we entered into an operating lease commitment for office and laboratory space in Cambridge, Massachusetts. The term of the lease is for ten years, expiring in December 2013. The lease agreement provided for a landlord allowance of \$1.6 million to be paid to us to finance a portion of capital improvements to the facility. This landlord allowance was recorded as deferred rent which is being amortized as a reduction of rent over the ten year lease term. In connection with this operating lease commitment, a commercial bank issued a letter of credit in October 2003 for \$0.8 million collateralized by cash held with that bank. The letter of credit expires in December 2013.

In April 2005, we entered into a lease agreement for office and laboratory space in Montpellier, France. The term of the lease is for 12 years, expiring in April 2017 but is cancellable by either party with a one year notice period. The lease agreement also includes an option entitling us to purchase the building at any time after April 16, 2011. The purchase option extends until the expiration of the lease term. In January 2011, we amended this lease agreement to terminate the lease of certain floors in the building.

In June 2005, we entered into a lease agreement for additional office space in Cambridge, Massachusetts. The term of the lease was through December 2013. We were provided allowances totaling \$1.2 million to finance a portion of capital improvements to the facility. These allowances have been recorded as deferred rent which was being amortized as a reduction of rent over the lease term. In connection with this operating lease commitment, a commercial bank issued a letter of credit in May 2005 for \$0.4 million collateralized by cash we have on deposit with that bank and is recorded as restricted cash. In December 2011, we terminated this lease for a fee of \$0.6 million. In addition, the letter of credit of \$0.4 million was terminated in the first quarter of 2012.

**IDENIX PHARMACEUTICALS, INC.**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED**

***Contingencies***

***Product and Drug Candidates***

In connection with the resolution of matters relating to certain of our HCV drug candidates, in May 2004, we entered into a settlement agreement with UAB which provides for a milestone payment of \$1.0 million to UAB upon receipt of regulatory approval in the United States to market and sell certain HCV products invented or discovered by our former chief executive officer during the period from November 1, 1999 to November 1, 2000. This settlement agreement also provides that we will pay UAB an amount equal to 0.5% of worldwide net sales of such HCV products with a minimum sales-based payment equal to \$12.0 million. Currently, there are no such HCV products approved and therefore there was no related liability recorded as of December 31, 2011.

We have potential payment obligations under the license agreement with the University of Cagliari, pursuant to which we have the exclusive worldwide right to make, use and sell certain HCV and HIV technologies. We made certain payments to the University of Cagliari under these arrangements based on the payments we received from ViiV under the ViiV license transaction. As a result of the termination of the ViiV license agreement, we will not receive any additional milestone or royalty payments under the ViiV license agreement and therefore do not expect to make future payments to the University of Cagliari for the patent and patent applications related to '761. We are also liable for certain payments to the University of Cagliari if we receive license fees or milestone payments with respect to such technology from Novartis or another collaborator.

Pursuant to the license agreement between us and UAB, we were granted an exclusive license to the rights that UABRF, an affiliate of UAB, Emory University and CNRS have to a 1995 U.S. patent application and progeny thereof and counterpart patent applications in Europe, Canada, Japan and Australia that cover the use of certain synthetic nucleosides for the treatment of HBV. In July 2008, we entered into a settlement agreement with UAB, UABRF and Emory University relating to our telbivudine technology. Pursuant to this settlement agreement, all contractual disputes relating to patents covering the use of certain synthetic nucleosides for the treatment of HBV and all litigation matters relating to patents and patent applications related to the use of  $\beta$ -L-2'-deoxy-nucleosides for the treatment of HBV assigned to one or more of Idenix, CNRS and the University of Montpellier and which cover the use of telbivudine (Tyzeka<sup>®</sup>/Sebivo<sup>®</sup>) for the treatment of HBV have been resolved. UAB also agreed to abandon certain continuation patent applications it filed in July 2005. Under the terms of the settlement agreement, we paid UABRF (on behalf of UAB and Emory University) a \$4.0 million upfront payment and will make additional payments to UABRF equal to 20% of all royalty payments received by us from Novartis from worldwide sales of telbivudine, subject to minimum payment obligations aggregating \$11.0 million. Our payment obligations under the settlement agreement expire in August 2019. The settlement agreement was effective on June 1, 2008 and included mutual releases of all claims and covenants not to sue among the parties. It also included a release from a third-party scientist who had claimed to have inventorship rights in certain Idenix/CNRS/University of Montpellier patents.

