

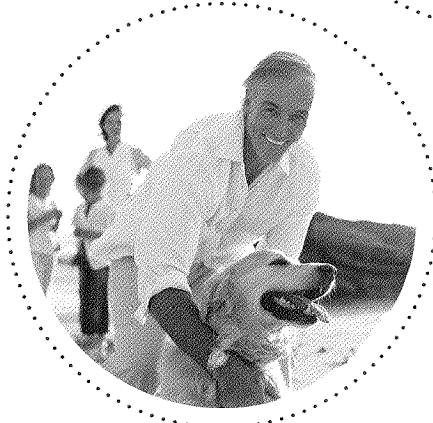
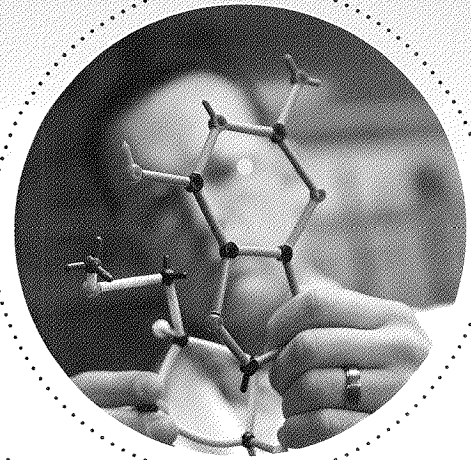
IDENIX PHARMACEUTICALS, INC.



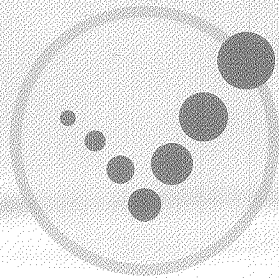
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2012 ANNUAL REPORT

# OLUTION. INNOVATION. PROGRESS.



# IMAGINE A WORLD WITHOUT HCV.

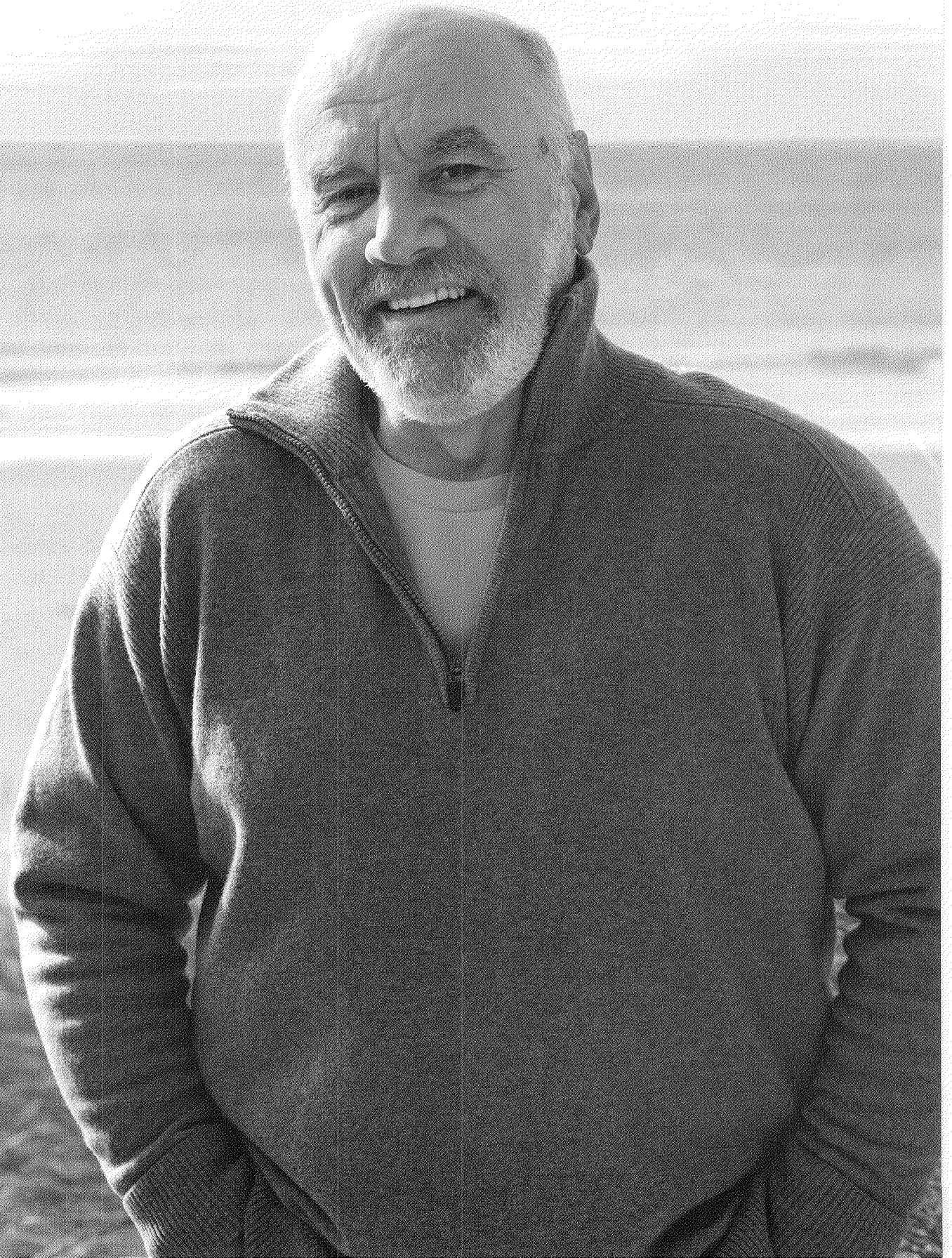


## **ABOUT IDENIX**

IDENIX PHARMACEUTICALS is engaged in the discovery and development of drugs for the treatment of human viral diseases. Idenix's current focus is on the treatment of hepatitis C virus (HCV) infections. Idenix discovered, co-developed and co-launched telbivudine (Tyzeka®/Sebivo®) for the treatment of HBV, for which Novartis Pharma AG now has worldwide commercialization rights. Idenix hopes to succeed in hepatitis C as well due to the global unmet medical need for this viral disease. It is estimated that more than 170 million people worldwide are chronically infected with HCV. The majority of those infected do not know it and current treatment can be ineffective and poorly tolerated. New all-oral combination HCV treatment regimens are on the horizon and Idenix's goal is to make an impact for patients through the advancement of its promising drug candidates.

Idenix is headquartered in Cambridge, Massachusetts. Its clinical development operations and drug discovery operations are conducted in Cambridge and in the Company's European laboratories in Montpellier, France.





# A MESSAGE TO OUR SHAREHOLDERS

In the past year, Idenix has made substantial progress toward our goal of initiating testing of all-oral combination therapies for the treatment of hepatitis C virus (HCV) infection. This will represent a true transformation in the way HCV will be treated for millions of patients. In addition, we believe it is paramount to develop treatments that will also be pan-genotypic. All-oral, pan-genotypic regimens that offer a "one size fits all" approach to HCV, by treating multiple strains, or genotypes, of the virus have the potential to have impact on a global scale.

With that goal as our focus, in 2012 and into 2013, Idenix advanced two different classes of drugs with promising profiles. Our lead program focuses on IDX719, a member of the class of NS5A inhibitors, which has demonstrated safe and potent viral reduction across HCV genotypes 1-4 in a three-day proof-of-concept study. To our knowledge, these are the first results to show pan-genotypic activity of an NS5A inhibitor candidate in the clinic.

Early this year, we entered into a non-exclusive collaboration with Janssen Pharmaceuticals, Inc. to evaluate all-oral HCV combination therapies including IDX719. We expect to initiate multiple all-oral combination trials in 2013 for IDX719, not only through the collaboration with Janssen, but also with a drug candidate from the second class of HCV drugs we are developing internally—nucleotide prodrug inhibitors.

Since Idenix's inception, much of our discovery efforts have focused on nucleosides/tides, and over the last two years we further raised the bar in this area based on our extensive

scientific expertise and strong intellectual property position. These efforts have culminated in the selection of a next-generation uridine analog, for which we plan to file an Investigational New Drug application (IND) in the first half of 2013. Pending clinical progress, we plan to evaluate the combination of IDX719 and our uridine analog by the end of 2013. We believe this would be one of the first all-oral, pan-genotypic HCV combinations of two direct-acting antiviral agents (DAAs) to enter the clinic. In addition to our uridine analog, we have several other nucleotide inhibitors from which we may select an additional candidate to bring forward toward the end of 2013.

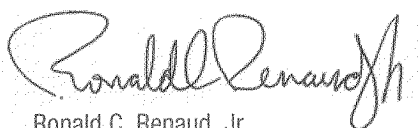
Further, as announced earlier this year, Idenix discontinued its development programs for IDX184 and IDX19368, two nucleotide inhibitor compounds that were placed on hold by the FDA due to severe cardiac adverse events seen in a competitor's phase II clinical trial. The decision to end these programs was a difficult one but made easier with the early promising results and progress of our next-generation nucleotide inhibitor program.

In addition, in 2012, we restructured the development and commercialization agreement with Novartis Pharma AG, which had been in place since 2003. Under the new agreement, Idenix regained the worldwide rights to develop, commercialize and license our drug candidates, and we believe this gives us increased flexibility to optimize the value of our pipeline, not only in HCV but also as we begin to explore other disease indications for which we could apply our nucleotide discovery capabilities.

As we look ahead, we anticipate 2013 will be a pivotal year for Idenix. With a strong cash position and promising HCV drug candidates, we are well-positioned to develop all-oral, pan-genotypic HCV combination treatments and look forward to further advancement of our programs in the coming year.

I want to thank our shareholders for their continued support and acknowledge the guidance of our scientific advisors and Board of Directors. I also want to recognize the talented group of employees at Idenix who work together to overcome challenges and seize opportunities and whose dedication and passion are the driving force behind our progress.

Sincerely,



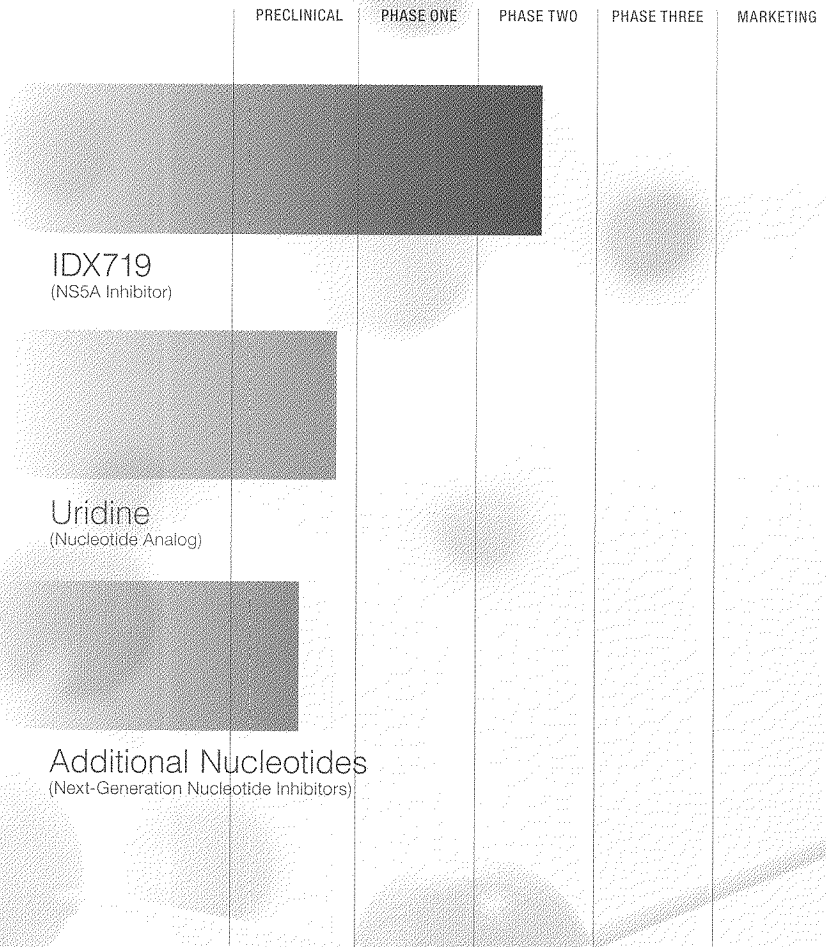
Ronald C. Renaud, Jr.  
President & Chief Executive Officer





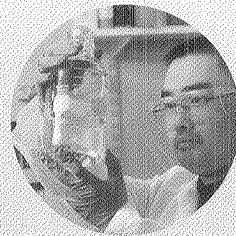
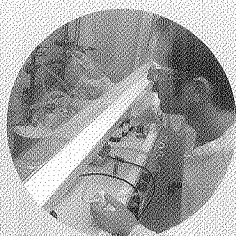
# DISCOVERING COMPOUNDS FOR A CURE

Idenix is focused on the development of all-oral combination therapies to cure hepatitis C and improve the lives of patients living with this life-threatening disease. The Company's goal is to bring compounds forward that have pan-genotypic antiviral activity and a favorable safety profile, can be administered once daily at low doses and are amenable to combination with other direct-acting antivirals. To date, Idenix's HCV pipeline compounds show promise toward achieving that goal. Furthermore, data from the all-oral combination studies expected to be initiated this year will potentially demonstrate that Idenix's drug candidates are key components of HCV combination treatments.



# IDX719 (NS5A INHIBITOR)

Idenix intends to initiate a phase II clinical trial evaluating IDX719 in combination therapy in 2013.



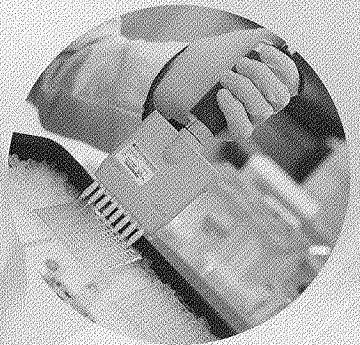
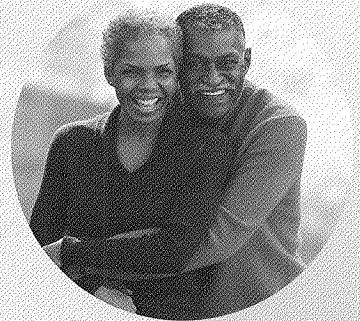
In 2012, Idenix conducted a phase I clinical study of IDX719, which evaluated single doses in healthy volunteers and HCV-infected patients. All doses were well-tolerated, pharmacokinetics supported once-daily dosing and antiviral activity confirmed the potent pan-genotypic results seen in preclinical studies. The Company subsequently conducted a three-day proof-of-concept study, which showed that IDX719 was well-tolerated in 64 treatment-naïve genotype 1, 2, 3 or 4 HCV-infected patients and achieved potent, pan-genotypic activity. In July 2012, the FDA granted Fast Track designation for IDX719 for the treatment of HCV.

In January 2013, Idenix announced a non-exclusive collaboration with Janssen Pharmaceuticals, Inc. for the clinical development of all-oral DAA HCV combination therapies. The collaboration will evaluate combinations including IDX719, simeprevir (TMC435), a once-daily protease inhibitor jointly developed by Janssen and Medivir AB, and TMC647055, a once-daily non-nucleoside polymerase inhibitor, boosted with low-dose ritonavir, being developed by Janssen. Clinical development plans include two-DAA and three-DAA phase II studies as agreed to by the companies, and pending approval from regulatory authorities.

# NUCLEOTIDE PRODRUG DEVELOPMENT

Over the past two years, Idenix intensified its discovery effort in next-generation nucleotide prodrug compounds by leveraging the Company's significant nucleotide chemistry expertise as well as its strong intellectual property position. Using enhanced screening criteria, Idenix plans to advance candidates into the clinic that have optimized *in vivo* triphosphate levels, liver-targeting specificity and a favorable preclinical safety profile. The lead candidate selected from several promising compounds is a uridine analog. Our goal is to submit an IND from this program in the first half of 2013. Two additional nucleotide prodrugs are in ongoing IND-enabling studies with potential IND submissions by year end. Idenix will continue to evaluate multiple candidates from this discovery program and has the potential to pursue the additional development of a combination of two nucleotide prodrugs, particularly with compounds that have non-overlapping resistance profiles.