In May 2003, we and Novartis entered into an amended and restated agreement with CNRS and the University of Montpellier pursuant to which we worked in collaboration with scientists from CNRS and the University of Montpellier to discover and develop technologies relating to antiviral substances, including telbivudine. This cooperative agreement expired in December 2006, but we retain rights to exploit the patents derived from the collaboration. Under the cooperative agreement, we are obligated to make royalty payments for products derived from such patents.

***Legal Contingency***

In December 2001, we retained the services of Clariant (subsequently acquired by Archimica Group), a provider of manufacturing services in the specialty chemicals industry, in the form of a multiproject development

**IDENIX PHARMACEUTICALS, INC.**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED**

and supply agreement. Under the terms of the agreement with Clariant, we would, on an “as needed” basis, utilize the Clariant process development and manufacture services in the development of certain of our drug candidates, including telbivudine. After reviewing respective bids from each of Novartis and Clariant, the joint manufacturing committee of Idenix and Novartis decided to proceed with Novartis as the primary manufacturer of telbivudine. In late 2007, we transferred full responsibility to Novartis for the development, commercialization and manufacturing of telbivudine. As a result, in January 2008, we exercised our right under the agreement with Clariant to terminate the relationship effective July 2008. In February 2008, Clariant asserted that they should have been able to participate in the manufacturing process for telbivudine as a non-primary supplier and therefore are due an unspecified amount. We do not agree with Clariant’s assertion and since no estimate of a potential loss can be made, we have not recorded a liability associated with this potential contingent matter. Clariant has not initiated legal proceedings. If legal proceedings are initiated, we intend to vigorously defend against such lawsuit.

***Other Legal Contingency***

We have been involved in a dispute with the City of Cambridge, Massachusetts and its License Commission pertaining to the level of noise emitted from certain rooftop equipment at our research facility located at 60 Hampshire Street in Cambridge. The License Commission has claimed that we are in violation of the local noise ordinance pertaining to sound emissions, based on a complaint from neighbors living adjacent to the property. We have contested this alleged violation before the License Commission, as well as the Middlesex County, Massachusetts, Superior Court. In July 2010, the License Commission granted us a special variance from the requirements of the local noise ordinance for a period of one-year, effective as of July 1, 2010. In August 2011, the License Commission granted an extension of the July 2010 variance until August 2012. We may, however, be required to cease certain activities at the building if: a) the noise emitted from certain rooftop equipment at our research facility exceeds the levels permitted by the special variance; b) the parties are unable to resolve this matter through negotiations and remedial action after August 2012; or c) a future legal challenge to the position of the City of Cambridge and the License Commission is unsuccessful. In any such event, we could be required to relocate to another facility which could interrupt some of our business activities and could be time consuming and costly. No estimate of a potential loss can be made and therefore we have not recorded a liability associated with this potential contingent matter.

***Indemnification***

We have agreed to indemnify Novartis and its affiliates against losses suffered as a result of any breach of representations and warranties in the development and commercialization agreement and the stock purchase agreement. Under these agreements with Novartis, we made numerous representations and warranties to Novartis regarding our HBV and HCV drug candidates, including representations regarding our ownership of the inventions and discoveries. If one or more of these representations or warranties were subsequently determined not to be true at the time they were made to Novartis, we would be in breach of one or both of these agreements. In the event of such a breach, Novartis has the right to seek indemnification from us and, under certain circumstances, us and our stockholders who sold shares to Novartis, which include many of our directors and officers, for damages suffered by Novartis as a result of such breach. While it is possible that we may be required to make payments pursuant to the indemnification obligations we have under these agreements, we cannot reasonably estimate the amount of such payments or the likelihood that such payments would be required.

Under the ViiV license agreement and the GSK stock purchase agreement, we have agreed to indemnify ViiV as sublicensee, GSK and their affiliates against losses suffered as a result of our breach of representations and warranties in these agreements. We made numerous representations and warranties regarding our NNRTI program, including ‘761, as well as representations regarding our ownership of inventions and discoveries. If one or more of these representations or warranties were not true at the time we made them, we would be in breach of

**IDENIX PHARMACEUTICALS, INC.**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED**

these agreements. In the event of a breach, the parties have the right to seek indemnification from us for damages suffered as a result of such breach. While it is possible that we may be required to make payments pursuant to the indemnification obligations we have under these agreements, we cannot reasonably estimate the amount of such payments or the likelihood that such payments would be required.

**16. Quarterly Financial Data (Unaudited)**

	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>	<u>Total Year</u>
	(In Thousands, Except per Share Data)				
<b>2011</b>					
Total revenues .....	\$ 4,001	\$ 1,044	\$ 2,638	\$ (732)	\$ 6,951
Total operating expenses .....	12,544	15,327	14,685	17,803	60,359
Net loss .....	(8,236)	(13,909)	(11,709)	(18,125)	(51,979)
Basic and diluted net loss per common share .....	(0.11)	(0.15)	(0.12)	(0.18)	(0.57)
<b>2010</b>					
Total revenues.....	\$ 2,683	\$ 1,316	\$ 3,788	\$ 2,435	\$ 10,222
Total operating expenses .....	19,335	17,915	16,643	19,055	72,948
Net loss .....	(16,212)	(16,256)	(12,930)	(16,157)	(61,555)
Basic and diluted net loss per common share .....	(0.24)	(0.23)	(0.18)	(0.22)	(0.87)

In the fourth quarter of 2011, we recorded a charge against revenue related to the impact of the stock subscription rights of Novartis. This policy is described more fully in Note 3.

## 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.

### IDENIX PHARMACEUTICALS, INC.

Date: March 6, 2012

/s/ Ronald C. Renaud, Jr.

Ronald C. Renaud, Jr.  
President and Chief Executive Officer

Pursuant to the requirements of the Securities 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.

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Ronald C. Renaud, Jr.</u> Ronald C. Renaud, Jr.	President and Chief Executive Officer and Director (Principal Executive Officer)	March 6, 2012
<u>/s/ Daniella Beckman</u> Daniella Beckman	Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 6, 2012
<u>/s/ Wayne Hockmeyer</u> Wayne Hockmeyer	Director	March 6, 2012
<u>/s/ Thomas Hodgson</u> Thomas Hodgson	Director	March 6, 2012
<u>/s/ Tamar Howson</u> Tamar Howson	Director	March 6, 2012
<u>/s/ Robert Pelzer</u> Robert Pelzer	Director	March 6, 2012
<u>/s/ Denise Pollard-Knight</u> Denise Pollard-Knight	Director	March 6, 2012
<u>/s/ Anthony Rosenberg</u> Anthony Rosenberg	Director	March 6, 2012
<u>/s/ Michael Wyzga</u> Michael Wyzga	Director	March 6, 2012

## EXHIBIT INDEX

Exhibit Number	Description	Incorporated by Reference to			
		Form	Exhibit No.	Filing Date	SEC File Number
<i>Articles of Incorporation and By-Laws</i>					
3.1	Restated Certificate of Incorporation of the Registrant	S-1	3.1	12/15/2003	333-111157
3.2	Certificate of Amendment of Restated Certificate of Incorporation	10-Q for 6/30/2004	3.1	8/26/2004	000-49839
3.3	Certificate of Amendment of Restated Certificate of Incorporation	10-K for 12/31/2005	3.3	3/16/2006	000-49839
3.4	Certificate of Amendment of Restated Certificate of Incorporation	10-K for 12/31/2007	3.4	3/14/2008	000-49839
3.5	Certificate of Amendment of Restated Certificate of Incorporation	10-Q for 6/30/2011	3.1	8/9/2011	000-49839
3.6	Amended and Restated By-Laws	10-Q for 6/30/2004	3.2	8/26/2004	000-49839
4.1	Specimen Certificate evidencing the Common Stock, \$.001 par value	S-1 Amendment 2	4.1	1/27/2004	333-111157
<i>Material contracts — real estate</i>					
10.1	Lease Agreement, dated as of October 15, 1998, by and between Idenix (Massachusetts) Inc. and CambridgePark One Limited Partnership, as amended by the First Amendment to Lease dated as of September 1, 2001	S-1	10.2	12/15/2003	333-111157
10.2	Lease Agreement, dated as of August 22, 2001, by and between Idenix (Massachusetts) Inc. and West Cambridge Sciences Park	S-1	10.3	12/15/2003	333-111157
10.3	Amended and Restated Lease of Premises at 60 Hampshire Street, Cambridge, Massachusetts, dated as of October 28, 2003, by and between Idenix (Massachusetts) Inc. and BHX, LLC, as trustee of 205 Broadway Realty Trust	S-1	10.4	12/15/2003	333-111157
10.4	Administrative Lease Hotel D'Enterprises Cap Gamma dated April 18, 2005 by and among Idenix SARL, Societe D'Equipment de la Region Montpellieraine and the Communate D'Agglomeration de Montpellier (English Translation)	8-K	10.1	4/20/2005	000-49839
10.5+	Offer of Sale Hotel	8-K	10.2	4/20/2005	000-49839
10.6	Joint Guarantee made as of December 15, 2005 between the Registrant and Societe D'Equipment de la Region Montpellieraine	8-K	10.3	4/20/2005	000-49839