We believe the Company's nucleoside discovery capability can also be applied to non-HCV therapeutic areas, and the Company is currently in the early stages of exploring new disease indications.



## MULTIPLE PATHS IN **2013**

With promising candidates from two HCV classes advancing in the clinic by the end of 2013, Idenix believes it will be well-positioned to evaluate multiple all-oral combination therapies for HCV. Idenix plans to initiate several all-oral combination studies, initially with IDX719 and external collaborators beginning in the first half of the year, and subsequently with IDX719 and its own nucleotide prodrug by year end.

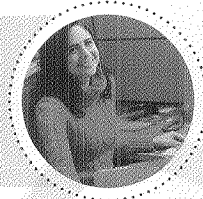
# CORPORATE VALUES

At Idenix, our corporate values—Innovation, Teamwork, Respect, Quality and Ownership—reflect a unique and dynamic culture.

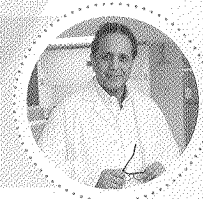
**INNOVATION.** Idenix is an innovative company striving for excellence in the discovery, development and commercialization of breakthrough advances for the treatment of life-threatening infectious diseases. By cultivating an environment of responsiveness and entrepreneurial spirit, we believe we can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



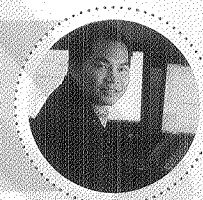
**TEAMWORK.** One team, many strengths. We can only be a successful company if we work together as a team—a team that is focused on action and results; one that communicates openly and honestly; one that maintains an engaging and positive spirit. We share in our successes, as well as in the insight we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



**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 shareholders play in driving Idenix forward to achieve this goal.



**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 disease.



**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.







FORM

10-K 2012

IDENIX PHARMACEUTICALS, INC.

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

Form 10-K

SEC  
Mail Processing  
Section

APR 26 2013

Washington DC  
405

(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, 2012

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)

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

60 Hampshire Street,  
Cambridge, Massachusetts  
(Address of Principal Executive Offices)

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, 2012 was approximately \$769.6 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 8, 2013 was 133,957,929 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 6, 2013 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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EX-10.24 Clinical Trial Collaboration Agreement, dated January 25, 2013, by and between the Registrant and Janssen Pharmaceuticals, Inc.

EX-21.1 Subsidiaries of the Company

EX-23.1 Consent of PricewaterhouseCoopers LLP

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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 France. Currently, our primary research and development focus is on the treatment of patients with 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 are seeking to build a combination development strategy, both internally and with partners, to advance the future of HCV treatments.

#### Business Highlights

##### HCV Programs

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

*Nucleotide Polymerase Inhibitors.* We believe that 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 nucleotide scientific expertise within our organization and should be able to leverage our intellectual patent portfolio to discover multiple novel nucleotide drug candidates.

In August 2012, the U.S. Food and Drug Administration, or FDA, placed IDX184, a novel liver-targeted nucleotide prodrug candidate and our most advanced program, on partial clinical hold and IDX19368, a next generation nucleotide polymerase inhibitor, on clinical hold due to serious cardiac adverse events observed with a competitor's nucleotide polymerase inhibitor, BMS-986094. These three compounds are guanosine-based nucleotide polymerase inhibitors. There are currently no patients worldwide receiving IDX184 and no patients have been dosed with IDX19368. In order to respond to the FDA regarding the clinical hold with respect to IDX184, we evaluated multiple cardiac safety measurements in our ongoing IDX184 phase II study and have observed no evidence of severe cardiac findings. In December 2012, we submitted a response package to the FDA for IDX184 and in February 2013, the FDA communicated to us that both of these programs will remain on clinical hold due to unresolved concerns regarding the potential for cardiac toxicity. As a result, we elected not to continue the development of these two programs. We intend to devote our resources to the development of IDX719, our NS5A inhibitor, and the discovery and development of additional novel nucleotide prodrugs as discussed below.

*Nucleotide Polymerase Inhibitor Discovery Program.* We believe that nucleotides will have a significant role in a combination DAA strategy for the treatment of HCV and therefore we have concentrated a substantial amount of our discovery efforts on this class of drugs. As part of our extensive nucleotide discovery effort, we have explored a diverse spectrum of nucleotides with novel bases, prodrugs and sugar moieties. Investigational new drug application, or IND, enabling studies have begun for a new uridine nucleotide prodrug and an IND is expected to be filed in the first half of 2013. We also expect to conduct IND-enabling studies for additional nucleotide prodrugs in 2013.

*NS5A Inhibitor.* Our lead drug candidate from our NS5A inhibitor program is IDX719, which has demonstrated potent, pan-genotypic activity in preclinical tests. In June 2012, we completed a three-day proof-of-concept study which demonstrated that IDX719 monotherapy was well-tolerated at daily doses up to 100 mg and showed potent antiviral activity across HCV genotypes 1-4, with mean maximal viral load reductions up to approximately 4.0 log<sub>10</sub> IU/mL.

We expect to initiate a drug-drug interaction study evaluating IDX719 and simeprevir (TMC435) in the first quarter of 2013 followed by phase II studies through a non-exclusive collaboration with Janssen Pharmaceuticals, Inc., or Janssen, as described more fully below.

In July 2012, the FDA granted Fast Track designation for IDX719. With a Fast Track designation, there is an opportunity for more frequent interactions with the FDA and the possibility of a priority review, which would reduce the length of the standard FDA review period leading to commercialization.

#### *August 2012 Underwritten Offering*

In August 2012, we issued approximately 25.3 million shares of our common stock pursuant to an underwritten offering and received \$190.5 million in net proceeds.

#### *Janssen Pharmaceuticals, Inc. Collaboration*

On January 25, 2013, we entered into a non-exclusive collaboration agreement with Janssen for the clinical evaluation of all oral DAA HCV combination therapies. The combination therapies involve IDX719, our once-daily pan-genotypic NS5A inhibitor, simeprevir (TMC435), a once-daily protease inhibitor jointly developed by Janssen and Medivir AB, or Medivir, and TMC647055, a once-daily non-nucleoside polymerase inhibitor, boosted with low dose ritonavir, being developed by Janssen.

Under the terms of this collaboration agreement, we will conduct the clinical trials. Clinical development plans include drug-drug interaction studies, followed by phase II studies as agreed between the companies, pending approval from regulatory authorities. The phase II program is expected to first evaluate the two-DAA combination of IDX719 and simeprevir (TMC435) plus ribavirin in treatment-naïve HCV-infected patients. Subsequently, the companies plan to evaluate a three-DAA combination of IDX719, simeprevir (TMC435), TMC647055 with low dose ritonavir, with and without ribavirin, in a broader group of HCV-infected patients.

#### *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. In May 2003, we also entered into a stockholders' agreement with Novartis and substantially all of our stockholders at that time, which we refer to as the stockholders' agreement. Under the development and commercialization agreement, we successfully co-developed and received worldwide marketing approval for telbivudine (Tyzeka®/Sebivo®), 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®/Sebivo®. Also under the development and commercialization agreement, Novartis had 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 maintained a certain ownership of our common stock. On July 31, 2012, we and Novartis materially modified our collaboration by executing a termination and revised relationship agreement, which we refer to as the termination agreement, and by amending the stockholders' agreement, which we refer to as the second amended and restated stockholders' agreement.

Under the termination agreement, Novartis' option right to license our current and future development-stage drug candidates in any therapeutic area was terminated. In exchange, we agreed to pay Novartis a royalty based on worldwide product sales of our future HCV drugs, unless they are used in combination with drugs from Novartis. The royalty percentage will vary based on the commercialized Idenix HCV drug. Further, Novartis has a non-exclusive option to conduct clinical trials evaluating a combination of any of our and Novartis' HCV drug candidates, subject to the drug candidates meeting several criteria. Novartis' ability to initiate combination trials expires on the seven year anniversary of the execution of the termination agreement, or July 2019. We no longer receive royalty or milestone payments from Novartis based upon worldwide product sales of Tyzeka®/Sebivo® for the treatment of HBV. Novartis is committed to reimburse us for payments to third-parties in connection with intellectual property related to Tyzeka®/Sebivo®. Novartis will retain the right to designate one member of our board of directors, reduced from two members, so long as it continues to own at least 15% of our common stock. Novartis has relinquished all other corporate governance rights, including approval rights over the authorization or issuance of additional shares of capital stock as well as significant acquisitions and dispositions. Novartis continues to have the right to participate in future public or private offerings of our securities in order to maintain its ownership and as of February 8, 2013, Novartis' ownership was 25% of our outstanding common stock.

## **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 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.

#### *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 in healthy volunteers and in July 2009, we successfully completed the proof-of-concept clinical trial in treatment-naïve HCV genotype 1-infected patients. In the fourth quarter of 2009, we initiated a phase IIa clinical trial for IDX184 in combination with pegylated interferon and ribavirin, or Peg-IFN/RBV, in treatment-naïve HCV genotype 1-infected patients. 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.

In July 2010, we conducted a 14 day phase I drug-drug interaction study of IDX184 and IDX320, a protease inhibitor, in 20 healthy volunteers. In September 2010, the FDA placed IDX184 and IDX320 on clinical hold due to the occurrence of three serious adverse events of liver injury in the study. In February 2011, the full clinical hold on IDX184 was removed and the program was placed on partial clinical hold, which allowed us to initiate a phase II 12-week clinical trial of IDX184 in July 2011. We believe the hepatotoxicity observed in this study was caused by IDX320 and therefore discontinued the clinical development of this drug candidate. Refer to the “Combination Drug-Drug Interaction Study” heading below for more details on the clinical hold in 2010.

In July 2011, we initiated a phase II clinical trial of IDX184 in treatment-naïve HCV genotype 1-infected patients. Patients were randomized to receive either 50 mg or 100 mg of IDX184, each for 12 weeks in combination with Peg-IFN/RBV. Patients received an additional 12 or 36 weeks of Peg-IFN/RBV, depending on virologic response. 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 FDA. In February 2012, the FDA removed the partial clinical hold on IDX184 and as a result we continued enrollment of the phase II study of IDX184. We completed enrollment in May 2012 with a total of 67 patients and we reported rates of rapid virologic response (RVR; virus levels < 25 IU/mL at four weeks) of 53% in the 50 mg arm and 55% in the 100 mg arm. Rates of complete early virologic response (cEVR; virus levels < 25 IU/mL at 12 weeks) were 76% in the 50 mg arm and 82% in the 100 mg arm. No patient experienced virologic breakthrough during the 12-week IDX184/Peg-IFN/RBV treatment period. The majority of patients are in the ongoing Peg-IFN/RBV extension treatment phase.

In July 2012, we submitted an IND for IDX19368, a next generation nucleotide polymerase inhibitor drug candidate. No patients have been dosed with IDX19368.

In August 2012, the FDA placed IDX184 on partial clinical hold and IDX19368 on clinical hold due to serious cardiac-related adverse events observed with a competitor’s nucleotide polymerase inhibitor, BMS-986094. These three compounds are guanosine-based nucleotide polymerase inhibitors. In previous clinical trials as well as in our ongoing phase II clinical trial of IDX184 in combination with Peg-IFN/RBV, we have observed no evidence of severe cardiac findings to date. No patients are currently receiving IDX184 and no patients have been dosed with IDX19368. In order to respond to the FDA’s concerns with respect to IDX184, we reviewed multiple cardiac safety measurements, *in vitro* cytotoxicity studies and *in vivo* animal studies using IDX184. In order to respond to the FDA’s concerns with respect to IDX19368, we conducted additional preclinical toxicology and metabolic studies. In December 2012, we submitted a response package to the FDA for IDX184 and in February 2013, the FDA communicated to us that both of these programs will remain on clinical hold due to unresolved concerns regarding the potential for cardiac toxicity. As a result, we elected not to continue the development of these two programs. We have agreed to two additional cardiac safety visits for the patients in the IDX184 phase II study at six months and 12 months following the echocardiograms we obtained when the clinical hold was initiated. We intend to devote our resources to the development of IDX719, our NS5A inhibitor, and the discovery and development of additional novel nucleotide prodrugs.

#### *Nucleotide Polymerase Inhibitor Discovery Program*

We believe that nucleotides will have a significant role in a combination DAA strategy for the treatment of HCV and therefore we have concentrated a substantial amount of our discovery efforts on this class of drugs. As part of our extensive nucleotide discovery effort, we have explored a diverse spectrum of nucleotides with novel

bases, prodrugs and sugar moieties. IND-enabling studies have begun for a new uridine nucleotide prodrug and an IND is expected to be filed in the first half of 2013. We also expect to conduct IND-enabling studies for additional nucleotide prodrugs in 2013.

#### *NS5A Inhibitor 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 of IDX719. The first part of the study evaluated the safety, pharmacokinetics and food effect of IDX719 in 48 healthy volunteers at single doses ranging from 5 mg to 100 mg. Eight healthy volunteers received 100 mg of IDX719 daily for seven days. All doses were well tolerated and pharmacokinetic data supported once-daily dosing in future studies. In the second quarter of 2012, we completed the second part of the phase I study, single-ascending doses of IDX719 in HCV genotype 1, 2 and 3-infected patients. IDX719 was well tolerated and demonstrated potent pan-genotypic antiviral activity with more than 3.0 log<sub>10</sub> IU/mL viral load reductions achieved in the 100 mg dose group.

In June 2012, we completed a three-day proof-of-concept study designed to evaluate 64 treatment-naïve HCV genotype 1, 2, 3 or 4-infected patients. HCV genotype 1 patients were randomized to receive placebo, 25 mg QD, 50 mg QD, 50 mg BID or 100 mg QD for three days. HCV genotype 2, 3 and 4 patients were randomized to receive placebo, 50 mg BID or 100 mg QD for three days. IDX719 was well tolerated with no treatment emergent serious adverse events reported. Treatment with IDX719 exhibited potent pan-genotypic activity across genotypes:

- in genotype 1a patients (n=29), mean maximal viral load reductions ranged from 3.2 log<sub>10</sub> IU/mL to 3.6 log<sub>10</sub> IU/mL across treatment groups;
- in genotype 1b patients (n=5), mean maximal viral load reductions were 3.0 log<sub>10</sub> IU/mL in the 25 mg QD arm, and 4.3 log<sub>10</sub> IU/mL in the 50 mg QD arm;
- in genotype 2 patients (n=10), the mean maximal viral load reduction was 2.0 log<sub>10</sub> IU/mL in both the 50 mg BID and 100 mg QD arms with a greater variability in responses among these patients (range: 0.3- 4.1 log<sub>10</sub> IU/mL). Four of the genotype 2 patients responded well to IDX719 treatment, and four patients had maximal reductions that were less than 1.0 log<sub>10</sub> IU/mL. The decrease in viral load response in genotype 2 patients was associated with the pre-existence or emergence of the M31 polymorphism in the HCV NS5A gene;
- in genotype 3 patients (n=10), mean maximal viral load reductions were 3.3 log<sub>10</sub> IU/mL in the 50 mg BID arm and 3.4 log<sub>10</sub> IU/mL in the 100 mg QD arm; and
- in genotype 4 patients (n=10), mean maximal viral load reductions were 3.9 log<sub>10</sub> IU/mL in the 50 mg BID arm and 3.6 log<sub>10</sub> IU/mL in the 100 mg QD arm.