Exhibit Number	Description	Incorporated by Reference to			
		Form	Exhibit No.	Filing Date	SEC File Number
10.7	Indenture of Lease, dated June 8, 2005, by and between the Registrant and One Kendall Square Associates LLC	8-K	10.1	6/13/2005	000-49839
10.8	First Amendment of Lease dated July 24, 2006 by and between the Registrant and RB Kendall Fee, LLC	10-Q for 6/30/2006	10.3	8/8/2006	000-49839
10.9	Second Amendment of Lease dated September 7, 2006 by and between the Registrant and RB Kendall Fee, LLC	10-Q for 9/30/2006	10.1	11/8/2006	000-49839
10.10	Third Amendment of Lease, dated July 23, 2009, between RB Kendall Fee, LLC and the Registrant	10-Q for 9/30/2009	10.1	10/29/2009	000-49839
10.11	Fourth Amendment of Lease, dated June 29, 2010, between RB Kendall Fee, LLC and the Registrant	10-Q for 6/30/2010	10.3	7/27/2010	000-49839
10.12	Fifth Amendment of Lease, dated November 30, 2011, between RB Kendall Fee, LLC and the Registrant	*			
	<b><i>Material contracts Novartis Pharma AG and GlaxoSmithKline</i></b>				
10.13	Letter Agreement, dated as of March 21, 2003, by and between the Registrant and Novartis Pharma AG	S-1	10.28	12/15/2003	333-111157
10.14	Amendment No. 1 to Letter Agreement, dated on or about January 28, 2009, by and between the Registrant and Novartis Pharma AG	8-K	10.3	2/6/2009	000-49839
10.15	Amendment No. 2 to Letter Agreement, dated April 6, 2011, by and between the Registrant and Novartis Pharma AG	8-K	10.3	4/7/2011	000-49839
10.16+	Restated and Amended Cooperative Agreement dated as of May 8, 2003, by among Idenix SARL and Le Centre National de la Recherche Scientifique, L'Universite Montpellier II and Novartis Pharma AG	S-1	10.14	12/15/2003	333-111157
10.17	Letter Agreement, dated May 8, 2003, by and among the Registrant, Idenix SARL, Novartis Pharma AG and the University of Cagliari, amending the Cooperative Agreement and License Agreement	S-1	10.19	12/15/2003	333-111157
10.18+	Development, License and Commercialization Agreement, dated as of May 8, 2003, by and among the Registrant, Idenix (Cayman) Limited and Novartis Pharma AG, as amended on April 30, 2004	S-1 Amendment 3	10.24	7/6/2004	333-111157

Exhibit Number	Description	Incorporated by Reference to			
		Form	Exhibit No.	Filing Date	SEC File Number
10.19+	Master Manufacturing and Supply Agreement, dated as of May 8, 2003, by and between Idenix (Cayman) Limited and Novartis Pharma AG	S-1	10.25	12/15/2003	333-111157
10.20+	Second Amendment, dated as of December 21, 2004, to the Development, License and Commercialization Agreement, by and among the Registrant, Idenix (Cayman) Limited and Novartis Pharma AG, as amended on April 30, 2004	10-K for 12/31/2004	10.16	3/17/2005	000-49839
10.21+	Amendment No. 3 to the Development, License and Commercialization Agreement, effective as of February 27, 2006, by and among the Registrant, Idenix (Cayman) Limited and Novartis Pharma AG	10-K for 12/31/2005	10.14	3/16/2006	000-49839
10.22+	Amendment No. 4 to the Development, License and Commercialization Agreement, dated as of September 28, 2007, by and among the Registrant, Idenix (Cayman) Limited and Novartis Pharma AG	10-Q for 9/30/2007	10.1	11/8/2007	000-49839
10.23	Amendment No. 5 to the Development License and Commercialization Agreement, dated on or about January 28, 2009, between the Registrant, Idenix (Cayman) Limited and Novartis Pharma AG	8-K	10.2	2/6/2009	000-49839
10.24	Amendment No. 6 to the Development, License and Commercialization Agreement, dated April 6, 2011, by and among the Registrant, Idenix (Cayman) Limited and Novartis Pharma AG	8-K	10.1	4/7/2011	000-49839
10.25+	Transition Services Agreement, dated as of September 28, 2007, by and among the Registrant, Idenix (Cayman) Limited and Novartis Pharma AG	10-Q for 9/30/2007	10.2	11/8/2007	000-49839
10.26	Amended and Restated Stockholders' Agreement, dated July 27, 2004, by and among the Registrant, Novartis Pharma AG and the stockholders identified on the signature pages thereto	10-K for 12/31/2004	10.20	3/17/2005	000-49839
10.27	Amendment No. 1 to Amended and Restated Stockholders' Agreement, dated April 6, 2011, by and among the Registrant, Novartis Pharma AG and the stockholders identified thereto	8-K	10.2	4/7/2011	000-49839
10.28	Par Value Stock Purchase Agreement, dated July 27, 2004, by and between the Registrant and Novartis Pharma AG	10-K for 12/31/2004	10.21	3/17/2005	000-49839

Exhibit Number	Description	Incorporated by Reference to			
		Form	Exhibit No.	Filing Date	SEC File Number
10.29+	Stock Purchase Agreement, dated as of March 21, 2003, by and among the Registrant, Novartis and the stockholders identified on the signature pages	S-1 Amendment 3	10.27	7/6/2004	333-11115
10.30	Concurrent Private Placement Stock Purchase Agreement, dated July 27, 2004, by and between the Registrant and Novartis Pharma AG	10-K for 12/31/2004	10.22	3/17/2005	000-49839
10.31	Concurrent Private Placement Stock Purchase Agreement, dated April 8, 2011, by and between the Registrant and Novartis Pharma AG	8-K	10.1	4/11/2011	000-49839
10.32+	Commercial Manufacturing Agreement dated as of June 22, 2006 by and between the Registrant and Novartis Pharma AG	10-Q for 6/30/2006	10.1	8/8/2006	000-49839
10.33+	Packaging Agreement dated as of June 22, 2006 by and between the Registrant and Novartis Pharma AG	10-Q for 6/30/2006	10.2	8/8/2006	000-49839
10.34	Stock Purchase Agreement, dated February 4, 2009, between the Registrant and SmithKline Beecham Corporate  <i>University of Cagliari</i>	8-K	10.1	2/6/2009	000-49839
10.35+	Cooperative Antiviral Research Activity Agreement (the "Cooperative Agreement"), dated January 4, 1999, by and between Idenix SARL and the University of Cagliari	S-1	10.16	12/15/2003	333-111157
10.36+	License Agreement, dated as of December 14, 2000, between the Registrant and the University of Cagliari	S-1	10.17	12/15/2003	333-111157
10.37+	Letter Agreement, dated April 10, 2002, by and between Idenix SARL and the University of Cagliari, amending the Cooperative Agreement and License Agreement	S-1	10.18	12/15/2003	333-111157
10.38+	Agreement, dated June 30, 2004, by and among the Registrant, Idenix SARL and the University of Cagliari	S-1 Amendment 3	10.18.1	7/6/2004	333-111157
10.39	Collaborative Activities	S-1	10.18.2	7/6/2004	333-111157
10.40+	Agreement, dated October 24, 2005, by and among the Registrant, Idenix SARL and the Università degli Studi di Cagliari	10-Q for 9/30/2005	10.1	11/08/2005	000-49839