No patients experienced a rebound (> 1.0 log<sub>10</sub> IU/mL increase over the lowest viral load) during the treatment period and maximum viral load reductions were typically achieved within 24 to 72 hours post dose. There were no safety-related discontinuations or treatment-emergent serious adverse events. IDX719 was safe and well tolerated at daily doses up to 100 mg for three days.

In July 2012, the FDA granted Fast Track designation for IDX719. With a Fast Track designation, there is an opportunity for more frequent interactions with the FDA and the possibility of a priority review, which would reduce the length of the standard FDA review period leading to commercialization.

In January 2013, we entered into a non-exclusive collaboration agreement with Janssen for the clinical evaluation of all oral DAA HCV combination therapies. The combination therapies involve IDX719, our once-daily pan-genotypic NS5A inhibitor, simeprevir (TMC435), a once-daily protease inhibitor jointly developed by Janssen and Medivir, and TMC647055 boosted with low dose ritonavir, being developed by Janssen.

Under the terms of this collaboration agreement, we will conduct the clinical trials. Clinical development plans include drug-drug interaction studies, followed by phase II studies as agreed between the companies, pending approval from regulatory authorities. The phase II program is expected to first evaluate the two-DAA combination of IDX719 and simeprevir (TMC435) plus ribavirin in treatment-naïve HCV-infected patients. Subsequently, the companies plan to evaluate a three-DAA combination of IDX719, simeprevir (TMC435), TMC647055 with low dose ritonavir, with and without ribavirin, in a broader group of HCV-infected patients.

#### *Other DAA Drug Candidates*

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. Subsequently, in 2011, we elected not to devote significant resources to our protease inhibitor program and reallocated these resources to the discovery and development of additional nucleotide drug candidates. We may evaluate potential partnerships and licensing agreements for this program and related intellectual property.

Our lead drug candidate for our non-nucleoside polymerase inhibitor program was IDX375, a novel palm-binding polymerase inhibitor. 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 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 drug-drug interaction study 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 IDX184 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 IDX320 placebo for the first week, subsequently adding 400 mg QD of IDX320 for the second week. There were three serious adverse events of elevated liver function tests and in September 2010, the FDA placed IDX184 and IDX320 on clinical hold. We believe the hepatotoxicity observed in this 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 II 12-week clinical trial of IDX184 in combination with Peg-IFN/RBV in July 2011. In February 2012, the FDA removed the partial clinical hold on IDX184 and as a result we continued enrollment of the phase II study of IDX184. Refer to the "Nucleotide Polymerase Inhibitors Development" heading above for more details on the IDX184 phase II clinical trial, subsequent partial clinical hold in August 2012 and discontinuation of the development of the IDX184 program.

#### *HIV*

We 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, including IDX899, now known as '761, 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. In the

fourth quarter of 2010, ViiV initiated a phase IIIb clinical study of ‘761 in HIV-infected patients. In February 2011, ViiV informed us that the FDA placed ‘761 on clinical hold and subsequently, the ViiV license agreement was terminated on March 15, 2012. Upon such termination, ViiV relinquished all rights it had in the intellectual property licensed from us and granted 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.

### ***Hepatitis B***

In collaboration with Novartis, we developed 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 Tyzeka®/Sebivo® in exchange for royalty payments equal to a percentage of net sales, with such percentage increasing according to specified tiers of net sales. Under the termination agreement executed in July 2012, we no longer receive royalty or milestone payments from Novartis based upon worldwide product sales of Tyzeka®/Sebivo® for the treatment of HBV.

### **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**

### ***Janssen Pharmaceuticals, Inc. Collaboration***

On January 25, 2013, we entered into a non-exclusive collaboration agreement with Janssen for the clinical evaluation of all oral DAA HCV combination therapies. The combination therapies involve IDX719, our once-daily pan-genotypic NS5A inhibitor, simeprevir (TMC435), a once-daily protease inhibitor jointly developed by Janssen and Medivir, and TMC647055, a once-daily non-nucleoside polymerase inhibitor, boosted with low dose ritonavir, being developed by Janssen.

Under the terms of this collaboration agreement, we will conduct the clinical trials. Clinical development plans include drug-drug interaction studies, followed by phase II studies as agreed between the companies, pending approval from regulatory authorities. The phase II program is expected to first evaluate the two-DAA combination of IDX719 and simeprevir (TMC435) plus ribavirin in treatment-naïve HCV-infected patients. Subsequently, the companies plan to evaluate a three-DAA combination of IDX719, simeprevir (TMC435), TMC647055 with low dose ritonavir, with and without ribavirin, in a broader group of HCV-infected patients.

The clinical trials will be conducted under an arrangement whereby Janssen provides us with clinical supply of simeprevir (TMC435) and TMC647055 at no cost. Neither party will receive any milestone or royalty payments from the other party under this agreement. Both companies retain all rights to their respective compounds under this agreement. The parties have no obligation to conduct additional clinical trials beyond those described here. Neither party has licensed any commercial rights to the other party.

This collaboration agreement may be terminated by either party in certain circumstances. This collaboration agreement will terminate if the parties do not agree to proceed with a two-DAA combination clinical trial of IDX719 and simeprevir (TMC435) plus ribavirin in treatment-naïve HCV-infected patients within a certain period of time following the drug-drug interaction study involving these two compounds. Janssen may terminate the collaboration agreement, in its sole discretion, by providing us with 30 days written notice. If Janssen terminates the collaboration agreement in such instance, it shall reimburse us for certain of our costs associated with the collaboration. Janssen may also terminate the collaboration agreement if we fail to meet certain formulation requirements.

If either us or Janssen materially breaches the collaboration agreement and does not cure such breach within a specified time period, the non-breaching party may terminate the collaboration agreement in its entirety. Either party may also terminate the collaboration agreement, effective immediately, if the other party files for bankruptcy, is dissolved or has a receiver appointed for substantially all of its property. Either party may also terminate the collaboration agreement to protect the safety, health or welfare of subjects in the trials. We may terminate the collaboration agreement prior to the commencement of certain activities if Janssen's research development and license agreement with Medivir is terminated.

Under the collaboration agreement, we agreed to indemnify Janssen against losses suffered as a result of its breach of representations and warranties in the agreement and/or any injury to a subject in a clinical trial under the collaboration agreement caused by the use or manufacture of IDX719. We made numerous representations and warranties to Janssen. If one or more of these representations or warranties were not true at the time they

were made, we would be in breach of the agreement. In the event of a breach by us or in the event of injury to a subject in a clinical trial under the collaboration agreement caused by the use or manufacture of IDX719, Janssen has the right to seek indemnification from us for damages suffered as a result of such breach or subject injury. The amounts for which we could be liable to Janssen under these circumstances may be substantial. In the instance where a subject in a clinical trial suffers injury or death and it is not determinable which compound caused the injury or death, each party shall be responsible for defending any third-party claims alleged against the party after the application of our clinical trial insurance, to the extent applicable.

### ***Novartis Collaboration***

On May 8, 2003, we entered into the development and commercialization agreement with Novartis related to the worldwide development and commercialization of our drug candidates. In July 2012, we and Novartis materially modified our collaboration by executing the termination agreement and the second amended and restated stockholders' agreement.

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

- the development and commercialization agreement, under which we collaborated with Novartis to develop, manufacture and commercialize our drug candidates which Novartis licensed from us;
- the manufacturing and supply agreement, under which Novartis manufactured for us the active pharmaceutical ingredient for the clinical development and, under certain circumstances, commercial supply of drug candidates Novartis licensed from us and for the finishing and packaging of licensed products;
- the stock purchase agreement, under which Novartis purchased approximately 54% of our then outstanding capital stock from certain 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;
- the stockholders' agreement, which was subsequently amended and restated in July 2004 and amended in April 2011, which provided Novartis with, among other things, registration rights, certain corporate governance rights including board representation and participation rights in future issuances of our securities; and
- a letter agreement, which was subsequently amended in January 2009 and April 2011. The letter agreement provided Novartis with rights regarding the selection, appointment and removal of our chief financial officer and other matters.

### **Termination Agreement**

#### ***Termination of Novartis' Option to License our Development Stage Drug Candidates***

Under the development and commercialization agreement, Novartis had 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 maintained at least 30% ownership of our voting stock. If Novartis licensed a drug candidate, the terms, including license fees, milestone payments and payments in reimbursement of development expenses, varied 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. For the drug candidates Novartis licensed, Novartis had the right to approve, in its reasonable discretion, the corresponding development budget. Each licensed product was developed in accordance with a development plan approved by a joint steering committee, which was comprised of an equal number of representatives from Idenix and Novartis. The development and commercialization agreement had several joint committees in which we and Novartis participated. We participated in these committees as a means to govern or protect our interests. The committees spanned the period from early development through commercialization of drug candidates licensed by Novartis.

In the past, Novartis licensed drugs or waived its option to license drugs under the development and commercialization agreement. In 2003, Novartis licensed Tyzeka®/Sebivo® from us for the treatment of HBV. In September 2007, we transferred to Novartis worldwide development, commercialization and manufacturing rights and obligations pertaining to Tyzeka®/Sebivo®. Subsequently, we began receiving royalty payments equal to a percentage of net sales of Tyzeka®/Sebivo®. The royalty percentage varied 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. In October 2009, Novartis waived its option to license IDX184.

Pursuant to the termination agreement executed in July 2012, Novartis' option right to license our current and future development-stage drug candidates in any therapeutic area was terminated. In exchange, we agreed to pay Novartis a royalty based on worldwide product sales of our HCV drug products, unless such drug products are prescribed in combination with Novartis' HCV drug products. The royalty percentage will vary based on our commercialized HCV drug product, but range from the high single digits to the low double digit percentages. Royalties are payable until the later to occur of: a) expiration of the last-to-expire of specified patent rights in a country; or b) ten years after the first commercial sale of a product in such country, provided that if royalties are payable on a product after the expiration of the patent rights in a country, each of the respective royalty rates for such product in such country would be reduced by one-half.

#### *Novartis' Non-Exclusive License to Conduct Combination Trials*

Pursuant to the termination agreement, we granted Novartis a non-exclusive license to conduct clinical trials evaluating a combination of any of our and Novartis' HCV drug candidates after the HCV drug candidates have completed dose-ranging studies, subject to meeting certain criteria. Under certain circumstances Novartis may conduct a dose-ranging study with respect to our HCV drug candidates. With respect to any combination trial, certain criteria must first be met prior to the commencement of such combination clinical trial, including, but not limited to: a) the Novartis HCV drug candidate at issue cannot be subject to any clinical hold imposed by a regulatory authority; and b) a drug-drug interaction study between the Novartis HCV drug candidate and our HCV drug candidate must be conducted by either Novartis or us. If the parties cannot agree to the initiation of a combination trial, an independent DSMB will determine whether or not the combination trial should be initiated based on the safety profile of each HCV drug candidate. We have agreed to supply Novartis with our HCV drug candidates for use in such combination trials. We and Novartis have agreed to use commercially reasonable efforts to, in good faith, enter into a supply agreement and other relevant agreements in connection with any such combination trial. Novartis' ability to initiate combination trials expires on the seven year anniversary of the execution of the termination agreement, or July 2019, although any then existing combination study commenced prior to such expiration date may continue after the expiration date.

#### *Product Sales of Tyzeka®/Sebivo® for the Treatment of HBV*

In 2003 under the development and commercialization agreement, Novartis licensed Tyzeka®/Sebivo® from us for the treatment of HBV. In September 2007, we and Novartis entered into an amendment to the development and commercialization agreement pursuant to which we transferred to Novartis worldwide development, commercialization and manufacturing rights and obligations pertaining to Tyzeka®/Sebivo®.

Under the termination agreement executed in July 2012, we no longer receive royalty or milestone payments from Novartis based upon worldwide product sales of Tyzeka®/Sebivo® for the treatment of HBV. Novartis is committed to reimburse us for contractual payments to third-parties in connection with intellectual property related to Tyzeka®/Sebivo®. We will otherwise be responsible for any payments to third-parties in connection with intellectual property necessary to sell Tyzeka®/Sebivo®.

### *Termination or Breach by Either Party*

If either we or Novartis materially breaches the termination agreement and does not cure such breach within 30 days, the non-breaching party may terminate this agreement in its entirety. Either party may also terminate this agreement, effective immediately, if the other party files for bankruptcy, is dissolved, or has a receiver appointed for substantially all of its property. Novartis may also terminate this agreement for convenience. If Novartis terminates this agreement either because of a material breach by us that has not been cured or because we have filed for bankruptcy, Novartis may, at its election, retain the licenses granted to it by us under the termination agreement to conduct clinical trials evaluating a combination of any of our HCV drug candidates and any of Novartis' HCV drug candidates and we would remain obligated to make royalty payments to Novartis on sales of our HCV drug products. If we terminate this agreement either because of a material breach by Novartis that has not been cured or because Novartis has filed for bankruptcy, or if Novartis terminates this agreement for convenience, the licenses granted to Novartis to conduct combination trials terminate and we would remain obligated to make royalty payments to Novartis on sales of our HCV drug products.

### *Indemnification*

We have agreed to indemnify Novartis and its affiliates against losses suffered as a result of the development, manufacture and commercialization of our HCV products. We have also agreed to indemnify Novartis and its affiliates against losses suffered as a result of any breach of representations and warranties in the termination agreement, 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 drug candidates for the treatment of HBV and HCV, including representations regarding ownership of related inventions and discoveries. In the event of a breach of any such representation or warranty by us, Novartis has the right to seek indemnification from us, and, under certain circumstances, from our stockholders who sold shares to Novartis in 2003 which includes certain of our current and former directors and officers, for damages suffered by Novartis as a result of such breach. The amounts for which we and our stockholders could be liable to Novartis could be substantial.

### *Future Agreements and Possible Competition with Novartis*

Under the termination agreement, following the receipt of certain data related to a combination trial and upon Novartis' request, we and Novartis are obligated to use, in good faith, commercially reasonable efforts to negotiate a future agreement for the development, manufacture and commercialization of such combination therapy for the treatment of HCV. Any future arrangement may set forth any co-promotion and co-marketing rights we may retain and any net benefit to us and Novartis attributable to such rights. Neither party is obligated to negotiate for a period longer than 180 days. Also under the termination agreement, Novartis has a non-exclusive license to conduct clinical trials evaluating a combination of any of our HCV drug candidates and any of Novartis' HCV drug candidates after certain criteria have been met. If Novartis obtains regulatory approval to co-label a Novartis HCV drug product with one or more of our HCV drug products, Novartis could market and sell a combination that may compete with our drug candidates and/or combination products that we market and sell in the future.

### **Stock Purchase Agreement**

On May 21, 2003, Novartis purchased approximately 54% of our then outstanding capital stock from our stockholders. In connection with Novartis' purchase of stock from our stockholders, we, Novartis and substantially all of our stockholders at that time entered into the stockholders' agreement which was amended and restated in 2004 and amended in April 2011. 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. The future contingent payments are payable in cash or, under certain circumstances, Novartis AG American Depository Shares. The stock purchase agreement remains unchanged and Novartis is still obligated to make such contingent payments.



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 “Termination Agreement”, “Risk Factors — Factors Related to Our Relationship with Novartis” and “Risk Factors — Factors Related to Patents and Licenses”.

### **Second Amended and Restated Stockholders’ Agreement**

In July 2012, we, Novartis and certain other stockholders entered into the second amended and restated stockholders’ agreement which includes the terms as described below.

#### *Novartis’ Registration Rights*

Under the second amended and restated stockholders’ agreement, Novartis maintains its rights to cause us to register for resale, under the Securities Act of 1933, as amended, shares held by Novartis and/or its affiliates.

#### *Corporate Governance Rights*

Under the stockholders’ agreement, we 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 owned at least 30% of our voting stock and at least one designee of Novartis for so long as Novartis and its affiliates owned at least 19.4% of our voting stock. Furthermore, Novartis had approval rights over a number of corporate actions that we or our subsidiaries may take, including the authorization or issuance of additional shares of capital stock and significant acquisitions and dispositions, as long as Novartis and its affiliates continued to own at least 19.4% of our voting stock.