Exhibit Number	Description	Incorporated by Reference to			
		Form	Exhibit No.	Filing Date	SEC File Number
<i>Miscellaneous</i>					
10.41	License Agreement dated as of June 20, 1998 by and between the Registrant and the UAB Research Foundation, as amended by that First Amendment Agreement, dated as of June 20, 1998, and by that Second Amendment Agreement, dated as of July 16, 1999	S-1 Amendment 2	10.31	6/1/2004	333-111157
10.42+	Master Services Agreement, dated February 25, 2003, by and between the Registrant and Quintiles, Inc.	S-1	10.21	12/15/2003	333-111157
10.43	Master Services Agreement, dated May 27, 1999, between Idenix (Massachusetts), Inc. and Quintiles Scotland Ltd	S-1	10.20	12/15/2003	333-111157
10.44	Multiproject Development and Supply Agreement, dated as of December 20, 2001, by and among the Registrant, Idenix SARL and Clariant Life Science Molecules (Missouri) Inc.	S-1	10.22	12/15/2003	333-111157
10.45+	Agreement, dated as of May 1, 2003, between Idenix (Cayman Limited and Microbiologica Quimica E Farmaceutica Ltda.	S-1 Amendment 3	10.23	7/6/2004	333-111157
10.46	Final Settlement Agreement, dated March 26, 2003, by and between the Registrant and Sumitomo Pharmaceuticals Co., Ltd.	S-1	10.13	12/15/2003	333-111157
10.47	Settlement Agreement, dated as of May 28, 2004, by and between the Registrant, Jean-Pierre Sommadossi, the University of Alabama at Birmingham and the University of Alabama Research Foundation	S-1 Amendment 2	10.34	6/1/2004	333-111157
10.48	Settlement Agreement, effective June 1, 2008, by and among the Registrant, Jean-Pierre Sommadossi, the University of Montpellier II, Le Centre National de la Recherche Scientifique, the Board of Trustees of the University of Alabama on behalf of the University of Alabama at Birmingham, the University of Alabama Research Foundation and Emory University	8-K	10.1	8/5/2008	000-49839
10.49	Master Service Agreement, dated April 1, 2008, by and between the Registrant and Parexel International LLC	10-Q for 6/30/2008	10.1	8/7/2008	000-49839
10.50+	Master Agreement for Clinical Trial Management Services, dated September 16, 2009, between Pharmaceutical Research Associates, Inc. and the Registrant	10-Q for 9/30/2009	10.2+	10/29/2009	000-49839

Exhibit Number	Description	Incorporated by Reference to			
		Form	Exhibit No.	Filing Date	SEC File Number
10.51	Master Agreement for Clinical Research Services, dated January 30, 2009, by and between Registrant and ACLIRES International, Ltd.	10-K for 12/31/2009	10.49	3/9/2010	000-49839
	<i>Material contracts — management contracts and compensatory plans</i>				
10.52#	Form of Incentive Stock Option Agreement for awards granted pursuant to the 2005 Stock Incentive Plan, as amended	8-K	10.2	6/13/2005	000-49839
10.53#	Form of Non-Statutory Stock Option Agreement for awards granted pursuant to the 2005 Stock Incentive Plan, as amended	8-K	10.3	6/13/2005	000-49839
10.54#	Form of Incentive Stock Option Agreement for awards granted pursuant to the 2004 Stock Incentive Plan	10-K for 12/31/2004	10.28	3/17/2005	000-49839
10.55#	Form of Non-Statutory Stock Option Agreement for awards granted pursuant to the 2004 Stock Incentive Plan	10-K for 12/31/2004	10.29	3/17/2005	000-49839
10.56#	2005 Stock Incentive Plan, as amended	10-Q for 6/30/2010	10.1	7/27/2010	000-49839
10.57#	2004 Stock Incentive Plan	S-1 Amendment 2	10.32	5/28/2004	333-111157
10.58#	Amended and Restated 1998 Equity Incentive Plan	S-1 Amendment 2	10.1	6/1/2004	333-111157
10.59#	Separation and General Release Agreement, dated as of December 23, 2010, by and between the Registrant and Jean-Pierre Sommadossi	8-K	10.1	12/30/2010	000-49839
10.60#	Employment Letter, dated December 1, 2010, by and between the Registrant and Ronald C. Renaud, Jr.	8-K	10.1	12/6/2010	000-49839
10.61#	Employment Letter, dated December 8, 2010, by and between the Registrant and Douglas L. Mayers, M.D.	10-K	10.60	3/7/2011	000-49839
10.62#	Employment Letter, dated December 9, 2010, by and between the Registrant and David N. Standring, PH.D.	10-K	10.61	3/7/2011	000-49839
10.63#	Employment Letter, dated November 30, 2010, by and between the Registrant and Maria Stahl	10-K	10.62	3/7/2011	000-49839
10.64#	Employment Letter, dated June 20, 2011, by and between the Registrant and Daniella Beckman	8-K	10.1	6/24/2011	000-49839

<u>Exhibit Number</u>	<u>Description</u>	<u>Incorporated by Reference to</u>			
		<u>Form</u>	<u>Exhibit No.</u>	<u>Filing Date</u>	<u>SEC File Number</u>
<b><i>Additional Exhibits</i></b>					
21.1	Subsidiaries of the Company	*			
23.1	Consent of PricewaterhouseCoopers LLP, an independent registered public accounting firm	*			
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended	*			
31.2	Certification of Interim Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended	*			
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	*			
32.2	Certification of Interim Chief Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	*			
101.INS	XBRL Instance Document				
101.SCH	XBRL Taxonomy Extension Schema Document				
101.CAL	XBRL Taxonomy Extension Calculations Linkbase Document				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				