Under the second amended and restated stockholders’ agreement executed in July 2012, we agreed to use our reasonable best efforts to nominate for election one designee of Novartis for so long as Novartis and its affiliates own at least 15% of our voting stock. Novartis maintains its rights to appoint a non-voting observer to any committee of our board of directors. All of Novartis’ other corporate governance rights, including its rights under the letter agreement, were terminated pursuant to the second amended and restated stockholders’ agreement.

#### *Novartis’ Stock Subscription Rights*

Under the stockholders’ agreement, Novartis had the right to purchase, at par value of \$0.001 per share, such number of shares as was required to maintain its percentage ownership of our voting stock if we issued 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 have been terminated under the second amended and restated stockholders’ agreement.

In addition to the right to purchase shares of our stock at par value as described above under the stockholders’ agreement, if we issued any shares of capital stock, other than in certain situations, Novartis had 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. Under the second amended and restated stockholders' agreement executed in July 2012, if we issue any shares of our capital stock, other than in limited situations, Novartis continues to have the right to purchase such number of shares required to maintain its percentage ownership of our voting stock for either the same consideration per share paid by others acquiring our stock or, in specified situations, for a 10% premium to the consideration per share paid by others acquiring our stock. Novartis' stock subscription 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".

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, November 2011 or August 2012. We issued 1.8 million shares of our common stock to Novartis for an aggregate purchase price of \$5.0 million 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 25% as of February 8, 2013.

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 retained the exclusive option to obtain rights to drug candidates developed by us so long as Novartis maintained 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 would use reasonable best efforts to nominate for election as directors at least two designees of Novartis so long as Novartis maintained 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 was required for the selection, appointment and removal of our chief financial officer so long as Novartis owned at least 30% of our common stock, rather than ownership of at least 40% as was the case prior to the amendment. These rights were terminated in July 2012 under the second amended and restated stockholders' agreement.

#### ***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 \$26.5 million in milestone payments for the achievement of a preclinical operational milestone and the initiation of a phase IIb clinical study of '761.

In February 2011, ViiV informed us that the FDA placed '761 on clinical hold and subsequently, the ViiV license agreement was terminated on March 15, 2012. Upon termination, ViiV relinquished all rights it had in the intellectual property licensed from us and granted 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 were not subject to early termination penalties under the ViiV license agreement.

Under the terms of the GSK stock purchase agreement, we 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 occurred after the first anniversary of the closing date.

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, 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.

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 were liable for certain payments to the University of Cagliari if we received 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 included provisions with respect to cost sharing, ownership and commercialization of the technology which was 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, milestone payments or any other 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, 2012, 2011 and 2010 were \$70.2 million, \$41.3 million and \$44.5 million, respectively, and represented 67%, 68% and 61%, 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 kilogram batch levels 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 by providing non-current good manufacturing practices materials in multi-kilogram quantities. 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**

Prior to August 2012, under the development and commercialization agreement, we granted Novartis an exclusive worldwide license to market and sell drug candidates that Novartis chose to license from us. The commercialization rights under the development and commercialization agreement also included our right to co-promote and co-market all licensed products in the United States, United Kingdom, France, Germany, Italy and Spain. In other countries, we would receive a royalty payment from Novartis based on net product sales.

Under the termination agreement with Novartis, following the receipt of certain data related to a combination trial and upon Novartis' request, we and Novartis are obligated to use, in good faith, commercially reasonable efforts to negotiate a future agreement for the development, manufacture and commercialization of such combination therapy for the treatment of HCV. Any future arrangement may set forth any co-promotion and co-marketing rights we may retain and any net benefit to us and Novartis attributable to such rights. Neither party

is obligated to negotiate for a period longer than 180 days. Also under the termination agreement, Novartis has a non-exclusive license to conduct clinical trials evaluating a combination of any of our HCV drug candidates and any of Novartis' HCV drug candidates after certain criteria have been met. If Novartis obtains regulatory approval to co-label a Novartis HCV drug product with one or more of our HCV drug products, Novartis could market and sell a combination that may compete with our drug candidates and/or combination products that we market and sell in the future.

## **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 26 issued U.S. patents, at least 22 pending U.S. patent applications, at least 69 granted foreign patents and at least 175 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.

In February 2012, an interference was declared by the United States Patent and Trademark Office, or the USPTO, concerning a patent application co-owned by us and a patent owned by Gilead Pharmasset LLC. Both the application and patent claim certain nucleoside compounds useful in treating HCV. While we cannot predict whether we will prevail, we intend to vigorously defend these actions and any others like it brought by any third-party. We do not believe our co-owned application at issue in the interference is relevant to any compounds we currently have under development. An interference is based upon complex specialized U.S. patent law and the interference proceeding is likely to be expensive and time consuming.

In June 2012, Gilead Sciences, Inc. filed suit against us in Canadian Federal Court seeking to invalidate one of our issued Canadian patents. Our patent, which is the subject of the Canadian litigation, covers similar subject

matter to that patent application at issue in the U.S. interference. In September 2012, Gilead Sciences, Ltd. filed suit against us in the Norway District Court of Oslo seeking to invalidate one of our issued Norwegian patents. Our patent at issue in the potential Norwegian litigation covers similar subject matter to that patent application at issue in the U.S. interference. In January 2013, Gilead Sciences Australia Pty Ltd. commenced proceedings in the Federal Court of Australia seeking a declaration that certain claims of one of our issued Australian patents, covering similar subject matter to that patent application at issue in the U.S. interference, are invalid and an order that such claims be revoked. We do not believe the respective patents at issue in these cases are relevant to any compounds we currently have under development. Gilead Sciences, Inc. may make similar claims or bring additional legal proceedings in the U.S. or other jurisdictions where we have granted patents. While we cannot predict whether we will prevail, we intend to vigorously defend these actions and any others like it brought by any third-party. These litigation proceedings are likely to be expensive and time consuming.

### ***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 50 granted foreign patents and at least four 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- $\beta$ -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 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 agreed to make additional payments to UABRF equal to 20% of all royalty payments received by us from Novartis from worldwide sales of Tyzeka<sup>®</sup>/Sebivo<sup>®</sup>, 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. Under the termination agreement we entered into with Novartis in July 2012, we no longer receive royalty or milestone payments from Novartis based upon worldwide product sales of Tyzeka<sup>®</sup>/Sebivo<sup>®</sup> for the treatment of HBV. Novartis is required to reimburse us for our contractual payments we make to UABRF.

## ***HIV Patent Portfolio***

Our HIV patent portfolio includes at least seven issued U.S. patents, one pending U.S. application, at least 70 granted foreign patents and at least 40 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 and 8,044,091 will each expire in 2025 and U.S. Patent No. 7,960,428 will expire in 2027, all of which 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.

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. Companies we expect to compete with in the HCV market include Abbott Laboratories, Achillion Pharmaceuticals, Inc., Biota Pharmaceuticals, Inc., Boehringer Ingelheim International GmbH, Bristol-Myers Squibb Company, Enanta Pharmaceuticals, Inc., F. Hoffman-LaRoche & Co., Gilead Sciences, Inc., GSK, Johnson & Johnson, Medivir, Merck & Co., Inc., Novartis, Presidio Pharmaceuticals, Inc. and Vertex 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.

Under the termination agreement, Novartis has a non-exclusive license to conduct clinical trials evaluating a combination of any of our HCV drug candidates and any of Novartis' HCV drug candidates after certain criteria have been met. If Novartis obtains regulatory approval to co-label a Novartis HCV drug product with one or more of our HCV drug products, Novartis could market and sell a combination that may compete with our drug candidates and/or combination products that we may market and sell in the future.

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. 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<sup>®</sup> in the United States. In 2007, Sebivo<sup>®</sup> 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 Tyzeka<sup>®</sup>/Sebivo<sup>®</sup>.

In June 2008, we submitted an IND with the FDA for IDX184, our 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 July 2012, we submitted an IND for IDX19368, a nucleotide polymerase inhibitor drug candidate.

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 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. 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 II 12-week clinical trial of IDX184 in July 2011 in combination with Peg-IFN/RBV. We provided an interim analysis of the first 31 patients following 28 days of treatment to an independent DSMB and to the FDA. In February 2012, the FDA removed the partial clinical hold on IDX184 and as a result we continued enrollment of the phase II study of IDX184. We completed enrollment in May 2012 with a total of 67 patients.

In August 2012, the FDA placed IDX184 on partial clinical hold and IDX19368 on clinical hold due to serious cardiac-related adverse events observed with a competitor's nucleotide polymerase inhibitor, BMS-986094. In December 2012, we submitted a response package to the FDA related to the partial hold on IDX184 and in February 2013, the FDA communicated to us that both of these programs will remain on clinical hold. As a result, we elected not to continue the development of these two programs.

### ***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 initial 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 over 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 an approximate 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 also 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 are now being 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, 2012, we had 107 full time employees. We had 81 employees engaged in research, development and manufacturing functions, 24 of whom hold Ph.D. degrees. We also had 26 employees engaged in administration and finance activities.

## **Available Information**

Our website address is [www.idenix.com](http://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](http://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 office is located at 60 Hampshire Street, Cambridge, Massachusetts 02139. The telephone number of our principal executive office 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 our Annual Report on Form 10-K for the year ended December 31, 2012 before deciding to invest in our securities.

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

***Regulatory agencies have expressed safety concerns following cardiac-related adverse events observed in nucleotide compounds previously in development for the treatment of patients with HCV. Our business may be adversely affected if such regulatory concerns lead to more burdensome preclinical or clinical studies that cause significant delays in developing our future nucleotide drug candidates.***

Our primary research and development focus is the treatment of patients with HCV. In August 2012, the FDA placed IDX184, our most advanced HCV compound under clinical development, on partial clinical hold,

and IDX19368, an HCV nucleotide inhibitor, on clinical hold. Both of these holds were due to serious cardiac-related adverse events observed with a competitor's nucleotide polymerase inhibitor, BMS-986094. These three compounds are guanosine-based nucleotide polymerase inhibitors. In February 2013, the FDA communicated to us that IDX184 and IDX19368 will remain on clinical hold due to unresolved concerns regarding the potential for cardiac toxicity. As a result, we elected not to continue the development of these two programs. If the FDA or other regulatory agencies continue to express safety concerns regarding the possibility of cardiac-related adverse events with respect to nucleotide drug candidates, future preclinical and clinical studies involving such compounds may be more burdensome or include additional preclinical or clinical end-points that are difficult to meet. In such instance, our progress in the development of these drug candidates may be significantly slowed. If our development timelines are significantly slowed, our business may be adversely affected.

***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 for the treatment of HCV, IDX184 and IDX320, were placed on clinical hold by the FDA following a 14-day drug-drug interaction study of a combination of IDX184 and IDX320 in healthy volunteers. We discontinued the clinical development of IDX320. In February 2011, the IDX184 program was placed on partial clinical hold, which allowed us to initiate a phase II 12-week clinical trial of IDX184 in HCV-infected patients in July 2011. In February 2012, the FDA removed the partial clinical hold on IDX184. In August 2012, the FDA placed IDX184 on partial clinical hold and IDX19368 on clinical hold due to serious cardiac-related adverse events observed with a competitor's nucleotide polymerase inhibitor, BMS-986094. In February 2013, the FDA communicated to us that both of these programs will remain on clinical hold. As a result, we elected not to continue the development of these two programs. 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. We expect to report a net loss for the next several years as we continue to expand our drug discovery and development efforts. Tyzeka®/Sebivo®, our only product to reach commercialization, is marketed by Novartis and we received royalty payments associated with sales of this product through July 2012. Subsequent to July 2012, under the termination agreement entered into with Novartis, we no longer receive royalty or milestone payments from Novartis based upon worldwide product sales of Tyzeka®/Sebivo® for the treatment of HBV. We will not be able to generate 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 and 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.***

We believe our cash and cash equivalents balance at December 31, 2012 will be sufficient to sustain operations into at least the second half of 2014. 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 we enter into development and commercialization agreements with third-parties and receive related license fees, milestone payments and development expense reimbursement payments thereunder with respect to our drug candidates.

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.

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 August 2012, the FDA placed IDX184, our most advanced HCV compound under clinical development, on partial clinical hold, and IDX19368, an HCV nucleotide inhibitor, on clinical hold. Both of these holds were due to serious cardiac-related adverse events observed with a competitor's nucleotide polymerase inhibitor, BMS-986094. In previous clinical trials as well as our ongoing phase II clinical trial of IDX184 in combination with Peg-IFN/RBV, we have observed no evidence of severe cardiac findings to date. We reviewed additional preclinical and clinical data and conducted further testing to respond to the FDA's concerns with respect to IDX19368. In December 2012, we submitted a response package to the FDA and in February 2013, the FDA communicated to us that both of these programs will remain on clinical hold due to unresolved concerns regarding the potential for cardiac toxicity. As a result, we elected not to continue the development of these two programs.

Drug candidates we discover, license or acquire will require additional and likely substantial development, including formulation optimization, 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, 2012, all of our cash and cash equivalents were invested in money market funds. 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 HCV, Peg-IFN/RBV, Incivek (telaprevir) and Victrelis (boceprevir) are approved by the FDA for commercial sale. Increased costs associated with the evolving standard of care treatment regimens and the cure rates of patients using 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 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.

Under the termination agreement, Novartis has a non-exclusive license for a period of seven years from July 2012 to conduct clinical trials evaluating a combination of any of our HCV drug candidates and any of Novartis' HCV drug candidates after each drug candidate has completed a dose-ranging study. If Novartis obtains regulatory approval to co-label a Novartis HCV drug with one or more of our HCV drugs, Novartis could market and sell a combination that may compete with our drug candidates and/or combination products that we market and sell in the future. In addition, Novartis may market, sell, promote or license other competitive products. Novartis has significantly greater financial, technical and human resources than we have, is better equipped to discover, develop, manufacture and commercialize products, and 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.

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 drug candidates, if any, that 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 and Pharmasset, Inc., by F. Hoffman-LaRoche & Co. and Gilead Sciences, Inc., 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 invest in 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 require us 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®/Sebivo®, 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®/Sebivo®. For Tyzeka®/Sebivo®, product liability claims could be made against us based on the use of our drug candidates in clinical trials we conducted prior to 2007. We have obtained product liability insurance for Tyzeka®/Sebivo® 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. Different assumptions could yield materially different financial results.

***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 independent registered 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 operations in France;
- 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. In June 2012, the License Commission granted an extension of the July 2010 variance until the end of the original lease term, or December 31, 2013. 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; or b) 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 our ability, or that of any future collaboration partner, to successfully commercialize other products we may successfully develop.

Our drug candidates are in various 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 August 2012, the FDA placed IDX184, our most advanced HCV compound under clinical development, on partial clinical hold, and IDX19368, an HCV nucleotide inhibitor, on clinical hold. Both of these holds were due to serious cardiac-related adverse events observed with a competitor's nucleotide polymerase inhibitor, BMS-986094. In February 2013, the FDA communicated to us that both of these programs will remain on clinical hold. As a result, we elected not to continue the development of these two programs.

***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. In August 2012, the FDA placed IDX184 on partial clinical hold and IDX19368 on clinical hold. Both of these holds were due to serious cardiac-related adverse events observed with a competitor's nucleotide polymerase inhibitor, BMS-986094. In February 2013, the FDA communicated to us that both of these programs will remain on clinical hold. As a result, we elected not to continue the development of these two programs. 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 candidates.

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 terminations 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 own or any future 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; 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 any future 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 any 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 future 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 any partner to generate revenues from a particular drug candidate. In August 2012, the FDA placed IDX184 on partial clinical hold and IDX19368 on clinical hold. In February 2013, the FDA communicated to us that both of these programs will remain on clinical hold. As a result, we elected not to continue the development of these two programs. In February 2011, ViiV informed us that the FDA placed '761, our product candidate for the treatment of HIV which we licensed to ViiV in 2009, on clinical hold and subsequently, the ViiV license agreement was terminated on March 15, 2012. Furthermore, any regulatory approval to market a product may be subject to limitations on the indicated uses for which we or any partner may market the product. These restrictions may limit the size of the market for the product. Additionally, drug candidates we or any future 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 any 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 any future partners fail to comply with applicable United States and foreign regulations, we or such 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 any 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 any 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 any 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 any 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 any collaboration partners fail to comply with applicable continuing regulatory requirements, we or such 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 any future partners fail to comply with ongoing regulatory requirements after receipt of approval to commercialize a product, we or such 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 future 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 bloodborne 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**

***If we breach any of the numerous representations and warranties we made to Novartis under the development and commercialization agreement, the termination 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, the termination agreement and the stock purchase agreement. Under these agreements, 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, our stockholders who sold shares to Novartis, which include some 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 products associated with certain technology. Such payments would be due even in the instance where we licensed such technology to a third-party. Novartis may seek to recover from us and, under certain circumstances, 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 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 agreed to make additional payments to UABRF equal to 20% of all royalty payments received by us from Novartis based on worldwide sales of Tyzeka<sup>®</sup>/Sebivo<sup>®</sup>, subject to minimum payment obligations aggregating \$11.0 million. Novartis may seek to recover from us and, under certain circumstances, those of our officers, directors and other stockholders who sold shares to Novartis, losses it suffers as a result of any breach of the representations and warranties we made to Novartis relating to our HBV drug candidates and may assert that such losses include the settlement payments. Under the termination agreement we entered into with Novartis in July 2012, Novartis is required to reimburse us for our contractual payments we make to UABRF under the settlement agreement.

***If we issue capital stock, in certain situations, Novartis will be able to purchase a pro rata portion of shares that we may issue to maintain its percentage ownership in Idenix.***

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 either 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 or, in specified situations, for a 10% premium to the consideration per share paid by others acquiring our stock. 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 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.

Except as noted above, 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, November 2011 or August 2012. 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 25% as of February 8, 2013.

***The safety or efficacy profile of any of our HCV clinical candidates may differ in combination with other existing or future drugs used to treat HCV, including those being developed by Novartis, and therefore may preclude the further development or approval of our HCV clinical candidates, which could materially harm our business.***

Phase II and phase III clinical trials of other DAAs similar to those being developed by us are now being conducted in combination with the current standard of care and increasingly, with other DAAs in clinical development. Therefore, the clinical development and commercialization pathway for our product candidates we may develop in the future for the treatment of HCV will require that it be evaluated during clinical trials in combination with other existing or future DAAs. When combined with other HCV therapies, our product candidates may demonstrate unexpected side effects even if our product candidates demonstrate meaningful therapeutic benefits equal to or better than our competitors' compounds, an acceptable safety profile, and a dose amenable to combination therapy in phase I and other early-stage clinical trials. Under limited circumstances, Novartis has rights to combine its HCV clinical candidates, including alisporivir, with our HCV clinical candidates, including IDX719. Although we elected to discontinue the development of IDX184 in February 2013, Novartis may elect to perform certain combination trials with IDX184 and its clinical candidates, subject to regulatory approval. We believe the optimized treatment of HCV will involve the combination of three or more antiviral compounds. We cannot assure that any of our HCV clinical candidates will be amenable for use in combination with some, or any, existing therapies or those in clinical development, including HCV clinical candidates developed by Novartis now or in the future.

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

Following the receipt of certain data related to a combination trial and upon Novartis' request, we and Novartis are obligated to use, in good faith, commercially reasonable efforts to negotiate a future agreement for the development, manufacture and commercialization of such combination therapy for the treatment of HCV. Neither party is obligated to negotiate for a period longer than 180 days. We may not be able to obtain terms that are favorable to us, including obtaining co-promotion and co-marketing rights or a reasonable royalty for future sales of combination therapies including our HCV drug candidates. If we do enter into such an agreement, we will likely depend upon the success of the efforts of Novartis to manufacture, market and sell such combination therapies, if any, that are successfully developed. We will 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.

If Novartis were to breach or terminate a future commercialization 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.

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

***If we seek to enter into collaboration agreements for any drug candidates 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. We may seek to enter into collaboration agreements with other pharmaceutical companies to fund all or part of the costs of drug development and commercialization of drug candidates. We may seek a partner who will assist in the future development and commercialization of our drug candidates for the treatment of HCV, as we have with Janssen. The terms and conditions of our termination agreement with Novartis may discourage other third-parties from entering into future collaboration agreements and relationships with us. We may not be able to enter into collaboration agreements and the terms of any such collaboration agreements may not be favorable to us. In August 2012, the FDA placed IDX184, our most advanced HCV compound under clinical development, on partial clinical hold and IDX19368 on clinical hold. Both of these holds were due to serious cardiac-related adverse events observed with a competitor's nucleotide polymerase inhibitor, BMS-986094. In previous clinical trials as well as our ongoing phase II clinical trial of IDX184 in combination with Peg-IFN/RBV we have observed no evidence of severe cardiac findings to date. In February 2013, the FDA communicated to us that both of these programs will remain on clinical hold due to unresolved concerns regarding the potential for cardiac toxicity. As a result, we elected not to continue the development of these two programs. Even if the FDA permits us to develop future drug candidates, 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 collaboration agreement with Janssen is important to our business. The development of IDX719, our NS5A inhibitor, in combination with other DAAs could be significantly delayed if Janssen terminates or fails to perform its obligations under its agreement with us.***

In January 2013, we entered into a non-exclusive collaboration agreement with Janssen for the clinical evaluation of all oral DAA HCV combination therapies. The combination therapies involve IDX719, our once-daily pan-genotypic NS5A inhibitor, simeprevir (TMC435), a once-daily protease inhibitor jointly developed by Janssen and Medivir, and TMC647055, a once-daily non-nucleoside polymerase inhibitor, boosted with low dose ritonavir, being developed by Janssen.

If Janssen was to breach or terminate its agreement with us or fail to perform its obligations to us in a timely manner, the development of IDX719 in combination with other DAAs could be significantly delayed. Any delay or termination of this type could have a material adverse effect on our business.

***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 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 U.S. patent law in part by changing the standard for patent approval from a “first to invent” standard to a “first inventor to file” standard and developing a post-grant review system. This new legislation affects U.S. patent law in a manner that may impact our ability to obtain or maintain patent protection for current or future inventions in the U.S. or otherwise cause uncertainty as to our patent protection.

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 at least 18 months after their filing. In some cases, patent applications remain confidential in the USPTO 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 inventors to file, patent applications on our product or drug candidates or for their uses. In the event that another party has filed a U.S. patent application covering the same invention as one of our patent applications or patents, we may have to participate in an adversarial proceeding, known as an interference, declared by the USPTO to determine priority of invention in the United States. In February 2012, an interference was declared by the USPTO concerning a patent application co-owned by us and a patent owned by Gilead Pharmasset LLC. Both the application and patent claim certain nucleoside compounds useful in treating HCV. While we cannot predict whether we will prevail, we intend to vigorously defend these actions and any others like it brought by any third-party. We do not believe our co-owned application at issue in the interference is relevant to any compounds we currently have under development. An interference is based upon complex specialized U.S. patent law and the interference proceeding is likely to be expensive and time consuming.

The costs of these proceedings could be substantial and it is possible that our efforts could be unsuccessful, potentially resulting in loss of our U.S. patent application at issue in the interference, which as noted above is not relevant to any compounds we currently have under development. 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 the termination agreement, we have agreed to transfer all our rights to patents and patent applications associated with telbivudine to Novartis.

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 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 agreed to make additional payments to UABRF equal to 20% of all royalty payments received by us from Novartis based on worldwide sales of Tyzeka<sup>®</sup>/Sebivo<sup>®</sup>, subject to minimum payment obligations in the aggregate of \$11.0 million. Under the termination agreement, we no longer receive royalty or milestone payments from Novartis based upon worldwide product sales of Tyzeka<sup>®</sup>/Sebivo<sup>®</sup> for the treatment of HBV. Novartis is required to reimburse us for our contractual payments we make to UABRF under the settlement agreement.

In accordance with our patent strategy, we are attempting to obtain patent protection for our HCV drug candidates, including IDX719. We have filed U.S. and foreign patent applications for our drug candidates, and in some jurisdictions have obtained patent protection, related to specific compounds, as well as to methods of treating HCV with such compounds. 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 and/or our NS5A inhibitor, IDX719. 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., Bristol-Myers Squibb Company, Enanta Pharmaceuticals, Inc., Presidio Pharmaceuticals, Inc. 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 USPTO 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, Canada, Australia 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.

In June 2012, Gilead Sciences, Inc. filed suit against us in Canadian Federal Court seeking to invalidate one of our issued Canadian patents. Our patent, which is the subject of the Canadian litigation, covers similar subject matter to that patent application at issue in the U.S. interference. In September 2012, Gilead Sciences, Ltd. filed suit against us in the Norway District Court of Oslo seeking to invalidate one of our issued Norwegian patents. Our patent at issue in the potential Norwegian litigation covers similar subject matter to that patent application at issue in the U.S. interference. In January 2013, Gilead Sciences Australia Pty Ltd. commenced proceedings in the Federal Court of Australia seeking a declaration that certain claims of one of our issued Australian patents, covering similar subject matter to that patent application at issue in the U.S. interference, are invalid and an order that such claims be revoked. We do not believe the respective patents at issue in these cases are relevant to any compounds we currently have under development. Gilead Sciences, Inc. may make similar claims or bring additional legal proceedings in other jurisdictions where we have granted patents. While we cannot predict whether we will prevail, we intend to vigorously defend these actions and any others like it brought by any third-party. These litigation proceedings are likely to 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 HCV that could materially affect the ability to develop and commercialize current drug candidates 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 USPTO. 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;
- rights concerning our licenses;
- 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 IDX184, our former nucleotide polymerase inhibitor drug candidate, and patents generally related to nucleoside/nucleotide inhibitors.

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, termination 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, 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 future 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 compounds Novartis previously licensed from us. 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 compounds Novartis previously licensed from us. 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. Our relationship with Cagliari ended in December 2010 although many of the terms remain in effect for the duration of the patent life of the affected products. 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 and CNRS, respectively, 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:

- 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 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;
- the decision by Novartis to initiate a combination trial with one of our HCV drug candidates;
- 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, such as the clinical holds placed on IDX184 and IDX19368 in August 2012;
- 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; and
- general and industry-specific economic conditions.

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 8, 2013, we had 133,957,929 shares of common stock issued and outstanding, together with outstanding options to purchase 7,554,969 shares of common stock with a weighted average exercise price of \$7.60 per share.

Novartis has rights, subject to certain conditions, to require us to file registration statements covering their shares or to include its shares in registration statements that we may file for ourselves.

***Novartis' ownership of our common stock could delay or prevent a change in corporate control.***

As of February 8, 2013, Novartis owned approximately 25% of our outstanding common stock. This concentration of ownership may harm the market price of our common stock by:

- delaying, deferring or preventing a change in control of our company;
- impeding a merger, consolidation, takeover or other business combination involving our company; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company.

***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:

- the results of our clinical trials pertaining to any of our drug candidates, including the results of our collaboration with Janssen;
- 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;
- 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 August 2012, we experienced a significant decline in our stock price based, in part, on the FDA's decision to place a partial clinical hold on IDX184 and a clinical hold on IDX19368, 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, 2012, 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	April 2013
Montpellier, France	35,215 sq. ft.	Office and Laboratory	April 2017

On September 25, 2012, we entered into a seven year lease agreement for 46,418 square feet of office and laboratory space located at 320 Bent Street in Cambridge, Massachusetts beginning on or about April 1, 2013. As part of this lease agreement, we will terminate our current lease for 39,014 square feet of office and laboratory space in Cambridge, Massachusetts when we take possession of the new space on or about April 1, 2013. Refer to the footnotes to the financial statements to this Annual Report on Form 10-K for more details.

### **Item 3. Legal Proceedings**

In February 2012, an interference was declared by the USPTO, concerning a patent application co-owned by us and a patent owned by Gilead Pharmasset LLC. Both the application and patent claim certain nucleoside compounds useful in treating HCV. While we cannot predict whether we will prevail, we intend to vigorously defend these actions and any others like it brought by any third-party. We do not believe our co-owned application at issue in the interference is relevant to any compounds we currently have under development. An interference is based upon complex specialized U.S. patent law. In the event we do not prevail in the interference, certain or all claims in our application may not be issued. In the event we do not prevail, we do not believe we will be required to make any payments to any third-parties.

In June 2012, Gilead Sciences, Inc. filed suit against us in Canadian Federal Court seeking to invalidate one of our issued Canadian patents. Our patent, which is the subject of the Canadian litigation, covers similar subject matter to that patent application at issue in the U.S. interference. In September 2012, Gilead Sciences, Ltd. filed suit against us in the Norway District Court of Oslo seeking to invalidate one of our issued Norwegian patents. Our patent at issue in the potential Norwegian litigation covers similar subject matter to that patent application at issue in the U.S. interference. In January 2013, Gilead Sciences Australia Pty Ltd. commenced proceedings in the Federal Court of Australia seeking a declaration that certain claims of one of our issued Australian patents, covering similar subject matter to that patent application at issue in the U.S. interference, are invalid and an order that such claims be revoked. We do not believe the respective patents at issue in these cases are relevant to any compounds we currently have under development. Gilead Sciences, Inc. may make similar claims or bring additional legal proceedings in the U.S. other jurisdictions where we have granted patents. While we cannot predict whether we will prevail, we intend to vigorously defend these actions and any others like it brought by any third-party. In the event we do not prevail, we do not believe we will be required to make any payments to any third-parties.

### **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 8, 2013 the closing price of our common stock, as reported on the NASDAQ Global Market, was \$4.73 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>2012</b>		
First quarter .....	\$15.25	\$7.00
Second quarter .....	11.05	7.17
Third quarter .....	11.30	4.32
Fourth quarter .....	5.43	3.35
<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

#### Stockholders

On February 8, 2013, we had approximately 43 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,				
	2012	2011	2010	2009	2008
	(In Thousands, Except per Share Data)				
<b>Consolidated Statements of Operations Data:</b>					
Total revenues	\$ 69,663	\$ 6,951	\$ 10,222	\$ 12,616	\$ 10,049
Operating expenses:					
Cost of revenues	2,654	2,324	2,765	2,210	1,745
Research and development	70,182	41,341	44,506	41,867	53,887
General and administrative	24,163	16,694	23,439	21,467	27,130
Intangible asset impairment	8,045	—	—	—	—
Restructuring charges	—	—	2,238	1,506	297
Total operating expenses	105,044	60,359	72,948	67,050	83,059
Loss from operations	(35,381)	(53,408)	(62,726)	(54,434)	(73,010)
Other income, net	2,892	1,368	1,131	1,266	2,848
Income tax benefit (expense)	89	61	40	(51)	(44)
Net loss	\$ (32,400)	\$ (51,979)	\$ (61,555)	\$ (53,219)	\$ (70,206)
Basic and diluted net loss per common share	\$ (0.27)	\$ (0.57)	\$ (0.87)	\$ (0.87)	\$ (1.24)
Shares used in computing basic and diluted net loss per common share	118,755	90,831	70,715	61,498	56,403
	December 31,				
	2012	2011	2010	2009	2008
	(In Thousands)				
<b>Consolidated Balance Sheets Data:</b>					
Cash and cash equivalents	\$ 230,826	\$ 118,271	\$ 46,115	\$ 46,519	\$ 41,509
Working capital	221,860	73,313	29,496	33,236	30,465
Total assets	250,865	141,044	69,884	76,650	79,780
Deferred revenue	—	36,068	2,623	1,025	—
Deferred revenue, related party	714	2,897	3,036	6,155	5,965
Deferred revenue, net of current portion	4,272	4,272	40,340	19,393	4,272
Deferred revenue, related party, net of current portion	3,988	24,382	28,588	30,776	35,790
Other long-term liabilities	7,513	10,640	12,058	13,590	12,789
Accumulated deficit	(708,115)	(675,715)	(623,736)	(562,181)	(508,962)
Total stockholders' equity (deficit)	219,160	51,225	(31,096)	(5,453)	7,353

## 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 are seeking to build a combination development strategy, both internally and with partners, to advance the future of HCV treatments. We believe that 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 nucleotide scientific expertise within our organization and should be able to leverage our intellectual patent portfolio to develop additional novel nucleotide drug candidates.