\* Filed herewith

# Management contract or compensatory plan or arrangement filed as an exhibit to this report pursuant to Items 15(a) and 15(c) of Form 10-K

+ Confidential treatment requested as to certain portions, which portions have been separately filed with the Securities and Exchange Commission

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Subsidiaries

<u>Name of Subsidiary</u>	<u>State or Other Jurisdiction of Incorporation or Organization</u>
Idenix (Massachusetts) Inc.	Massachusetts
Idenix (Cayman) Limited	Cayman Islands
Idenix SARL*	France

\* Wholly-owned by Idenix (Cayman) Limited

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CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (File Nos. 333-118341, 333-128882, 333-143620 and 333-167330) and Form S-3 (File Nos. 333-127710, 333-129213, 333-153471, 333-159716, 333-173374 and 333-177167) of Idenix Pharmaceuticals, Inc. of our report dated March 6, 2012 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP  
Boston, Massachusetts  
March 6, 2012

CERTIFICATION PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ronald C. Renaud, Jr., certify that:

1. I have reviewed this Annual Report on Form 10-K of Idenix Pharmaceuticals, Inc. (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
  - c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of registrant’s board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: March 6, 2012

/s/ Ronald C. Renaud, Jr.  
Ronald C. Renaud, Jr.  
President and Chief Executive Officer

CERTIFICATION PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Daniella Beckman, certify that:

1. I have reviewed this Annual Report on Form 10-K of Idenix Pharmaceuticals, Inc. (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
  - c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of registrant’s board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: March 6, 2012

/s/ Daniella Beckman

Daniella Beckman  
Chief Financial Officer

CERTIFICATION PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Idenix Pharmaceuticals, Inc. (the "Company") for the period ended December 31, 2011 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Ronald C. Renaud, Jr., President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350 as adopted by Section 906 of the Sarbanes-Oxley Act of 2002, that, to his knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 6, 2012

/s/ Ronald C. Renaud, Jr.

Ronald C. Renaud, Jr.  
President and Chief Executive Officer

A signed original of this written statement required by Section 906 has been provided to Idenix Pharmaceuticals, Inc. and will be retained by Idenix Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

CERTIFICATION PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Idenix Pharmaceuticals, Inc. (the "Company") for the period ended December 31, 2011 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Daniella Beckman, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350 as adopted by Section 906 of the Sarbanes-Oxley Act of 2002, that, to her knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 6, 2012

/s/ Daniella Beckman \_\_\_\_\_

Daniella Beckman  
Chief Financial Officer

A signed original of this written statement required by Section 906 has been provided to Idenix Pharmaceuticals, Inc. and will be retained by Idenix Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

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# Stockholder Information

## Board of Directors

### Ronald C. Renaud, Jr.

President and Chief Executive Officer  
Idenix Pharmaceuticals, Inc.

### Brian Goff

Vice President, Head of Primary Care  
and Established Medicines  
Novartis Pharmaceuticals Corporation

### Wayne T. Hockmeyer, Ph.D.

Former Chairman of the Board of Directors  
MedImmune, Inc.

### Thomas R. Hodgson

Chairman of the Board  
Former President and Chief Operating Officer  
Abbott Laboratories

### Tamar D. Howson

Former Partner  
JSB-Partners

### Robert Pelzer

President  
Novartis Corporation

### Denise Pollard-Knight, Ph.D.

Managing Partner of Phase 4 Ventures

### Michael S. Wyzga

Chief Executive Officer  
Radius Health, Inc.

## Executive Team

### Ronald C. Renaud, Jr.

President and Chief Executive Officer

### Daniella Beckman

Senior Vice President, Chief Financial  
Officer and Treasurer

### Douglas L. Mayers, M.D.

Executive Vice President, Clinical Development  
and Chief Medical Officer

### David N. Standing, Ph.D.

Executive Vice President and  
Chief Scientific Officer

### Paul J. Fanning

Senior Vice President, Human Resources

### María D. Stahl

Senior Vice President, General Counsel  
and Secretary

## Annual Meeting

The Annual Meeting of Stockholders will be held on Thursday, June 7, 2012 at 9 a.m. Eastern Daylight Time, at the offices of WilmerHale, 60 State Street, Boston, Massachusetts.