The following table summarizes key information regarding our pipeline of HCV drug candidates as well as telbivudine (Tyzeka®/Sebivo®):

<u>Indication</u>	<u>Product/Drug Candidates/Programs</u>	<u>Description</u>
HCV	Nucleotide Polymerase Inhibitor (IDX184)	<p>In September 2010, the U.S. Food and Drug Administration, or FDA, placed two of our HCV drug candidates, IDX184 and our protease inhibitor, IDX320, on clinical hold. The hold was imposed following a 14-day drug-drug interaction study of a combination of IDX184 and IDX320 in 20 healthy volunteers. We believe hepatotoxicity observed in this drug-drug interaction study was caused by IDX320 and therefore discontinued the clinical development of IDX320. In February 2011, the full clinical hold on IDX184 was removed.</p> <p>In July of 2011, we initiated the phase II clinical trial of IDX184 in treatment-naïve HCV genotype 1-infected patients under a partial clinical hold. We provided an interim analysis of the first 31 patients following 28 days of treatment to the FDA and in February 2012, the partial clinical hold was removed. We completed enrollment in May 2012 with a total of 67 patients and we reported rates of rapid virologic response (RVR; virus levels &lt; 25 IU/mL at 4 weeks) of 53% in the 50 mg arm and 55% in the 100 mg arm. Rates of complete early virologic response (cEVR; virus levels &lt; 25 IU/mL at 12 weeks) were 76% in the 50 mg arm and 82% in the 100 mg arm. No patient experienced virologic breakthrough during the 12-week IDX184 and pegylated interferon and ribavirin, or Peg-IFN/RBV, treatment period. The majority of patients are in the ongoing Peg-IFN/RBV extension treatment phase.</p> <p>In August 2012, the FDA placed IDX184 on partial clinical hold due to serious cardiac-related adverse events observed with a competitor's nucleotide polymerase inhibitor, BMS-986094. In previous clinical trials as well as in our ongoing phase II clinical trial of IDX184 in combination with Peg-IFN/RBV, we have</p>

Indication	Product/Drug Candidates/Programs	Description
		<p>observed no evidence of severe cardiac findings to date. In December 2012, we submitted a response package to the FDA and in February 2013, the FDA communicated to us that this program will remain on clinical hold due to unresolved concerns regarding the potential for cardiac toxicity. As a result, we elected not to continue the development of IDX184.</p>
	<p>Nucleotide Polymerase Inhibitor (IDX19368)</p>	<p>In July 2012, we submitted an investigational new drug application, or IND, for IDX19368, our lead candidate for a nucleotide polymerase inhibitor drug candidate. In August 2012, the FDA placed IDX19368 on clinical hold due to serious cardiac-related adverse events observed with a competitor's nucleotide polymerase inhibitor, BMS-986094. No patients have been dosed with IDX19368. In order to respond to the FDA's concerns with respect to IDX19368, we conducted additional preclinical toxicology and metabolic studies. In February 2013, the FDA communicated to us that this program will remain on clinical hold due to unresolved concerns regarding the potential for cardiac toxicity. As a result, we elected not to continue the development of IDX19368.</p>
	<p>Nucleotide Polymerase Inhibitor Discovery Program</p>	<p>As part of the ongoing extensive nucleotide discovery effort, we are exploring a diverse spectrum of nucleotides with novel bases, prodrugs and sugar moieties. IND-enabling studies have begun for a new uridine nucleotide prodrug and an IND is expected to be filed in the first half of 2013. We also anticipate conducting IND-enabling studies for additional nucleotide prodrugs in 2013.</p>
	<p>NS5A Inhibitors (IDX719)</p>	<p>In January 2012, we initiated a phase I clinical study of IDX719. The first part of the study evaluated the safety, pharmacokinetics and food effect of IDX719 in 48 healthy volunteers at single doses ranging from 5 mg to 100 mg. Eight healthy volunteers received 100 mg of IDX719 daily for seven days. All doses were well tolerated and pharmacokinetic data supports once-daily dosing in future studies. In the second quarter of 2012, we completed the second part of the phase I study, single-ascending doses of IDX719 in HCV genotype 1, 2 and 3-infected patients. IDX719 was well tolerated and demonstrated potent pan-genotypic antiviral activity with more than 3.0 log<sub>10</sub> viral load reductions achieved in the 100 mg dose group.</p> <p>In June 2012, we also completed a three-day proof-of-concept study designed to evaluate 64 treatment-naïve HCV genotype 1, 2, 3 or 4-infected patients. HCV genotype 1 patients were randomized to receive placebo, 25 mg QD (once-daily), 50 mg QD, 50 mg BID (twice-daily) or 100 mg QD for three days. HCV genotype 2, 3 and 4 patients were randomized to receive placebo, 50 mg BID or 100 mg QD for three days. IDX719 was well tolerated with no treatment emergent serious adverse events reported. Treatment with IDX719 exhibited potent pan-genotypic activity across genotypes:</p> <ul style="list-style-type: none"> <li>• in genotype 1a patients (n=29), mean maximal viral load reductions ranged from 3.2 log<sub>10</sub> IU/mL to 3.6 log<sub>10</sub> IU/mL across treatment groups;</li> </ul>



Indication	Product/Drug Candidates/Programs	Description
		<ul style="list-style-type: none"> <li>• in genotype 1b patients (n=5), mean maximal viral load reductions were 3.0 log<sub>10</sub> IU/mL in the 25 mg QD arm, and 4.3 log<sub>10</sub> IU/mL in the 50 mg QD arm;</li> <li>• in genotype 2 patients (n=10), the mean maximal viral load reduction was 2.0 log<sub>10</sub> IU/mL in both the 50 mg BID and 100 mg QD arms with a greater variability in responses among these patients (range: 0.3- 4.1 log<sub>10</sub> IU/mL). Four of the genotype 2 patients responded well to IDX719 treatment, and four patients had maximal reductions that were less than 1.0 log<sub>10</sub> IU/mL. The decrease in viral load response in genotype 2 patients was associated with the pre-existence or emergence of the M31 polymorphism in the HCV NS5A gene;</li> <li>• in genotype 3 patients (n=10), mean maximal viral load reductions were 3.3 log<sub>10</sub> IU/mL in the 50 mg BID arm and 3.4 log<sub>10</sub> IU/mL in the 100 mg QD arm; and</li> <li>• in genotype 4 patients (n=10), mean maximal viral load reductions were 3.9 log<sub>10</sub> IU/mL in the 50 mg BID arm and 3.6 log<sub>10</sub> IU/mL in the 100 mg QD arm.</li> </ul> <p>In July 2012, the FDA granted Fast Track designation for IDX719. With a Fast Track designation, there is an opportunity for more frequent interactions with the FDA and the possibility of a priority review, which would reduce the length of the standard FDA review period leading to commercialization.</p> <p>We expect to initiate a drug-drug interaction study evaluating IDX719 and simeprevir (TMC435) in the first quarter of 2013 followed by phase II studies with Janssen Pharmaceuticals, Inc., or Janssen, through a non-exclusive collaboration. Refer to the Janssen Pharmaceuticals, Inc. Collaboration heading below for further details.</p>
HBV	Tyzeka®/Sebivo® (telbivudine) (L-nucleoside)	Novartis Pharma AG, or Novartis, had worldwide development, commercialization and manufacturing rights and obligations related to Tyzeka®/Sebivo®. Prior to August 2012, we received royalty payments equal to a percentage of net sales of Tyzeka®/Sebivo®. Refer to the Novartis Collaboration heading below for details on the modification of the collaboration and the Tyzeka®/Sebivo® royalties.

In August 2012, the FDA placed IDX184 on partial clinical hold and IDX19368 on clinical hold due to serious cardiac-related adverse events observed with a competitor's nucleotide polymerase inhibitor, BMS-986094. These three compounds are guanosine-based nucleotide polymerase inhibitors. In order to respond to the FDA's concerns with respect to IDX184, we reviewed multiple cardiac safety measurements, *in vitro* cytotoxicity studies and *in vivo* animal studies using IDX184. In order to respond to the FDA's concerns with respect to IDX19368, we conducted additional preclinical toxicology and metabolic studies. In December 2012, we submitted a response package to the FDA related to the partial clinical hold on IDX184 and in February 2013, the

FDA communicated to us that both of these programs will remain on clinical hold due to unresolved concerns regarding the potential for cardiac toxicity. As a result, we elected not to continue the development of these two programs. We have agreed to two additional cardiac safety visits for the patients in the IDX184 phase II study at six months and 12 months following the echocardiograms we obtained when the clinical hold was initiated. We intend to devote our resources to the development of IDX719 and the discovery and development of additional novel nucleotide prodrugs.

All of our drug candidates are currently in preclinical or early 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,		
		2012	2011	2010
		(In Thousands)		
HCV	Nucleotide Polymerase Inhibitors	\$22,413	\$ 9,303	\$ 8,412
HCV	NS5A Inhibitor	17,431	5,479	5
HCV	Preclinical discovery program and other	3,912	257	508
HCV	Non-Nucleoside Polymerase Inhibitor	—	1,720	3,678
HCV	Protease Inhibitors	—	308	5,468
HCV	Combination drug-drug interaction study	—	6	747
HIV	Non-Nucleoside Reverse Transcriptase Inhibitor	—	—	(26)
		<u>\$43,756</u>	<u>\$17,073</u>	<u>\$18,792</u>

As shown in the table above, in 2012 our focus continued to be on the development of our nucleotide polymerase inhibitors program, which primarily included completing enrollment of the IDX184 phase II clinical trial and IND-enabling studies for IDX19368. During 2012, we also completed a phase I and proof-of-concept study for our NS5A inhibitor, IDX719. In 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 nucleotide polymerase inhibitors.

We have incurred significant losses each year since our inception in May 1998 and at December 31, 2012, we had an accumulated deficit of \$708.1 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 and cash equivalents will be sufficient to sustain operations into at least the second half of 2014.

#### ***Janssen Pharmaceuticals, Inc. Collaboration***

On January 25, 2013, we entered into a non-exclusive collaboration agreement with Janssen for the clinical evaluation of all oral direct DAA HCV combination therapies. The combination therapies involve IDX719, our

once-daily pan-genotypic NS5A inhibitor, simeprevir (TMC435), a once-daily protease inhibitor jointly developed by Janssen and Medivir AB, or Medivir, and TMC647055, a once-daily non-nucleoside polymerase inhibitor, boosted with low dose ritonavir, being developed by Janssen.

Under the terms of this collaboration agreement, we will conduct the clinical trials. Clinical development plans include drug-drug interaction studies, followed by phase II studies as agreed between the companies, pending approval from regulatory authorities. The phase II program is expected to first evaluate the two-DAA combination of IDX719 and simeprevir (TMC435) plus ribavirin in treatment-naïve HCV-infected patients. Subsequently, the companies plan to evaluate a three-DAA combination of IDX719, simeprevir (TMC435), TMC647055 with low dose ritonavir, with and without ribavirin, in a broader group of HCV-infected patients.

The clinical trials will be conducted under an arrangement whereby Janssen provides us with clinical supply of simeprevir (TMC435) and TMC647055 at no cost. Neither party will receive any milestone or royalty payments from the other party under this agreement. Both companies retain all rights to their respective compounds under this agreement. The parties have no obligation to conduct additional clinical trials beyond those described here. Neither party has licensed any commercial rights to the other party.

This collaboration agreement may be terminated by either party in certain circumstances. This collaboration agreement will terminate if the parties do not agree to proceed with a two-DAA combination clinical trial of IDX719 and simeprevir (TMC435) plus ribavirin in treatment-naïve HCV-infected patients within a certain period of time following the drug-drug interaction study involving these two compounds. Janssen may terminate the collaboration agreement, in its sole discretion, by providing us with 30 days written notice. If Janssen terminates the collaboration agreement in such instance, it shall reimburse us for certain of our costs associated with the collaboration. Janssen may also terminate the collaboration agreement if we fail to meet certain formulation requirements.

If either us or Janssen materially breaches the collaboration agreement and does not cure such breach within a specified time period, the non-breaching party may terminate the collaboration agreement in its entirety. Either party may also terminate the collaboration agreement, effective immediately, if the other party files for bankruptcy, is dissolved or has a receiver appointed for substantially all of its property. Either party may also terminate the collaboration agreement to protect the safety, health or welfare of subjects in the trials. We may terminate the collaboration agreement prior to the commencement of certain activities if Janssen's research development and license agreement with Medivir is terminated.

### ***Novartis Collaboration***

In May 2003, we entered into a collaboration with Novartis relating to the worldwide development and commercialization of our drug candidates, which we refer to as the development and commercialization agreement. In May 2003, we also entered into a stockholders' agreement with Novartis, which we refer to as the stockholders' agreement. On July 31, 2012, we and Novartis materially modified our collaboration by executing a termination and revised relationship agreement, which we refer to as the termination agreement, and by amending the stockholders' agreement, which we refer to as the second amended and restated stockholders' agreement.

Under the development and commercialization agreement, Novartis had 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 maintained at least 30% ownership of our voting stock. Pursuant to the termination agreement executed in July 2012, Novartis' option right to license our current and future development-stage drug candidates in any therapeutic area was terminated. In exchange, we have agreed to pay Novartis a royalty based on worldwide product sales of our HCV drug products, unless such drug products are prescribed in combination with Novartis' HCV drug products. The royalty percentage will vary based on our commercialized HCV drug product and range from the high single digits to the low double digit percentages. Royalties are payable until the

later to occur of: a) expiration of the last-to-expire of specified patent rights in a country; or b) ten years after the first commercial sale of a product in such country, provided that if royalties are payable on a product after the expiration of the patent rights in a country, each of the respective royalty rates for such product in such country would be reduced by one-half.

Pursuant to the termination agreement, we granted Novartis a non-exclusive license to conduct clinical trials evaluating a combination of any of our and Novartis' HCV drug candidates after the HCV drug candidates have completed dose-ranging studies, subject to meeting certain criteria. Under certain circumstances Novartis may conduct a dose-ranging study with respect to our HCV drug candidates. With respect to any combination trial, certain criteria must first be met prior to the commencement of such combination clinical trial. If the parties cannot agree to the initiation of a combination trial, an independent data safety monitoring board will determine whether or not the combination trial should be initiated based on the safety profile of each HCV drug candidate. We have agreed to supply Novartis with our HCV drug candidates for use in such combination trials. We and Novartis have agreed to use commercially reasonable efforts to, in good faith, enter into a supply agreement and other relevant agreements in connection with any such combination trial. Novartis' ability to initiate combination trials expires on the seven year anniversary of the execution of the termination agreement, or July 2019, although any then existing combination study commenced prior to such expiration date may continue after the expiration date.

Prior to the execution of the termination agreement, the balance of deferred revenue, related party was \$24.7 million. Since neither vendor-specific objective evidence, or VSOE, or third-party evidence, or TPE, for the non-exclusive license deliverable was available, we determined the best estimate of selling price, or BESP, of the non-exclusive license at July 31, 2012 to be \$5.0 million. We recognized the excess deferred revenue over the BESP, or \$19.7 million, as collaborative revenue – related party in the three months ended September 30, 2012. The remaining deferred revenue of \$5.0 million is being recognized as revenue on a straight-line basis over the term of the non-exclusive license, or seven years. During the year ended December 31, 2012, we recognized \$0.3 million of collaboration revenue related to the non-exclusive license and as of December 31, 2012, we had a balance of \$4.7 million of deferred revenue, related party in our consolidated balance sheet.

Under the termination agreement, following the receipt of certain data related to a combination trial and upon Novartis' request, we and Novartis are obligated to use, in good faith, commercially reasonable efforts to negotiate a future agreement for the development, manufacture and commercialization of such combination therapy for the treatment of HCV. Any future arrangement may set forth any co-promotion and co-marketing rights we may retain and any net benefit to us and Novartis attributable to such rights. Neither party is obligated to negotiate for a period longer than 180 days. Under the termination agreement, Novartis has a non-exclusive license to conduct clinical trials evaluating a combination of any of our HCV drug candidates and any of Novartis' HCV drug candidates after certain criteria have been met. If Novartis obtains regulatory approval to co-label a Novartis HCV drug product with one or more of our HCV drug products, Novartis could market and sell a combination that may compete with our drug candidates and/or combination products that we market and sell in the future.

In 2003, under the development and commercialization agreement, Novartis licensed Tyzeka<sup>®</sup>/Sebivo<sup>®</sup> from us for the treatment of hepatitis B virus, or HBV. In September 2007, we and Novartis entered into an amendment to the development and commercialization agreement pursuant to which we transferred to Novartis worldwide development, commercialization and manufacturing rights and obligations pertaining to Tyzeka<sup>®</sup>/Sebivo<sup>®</sup>. Subsequently, we began receiving royalty payments equal to a percentage of net sales of Tyzeka<sup>®</sup>/Sebivo<sup>®</sup> through July 31, 2012, the date of the termination agreement. Subsequent to July 31 2012, we no longer receive royalty or milestone payments from Novartis based upon worldwide product sales of Tyzeka<sup>®</sup>/Sebivo<sup>®</sup> for the treatment of HBV. Novartis is committed to reimburse us for our contractual payments to third-parties in connection with intellectual property related to Tyzeka<sup>®</sup>/Sebivo<sup>®</sup>. We will otherwise be responsible for any payments to third-parties in connection with intellectual property necessary to sell Tyzeka<sup>®</sup>/Sebivo<sup>®</sup>. The receivables from related party balance of \$7.4 million at December 31, 2012 consisted of the reimbursement by Novartis of the contractual payments to third-parties.

In July 2012, we, Novartis and certain other stockholders entered into the second amended and restated stockholder's agreement under which Novartis maintains its rights to cause us to register for resale, under the Securities Act of 1933, as amended, shares held by Novartis and/or its affiliates and we agreed to use our reasonable best efforts to nominate for election one designee of Novartis for so long as Novartis and its affiliates own at least 15% of our common stock. As of February 8, 2013, Novartis owned approximately 25% of our outstanding common stock.

***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 \$26.5 million in milestone payments for the achievement of a preclinical operational milestone and the initiation of a phase IIb clinical study of '761.

In February 2011, ViiV informed us that the FDA placed '761 on clinical hold and subsequently, the ViiV license agreement was terminated on March 15, 2012. During the first quarter of 2012, as a result of the termination, we recognized the deferred revenue balance of \$36.1 million as other collaboration revenue which was included in the consolidated statement of operations during the year ended December 31, 2012.

**Results of Operations**

***Comparison of Years Ended December 31, 2012 and 2011***

*Revenues*

Revenues for the years ended December 31, 2012 and 2011 were as follows:

	<b>Years Ended December 31,</b>	
	<b>2012</b>	<b>2011</b>
	<b>(In Thousands)</b>	
Collaboration revenue—related party:		
License fee revenue .....	\$23,327	\$ (183)
Royalty revenue .....	2,923	4,511
Reimbursement of royalties .....	7,345	—
	<u>33,595</u>	<u>4,328</u>
Other revenue:		
Collaboration revenue .....	36,068	2,623
Total revenues .....	<u>\$69,663</u>	<u>\$6,951</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, 2012, 2011 and 2010, collaboration revenue — related party was comprised of the following:

- through July 31, 2012, license and other fees received from Novartis for the license of HBV and HCV drug candidates, net of changes for Novartis' stock subscription rights, which were being recognized over the development period of our licensed drug candidates; subsequent to July 31, 2012, the value of the non-exclusive license that we granted to Novartis for combination trials pursuant to the termination agreement, net of changes for Novartis' stock subscription rights, which are being recognized over the term of the non-exclusive license, or seven years;
- through July 31, 2012, royalty payments associated with product sales of Tyzeka®/Sebivo® made by Novartis; and
- subsequent to July 31, 2012, reimbursement of royalties pursuant to Novartis' requirement to reimburse us for our contractual payments to the University of Alabama at Birmingham, or UAB, in connection with intellectual property related to Tyzeka®/Sebivo®.

Collaboration revenue — related party was \$33.6 million in 2012 as compared to \$4.3 million in the same period in 2011. The \$29.3 million increase was primarily due to the recognition of \$19.7 million representing the excess of deferred revenue over the BEP of the non-exclusive license granted to Novartis for combination trials pursuant to the termination agreement. Additionally, license fee revenue increased \$4.8 million in 2012 related to the impact of Novartis' stock subscription rights. Reimbursement of royalties consisted of \$7.3 million recognized as a result of Novartis' requirement under the termination agreement to reimburse us for our contractual payments to UAB in connection with intellectual property related to Tyzeka®/Sebivo®.

Collaboration revenue recognized under the ViiV license agreement was \$36.1 million in 2012 as compared to \$2.6 million in 2011. The ViiV license agreement was terminated on March 15, 2012 and as a result we recognized the deferred revenue balance of \$36.1 million as other collaboration revenue in the first quarter of 2012.

#### *Cost of Revenues*

Cost of revenues were \$2.7 million in 2012 as compared to \$2.3 million in 2011. The increase of \$0.4 million was primarily due to the recognition of deferred expenses related to the termination of the ViiV license agreement on March 15, 2012.

#### *Research and Development Expenses*

Research and development expenses were \$70.2 million in 2012 as compared to \$41.3 million in 2011. The increase of \$28.9 million was primarily due to \$17.6 million of expenses related to our phase II clinical trial of IDX184 and our clinical trials of IDX719 in 2012. Additionally, expenses increased \$7.8 million related to preclinical costs of IDX19368 and \$3.4 million related to our preclinical discovery program.

We expect our research and development expenses for 2013 to be higher than the amount incurred in 2012 mainly due to the development of our current clinical candidates and the expansion of our research pipeline.

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 \$24.2 million in 2012 as compared to \$16.7 million in 2011. The increase of \$7.5 million was primarily due to additional legal costs associated with the U.S. patent interference and patent litigation in various jurisdictions.

We expect our general and administrative expenses in 2013 to be significantly higher than those incurred in 2012 primarily due to expected higher legal costs associated with patent litigation in various jurisdictions.

### *Intangible Asset Impairment*

Under the termination agreement, we no longer receive royalty or milestone payments from Novartis based upon worldwide product sales of Tyzeka<sup>®</sup>/Sebivo<sup>®</sup> for the treatment of HBV. We concluded that the intangible asset was effectively abandoned on the effective date of the termination agreement since there are no future cash flows associated with its use and the intangible asset has no alternate future use. As a result, the carrying value of the related intangible asset is not recoverable and we recorded an impairment charge of \$8.0 million in our consolidated statement of operations during the year ended December 31, 2012.

### *Other Income, Net*

Other income, net was \$2.9 million in 2012 as compared to \$1.4 million in 2011. The increase of \$1.5 million was primarily due to the reversal of reserves related to foreign research and development credits because the statute of limitations expired.

### *Income Tax Benefit*

Income tax benefit was less than \$0.1 million in 2012 which was substantially unchanged as compared to 2011.

### ***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 .....	4,511	3,800
	<u>4,328</u>	<u>6,231</u>
Other revenue:		
Collaboration revenue .....	2,623	3,954
Government grants .....	—	37
Total revenues .....	<u>\$6,951</u>	<u>\$10,222</u>

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.

#### *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.

#### *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.

#### *Restructuring Charges*

In 2010, we recorded restructuring charges of \$2.2 million for employee severance costs related to the reduction of our workforce in the United States and France. 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*

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

### **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 through July 31, 2012;
- license, milestone and stock purchase payments from ViiV and GSK through March 15, 2012;
- reimbursements from Novartis for costs we have incurred subsequent to May 8, 2003 in connection with the development of Tyzeka®/Sebivo® and compounds Novartis previously licensed from us;



- 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, November 2011 and August 2012;
- net proceeds from private placements of our common stock concurrent with our public offerings in 2004, 2005 and April 2011; and
- proceeds from the exercise of stock options granted pursuant to our equity compensation plans.

Prior to August 2012, any financing requiring the issuance of additional shares of capital stock had to be first approved by Novartis for so long as Novartis continued to own at least 19.4% of our voting stock. This right was terminated in July 2012 under the second amended and restated stockholders' agreement with Novartis and therefore Novartis' approval was not required for the underwritten offering in August 2012. We received Novartis' approval for the following offerings in 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%. 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 this offering;
- 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 retained the exclusive option to obtain rights to drug candidates developed by us so long as Novartis maintained 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 maintained 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 was required for the selection, appointment and removal of our chief financial officer so long as Novartis owned 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.

In July 2012, we filed a universal, automatically effective, well-known seasoned issuer shelf registration statement with the SEC for the issuance, in one or more public offerings, of common stock, debt securities and other securities at prices and on terms to be determined at the time of the applicable offering. In August 2012, we issued 25.3 million shares of our common stock under this shelf registration and received \$190.5 million in net proceeds.

We have incurred losses in each year since our inception and at December 31, 2012, we had an accumulated deficit of \$708.1 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 our drug candidates. 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 and cash equivalents will be sufficient to sustain operations into at least the second half of 2014. 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.

We had total cash and cash equivalents of \$230.8 million and \$118.3 million as of December 31, 2012 and 2011, respectively. Our investment policy seeks to manage these assets to achieve our goals of preserving principal and maintaining adequate liquidity. As of December 31, 2012, all of our investments were in money market funds.

Net cash used in operating activities was \$81.6 million, \$54.5 million and \$28.1 million in 2012, 2011 and 2010, respectively. The increase in net cash used in operating activities of \$27.1 million in 2012 compared to 2011 was primarily due to \$36.6 million higher operating expenses, excluding the intangible asset impairment of \$8.0 million in 2012, partially offset by a \$6.5 million increase in accounts payable and accrued expenses. 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.

Net cash used in investing activities was \$2.0 million and \$0.8 million in 2012 and 2011, respectively, and net cash provided by investing activities was \$0.7 million in 2010. The increase of \$1.2 million in net cash used in 2012 compared to 2011 was primarily due to an increase in restricted cash for the issuance of a new letter of credit related to an operating lease for new office and laboratory space. The decrease of \$1.5 million in 2011 was due to the sale of a marketable security in 2010.

Net cash provided by financing activities was \$196.1 million, \$127.7 million and \$26.9 million in 2012, 2011 and 2010, respectively. The increase in net cash provided by financing activities in 2012 of \$68.4 million was due to the receipt of proceeds of \$190.5 million related to an underwritten offering in August 2012 compared to receipt of proceeds of \$126.0 million related to the underwritten offerings and a private placement in 2011. In addition, proceeds from the exercise of common stock options increased \$4.0 million in 2012 compared to 2011. 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 2011 of \$126.0 million as compared to the underwritten offering in 2010 of \$26.3 million.

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

Set forth below is a description of our contractual obligations as of December 31, 2012:

<u>Contractual Obligations</u>	<b>Payments Due by Period</b>				
	<b>Total</b>	<b>Less Than 1 Year</b>	<b>1-3 Years</b>	<b>4-5 Years</b>	<b>After 5 Years</b>
	(In Thousands)				
Operating leases . . . . .	\$23,039	\$2,899	\$6,735	\$ 6,556	\$6,849
Settlement payments and other agreements . . . . .	2,103	1,377	726	—	—
Long-term obligations . . . . .	6,660	—	—	6,210	450
Total contractual obligations . . . . .	<u>\$31,802</u>	<u>\$4,276</u>	<u>\$7,461</u>	<u>\$12,766</u>	<u>\$7,299</u>

Included in the table above was \$7.2 million related to a settlement agreement we entered into in July 2008 with 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®/Sebivo® 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 agreed to make additional payments to UABRF equal to 20% of all royalty payments received by us from Novartis based on worldwide sales of Tyzeka®/Sebivo®, 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. Under the July 2012 termination agreement with Novartis, we no longer receive royalty or milestone payments from Novartis based upon worldwide product sales of Tyzeka®/Sebivo® for the treatment of HBV. Novartis is required to reimburse us for contractual payments to UABRF in connection with our intellectual property related to Tyzeka®/Sebivo®. Included in receivables from related party was \$7.2 million for the reimbursement from Novartis for our contractual payments to UABRF which have been recorded as collaboration revenue – related party in our consolidated statement of operations during the year ended December 31, 2012.

In connection with the certain of our operating leases for office and laboratory space, we have two letters of credit with a commercial bank totaling \$2.1 million which expire at varying dates through December 31, 2013.

As of December 31, 2012, we had \$0.9 million of other long-term liabilities. 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 if such HCV products were approved and commercialized, 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. Such payments would be due even in the instance where we licensed such technology to a third-party. Currently, there are no such HCV products approved and therefore there was no related liability recorded as of December 31, 2012.

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 under the ViiV and GSK collaboration. 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 transaction 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, milestone payments or any other payments with respect to such technology from a collaborator or other third-party.

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, including products for HBV, HCV and HIV. Such payments would be due even in the instance where we licensed such patents to a third-party. Under the termination agreement, we no longer receive royalty or milestone payments from Novartis based upon worldwide product sales of Tyzeka®/Sebivo® for the treatment of HBV. Novartis is required to reimburse us for our contractual payments to CNRS and the University of Montpellier, subject to our assignment to Novartis of our patent rights under the amended and restated agreement with CNRS and the University of Montpellier within 12 months of the execution of the termination agreement, in connection with our intellectual property related to Tyzeka®/Sebivo®. Until the assignment of such patent rights to Novartis is effective, payments from Novartis to reimburse us for our contractual payments to CNRS will be recorded as a deferred payment obligation on our consolidated balance sheet and we will continue to charge payments we make to CNRS to cost of revenues on our consolidated statement of operations. We are in the process of assigning these patent rights to Novartis.

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 termination agreement, Novartis remains obligated to reimburse us for any such payment made to Sumitomo.

#### **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 which are described below. 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, 2012. 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, which: a) provides updated guidance on when multiple elements exist, how the elements in an arrangement should be separated and

how the arrangement considerations should be allocated to the separate elements; b) requires an entity to allocate arrangement considerations to each element based on a selling price hierarchy, where the selling price for an element is based on VSOE, if available, TPE, if available and VSOE is not available, or the BESP, if neither VSOE nor TPE is available; and c) eliminates the use of the residual method and requires an entity to allocate arrangement considerations using the selling price hierarchy.

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*

In May 2003, we entered into the development and commercialization agreement with Novartis which related to the worldwide development and commercialization of our drug candidates. This agreement along with several other agreements between us and Novartis constituted our collaborative arrangement with Novartis, which was treated as a single unit of accounting for revenue recognition purposes. In July 2012, the development and commercialization agreement was materially amended and the termination agreement was entered into between us and Novartis. The termination agreement is described in detail in Note 3 in the footnotes to the financial statements to this Annual Report on Form 10-K.

### *Development and Commercialization Agreement*

Prior to August 2012, under the development and commercialization agreement with Novartis, we received non-refundable license fees, milestones, collaborative research and development funding and royalty payments. This agreement had several joint committees in which we and Novartis participated. We participated in these committees as a means to govern or protect our interests. The committees spanned 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 did not attribute revenue to our involvement in the committees following the commercialization of the licensed products as we determined that our participation on the committees, as such participation relates to the commercialization of drug candidates, is protective. Our determination was 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 believed our obligation post commercialization was inconsequential.