## Transfer Agent

Computershare Trust Company, N.A.  
250 Royal Street  
Canton, Massachusetts 02021  
781-575-3400

## Outside Counsel

WilmerHale  
60 State Street  
Boston, Massachusetts 02109

## Independent Registered Public Accounting Firm

PricewaterhouseCoopers LLP  
125 High Street  
Boston, Massachusetts 02110

## Market Information

Idenix's common stock trades on the NASDAQ Global Market under the ticker symbol IDIX.

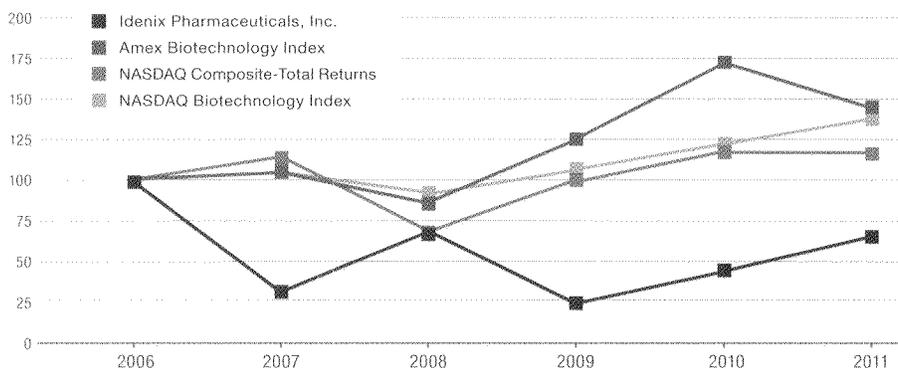
## Idenix Contact

Teri Dahlman  
Director  
Corporate Communications  
investor@idenix.com

## Corporate Headquarters

Idenix Pharmaceuticals, Inc.  
60 Hampshire Street  
Cambridge, Massachusetts 02139

## Comparative Stock Performance Graph



### Notes:

Data complete through last fiscal year.

Corporate Performance Graph with peer group uses peer group only performance (excludes only company).

Peer group indices use beginning of period market capitalization weighting.

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### CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains 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, as amended, concerning our business, operations and financial condition. All statements other than statement of historical facts included in this Annual Report may be deemed as forward-looking statements. Without limiting the foregoing, "expects", "anticipate", "intend", "may", "plan", "believe", "seek", "estimate", "projects", "will", "would" and similar expressions or express or implied discussions regarding potential clinical drug candidates or regarding future revenues from drug products, potential future expenditures or liabilities or any discussion of strategy, plans or intentions are also intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Because these forward-looking statements involve known and unknown risks and uncertainties, actual results, performance or achievements could differ materially from those expressed or implied by these forward-looking statements for a number of important reasons, including those discussed under "Risk Factors", "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in our Annual Report on Form 10-K for the year ended December 31, 2011 as filed with the U.S. Securities and Exchange Commission on March 6, 2012 (the "Annual Report on Form 10-K"). In particular, management's expectations could be affected by, among other things, uncertainties involved in the development of new pharmaceutical drug candidates, including unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; our ability to obtain or maintain patent or other proprietary intellectual property protection; our ability to maintain or enter into collaboration arrangements with third parties; competition in general; government, industry and general public pricing pressures; and uncertainties regarding necessary levels of expenditures in the future. There can be no guarantee that development of any drug candidates described will succeed or that any new drug products will obtain the necessary regulatory approvals required for commercialization or otherwise be brought to market. Similarly, there can be no guarantee that we or one or more of our current or future drug products, if any, will achieve any particular level of revenue.

You should be aware that the occurrence of any of the events described under "Risk Factors" and elsewhere in the Annual Report on Form 10-K could substantially harm our business, results of operations and financial condition and that upon the occurrence of any of these events, the price of our common stock could decline.

We cannot guarantee any future results, levels of activity, performance or achievements. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described in this Annual Report as anticipated, believed, estimated or expected. The forward-looking statements contained in this Annual Report represent our expectations as of the date of this Annual Report (unless another date is indicated) and should not be relied upon as representing our expectations as of any other date. While we may elect to update these forward-looking statements, we specifically disclaim any obligation to do so, even if our expectations change.

Information contained within the "Stockholder Information" section of this Annual Report is as of April 2, 2012.



IDENIX PHARMACEUTICALS, INC.  
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CAMBRIDGE, MASSACHUSETTS 02139  
[WWW.IDENIX.COM](http://WWW.IDENIX.COM)