Prior to August 2012, we recognized 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 then current judgments related to the product development timeline of our licensed drug candidates. We reviewed 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 changed, we would adjust the periodic revenue that was being recognized and would have recorded the remaining unrecognized non-refundable payments over the remaining development period during which our performance obligations would be completed. Significant judgments and estimates were involved in determining the estimated development period and different assumptions could yield materially different results.

Prior to August 2012, upon the grant of options and stock awards under our 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, was recorded as a reduction of the non-refundable payments associated with the Novartis collaboration. The amount was attributed proportionately between cumulative revenue recognized through the current date and the remaining amount of deferred revenue. Novartis retains these rights under the second amended and restated stockholders' agreement that was executed in July 2012. As of July 31, 2012, the aggregate impact of Novartis' stock subscription rights reduced the non-refundable payments by \$26.3 million, which was recorded as additional paid-in capital. Of this amount, \$6.3 million was recorded as a reduction of deferred revenue with the remaining amount of \$20.0 million recorded as a reduction of license fee revenue. For the period of January 2012 through July 2012, the impact of Novartis' stock subscription rights increased additional paid-in capital by \$3.6 million, decreased deferred revenue by \$0.9 million and decreased license fee revenue by \$2.7 million.

Commencing in August 2012, the change in fair value of Novartis' stock subscription rights under the second amended and restated stockholders' agreement is accounted for solely as an adjustment to the revenue recognized from Novartis' non-exclusive right to conduct combination trials under the termination agreement. Novartis' stock subscription rights no longer impact deferred revenue. The fair value of the stock subscription rights as of December 31, 2012 was estimated using a trinomial lattice valuation model which included inputs of our per share common stock price, exercise prices of outstanding options, expected term of our options and exercise rates as well as assumptions regarding expected volatility and exercise multiples. For the period of August 2012 through December 2012, using the trinomial lattice model, the impact of Novartis's stock subscription rights decreased additional paid-in capital by \$4.2 million and increased license fee revenue by \$4.2 million primarily due to the decline in our stock price.

For the year ended December 31, 2012, the impact of Novartis' stock subscription rights has decreased additional paid-in capital by \$0.6 million, decreased deferred revenue by \$0.9 million and increased license fee revenue by \$1.5 million.

Prior to August 2012, royalty revenue consisted of revenue earned under our license agreement with Novartis for sales of Tyzeka®/Sebivo®, which was recognized when reported from Novartis. Royalty revenue was equal to a percentage of Tyzeka®/Sebivo® net sales, with such percentage increasing according to specified tiers of net sales. The royalty percentage varied based on the specified territory and the aggregate dollar amount of net sales. Under the termination agreement executed in July 2012, we no longer receive royalty milestone payments from Novartis based upon worldwide product sales of Tyzeka®/Sebivo® for the treatment of HBV.

#### *Termination Agreement*

In July 2012, we and Novartis materially amended the development and commercialization agreement that was established in May 2003, which is considered a material modification under ASU No. 2009-13. Since August 2012, we recognize revenue related to the termination agreement with Novartis under ASU No. 2009-13 which: a) provides updated guidance on when multiple elements exist, how the elements in an arrangement should be separated and how the arrangement considerations should be allocated to the separate elements; b) requires an entity to allocate arrangement considerations to each element based on a selling price hierarchy, where the selling price for an element is based on VSOE, if available, or TPE, if available and VSOE is not available, or the BEBP, if neither VSOE nor TPE is available; and c) eliminates the use of the residual method and requires an entity to allocate arrangement considerations using the selling price hierarchy.

We evaluated our modified arrangement with Novartis and determined that the agreements should continue to be treated as a single unit of accounting. Under the termination agreement we granted Novartis a non-exclusive license to conduct clinical trials evaluating a combination of any of our and Novartis' HCV drug candidates after the HCV drug candidates have completed dose-ranging studies, subject to meeting certain criteria. The non-exclusive license is the only revenue-generating deliverable remaining under the modified arrangement and since neither VSOE nor TPE for the non-exclusive license deliverable was available, the selling price for the non-exclusive license was established using the BEBP. Prior to the execution of the termination agreement, the balance of deferred revenue, related party was \$24.7 million. We determined that the BEBP of Novartis' non-exclusive license at July 31, 2012 was \$5.0 million. We recognized the excess deferred revenue over the BEBP, or \$19.7 million, as collaborative revenue — related party in the third quarter of 2012. As of December 31, 2012, the remaining balance of \$4.7 million was included in deferred revenue, related party in our consolidated balance sheet and will be recognized as collaboration revenue — related party on a straight-line basis over the term of the non-exclusive license, or seven years.

In establishing BEBP for the non-exclusive license, we used a discounted cash flow model and considered the likelihood of our and Novartis' drugs being commercialized, the development and commercialization timeline, discount rate, and probable treatment combination and associated peak sales figures which generate royalty amounts. Our key assumptions in the discounted cash flow model included the following market conditions and entity-specific factors: a) the specific rights and limitations provided under the non-exclusive license to conduct clinical trials evaluating a combination of any of our and Novartis' HCV drug candidates; b) the current stage of development of Novartis' HCV drug candidates and related risks and estimated commercialization timelines; c) the probability of successfully developing and commercializing a combination HCV drug therapy; d) the probable treatment combination; e) the market size for the probable treatment combination including the associated sales figures which generate royalty revenue; and f) the expected product life of the probable treatment combination assuming commercialization. We utilized an industry standard royalty rate in our analysis representing the mean royalty rate for phase II product licensing. We utilized a discount rate representing the risk-adjusted weighted average cost of capital derived from returns on capital for comparable companies. These assumptions involve judgment and uncertainty.

### *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 the 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 and subsequently, the ViiV license agreement was terminated on March 15, 2012. Upon termination, ViiV relinquished all rights it had in the intellectual property licensed from us and granted 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. We will not receive any additional milestone or royalty payments under the ViiV license agreement. During the first quarter of 2012, as a result of the termination, we recognized the deferred revenue balance of \$36.1 million as other collaboration revenue.

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, 2012 and 2011 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 July 2012 termination agreement, Novartis remains obligated to 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*

We accrue expenses we have incurred but 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.

### ***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 2012, 2011 and 2010, 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 December 2011, FASB issued Accounting Standard Update No. 2011-11, *Disclosures about Offsetting Assets and Liabilities*. The amendments in this update require an entity to disclose information about offsetting and related arrangements to enable users of its financial statements to understand the effect of those arrangements on its financial position. An entity is required to apply the amendments for annual reporting periods beginning on or after January 1, 2013, and interim periods within those annual periods. An entity should provide the disclosures required by those amendments retrospectively for all comparative periods presented. We do not expect its adoption to have a material impact on our financial position or results of our operations.

## **Item 7A. Quantitative and Qualitative Disclosures 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 money market funds. 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 a subsidiary in France that is denominated in euros. 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, 2012. 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, 2012, 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, 2012. 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, 2012, 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, 2012 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, 2012 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 2013 Annual Meeting of Stockholders (the “2013 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 2013 Proxy Statement under the captions “Executive Compensation”, “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 2013 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 2013 Proxy Statement under the captions “Certain Relationships and Related Person Transactions”, “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 2013 Proxy Statement under the captions “Ratification of Selection of Independent Registered Public Accounting Firm — Principal Accounting Fees and Services” and “Ratification of Selection of Independent Registered Public Accounting Firm — 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:

	<u>Page</u>
Report of Independent Registered Public Accounting Firm .....	76
Consolidated Balance Sheets at December 31, 2012 and 2011 .....	77
Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2012, 2011 and 2010 .....	78
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(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 and comprehensive loss, of stockholders' equity (deficit) and of cash flows present fairly, in all material respects, the financial position of Idenix Pharmaceuticals, Inc. and its subsidiaries at December 31, 2012 and 2011, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2012 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, 2012, 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  
February 25, 2013

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

	December 31,	
	2012	2011
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents .....	\$ 230,826	\$ 118,271
Restricted cash .....	2,103	411
Receivables from related party .....	1,195	1,157
Other current assets .....	3,668	3,999
Total current assets .....	237,792	123,838
Intangible asset, net .....	—	8,708
Property and equipment, net .....	3,274	4,696
Restricted cash .....	—	750
Receivables from related party, net of current portion .....	6,210	—
Other assets .....	3,589	3,052
Total assets .....	\$ 250,865	\$ 141,044
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable .....	\$ 5,771	\$ 2,886
Accrued expenses .....	9,293	8,413
Deferred revenue .....	—	36,068
Deferred revenue, related party .....	714	2,897
Other current liabilities .....	154	261
Total current liabilities .....	15,932	50,525
Other long-term liabilities .....	7,513	10,640
Deferred revenue, net of current portion .....	4,272	4,272
Deferred revenue, related party, net of current portion .....	3,988	24,382
Total liabilities .....	31,705	89,819
Commitments and contingencies (Note 15)		
Stockholders' equity:		
Common stock, \$0.001 par value; 200,000,000 shares authorized at December 31, 2012 and 2011; 133,957,689 and 107,218,463 shares issued and outstanding December 31, 2012 and 2011, respectively .....	134	107
Additional paid-in capital .....	926,671	726,468
Accumulated other comprehensive income .....	470	365
Accumulated deficit .....	(708,115)	(675,715)
Total stockholders' equity .....	219,160	51,225
Total liabilities and stockholders' equity .....	\$ 250,865	\$ 141,044

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

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

	Years Ended December 31,		
	2012	2011	2010
Revenues:			
Collaboration revenue—related party .....	\$ 33,595	\$ 4,328	\$ 6,231
Other revenue .....	36,068	2,623	3,991
Total revenues .....	69,663	6,951	10,222
Operating expenses:			
Cost of revenues .....	2,654	2,324	2,765
Research and development .....	70,182	41,341	44,506
General and administrative .....	24,163	16,694	23,439
Intangible asset impairment .....	8,045	—	—
Restructuring charges .....	—	—	2,238
Total operating expenses .....	105,044	60,359	72,948
Loss from operations .....	(35,381)	(53,408)	(62,726)
Other income, net .....	2,892	1,368	1,131
Loss before income taxes .....	(32,489)	(52,040)	(61,595)
Income tax benefit .....	89	61	40
Net loss .....	<u>\$ (32,400)</u>	<u>\$ (51,979)</u>	<u>\$ (61,555)</u>
Basic and diluted net loss per common share .....	\$ (0.27)	\$ (0.57)	\$ (0.87)
Shares used in computing basic and diluted net loss per common share .....	118,755	90,831	70,715
Comprehensive loss:			
Net loss .....	\$ (32,400)	\$ (51,979)	\$ (61,555)
Changes in other comprehensive income:			
Foreign currency translation adjustment .....	105	(318)	(287)
Comprehensive loss .....	<u>\$ (32,295)</u>	<u>\$ (52,297)</u>	<u>\$ (61,842)</u>

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



**IDENIX PHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)**  
**DECEMBER 31, 2012, 2011 and 2010**  
**(IN THOUSANDS, EXCEPT SHARE DATA)**

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount				
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 to 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
Cumulative translation adjustment .....	—	—	—	(287)	—	(287)
Net loss .....	—	—	—	—	(61,555)	(61,555)
Balance at December 31, 2010 .....	<u>73,091,514</u>	<u>\$ 73</u>	<u>\$591,884</u>	<u>\$ 683</u>	<u>\$(623,736)</u>	<u>\$ (31,096)</u>
Issuance of common stock upon exercise of stock options .....	410,723	—	1,398	—	—	1,398
Issuance of common stock to 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
Cumulative translation adjustment .....	—	—	—	(318)	—	(318)
Net loss .....	—	—	—	—	(51,979)	(51,979)
Balance at December 31, 2011 .....	<u>107,218,463</u>	<u>\$107</u>	<u>\$726,468</u>	<u>\$ 365</u>	<u>\$(675,715)</u>	<u>\$ 51,225</u>
Issuance of common stock upon exercise of stock options .....	1,354,333	2	5,346	—	—	5,348
Issuance of common stock to related party .....	84,893	—	291	—	—	291
Issuance of common stock, net of offering costs .....	25,300,000	25	190,480	—	—	190,505
Share-based compensation .....	—	—	4,836	—	—	4,836
Antidilution shares contingently issuable to related party .....	—	—	(750)	—	—	(750)
Cumulative translation adjustment .....	—	—	—	105	—	105
Net loss .....	—	—	—	—	(32,400)	(32,400)
Balance at December 31, 2012 .....	<u>133,957,689</u>	<u>\$134</u>	<u>\$926,671</u>	<u>\$ 470</u>	<u>\$(708,115)</u>	<u>\$219,160</u>

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

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

	Years Ended December 31,		
	2012	2011	2010
<b>Cash flows from operating activities:</b>			
Net loss	\$(32,400)	\$(51,979)	\$(61,555)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3,100	4,199	4,576
Share-based compensation expense	4,836	2,423	6,417
Revenue adjustment for contingently issuable shares	(1,561)	3,308	1,956
Intangible asset impairment	8,045	—	—
Other	(4)	235	161
Changes in operating assets and liabilities:			
Receivables from related party	(6,248)	(317)	209
Other assets	(122)	(2,437)	419
Accounts payable	2,883	320	620
Accrued expenses and other current liabilities	820	(3,119)	2,581
Deferred revenue	(36,068)	(2,623)	22,545
Deferred revenue, related party	(21,766)	(3,124)	(4,387)
Other liabilities	(3,137)	(1,407)	(1,593)
Net cash used in operating activities	<u>(81,622)</u>	<u>(54,521)</u>	<u>(28,051)</u>
<b>Cash flows from investing activities:</b>			
Purchases of property and equipment	(1,066)	(837)	(727)
Increase in restricted cash	(942)	—	—
Sales and maturities of marketable securities	—	—	1,476
Net cash provided by (used in) investing activities	<u>(2,008)</u>	<u>(837)</u>	<u>749</u>
<b>Cash flows from financing activities:</b>			
Proceeds from exercise of common stock options	5,348	1,398	494
Proceeds from issuance of common stock to related party	291	5,262	145
Proceeds from issuance of common stock, net of offering costs	190,505	121,006	26,266
Net cash provided by financing activities	196,144	127,666	26,905
Effect of changes in exchange rates on cash and cash equivalents	41	(152)	(7)
Net increase (decrease) in cash and cash equivalents	112,555	72,156	(404)
Cash and cash equivalents at beginning of year	118,271	46,115	46,519
Cash and cash equivalents at end of year	<u>\$230,826</u>	<u>\$118,271</u>	<u>\$ 46,115</u>
<b>Supplemental disclosure of cash flow information:</b>			
Taxes paid	\$ 21	\$ 20	\$ 25
<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	(750)	4,529	2,877

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 France. Currently, our primary research and development focus is on the treatment of patients with hepatitis C virus, or HCV, using nucleotide polymerase inhibitors and NS5A inhibitors.

In August 2012, the U.S. Food and Drug Administration, or FDA, placed IDX184 on partial clinical hold and IDX19368 on clinical hold due to serious cardiac-related adverse events observed with a competitor's nucleotide polymerase inhibitor, BMS-986094. These three compounds are guanosine-based nucleotide polymerase inhibitors. There are currently no patients worldwide receiving IDX184 and no patients have been dosed with IDX19368. In order to respond to the FDA regarding the clinical hold with respect to IDX184, we evaluated multiple cardiac safety measurements in our ongoing IDX184 phase II study and have observed no evidence of severe cardiac findings to date. In December 2012, we submitted a response package to the FDA for IDX184 and in February 2013, the FDA communicated to us that both of these programs will remain on clinical hold due to unresolved concerns regarding the potential for cardiac toxicity. As a result, we elected not to continue the development of these two programs. We intend to devote our resources to the development of IDX719, our NS5A inhibitor, and the discovery and development of additional novel nucleotide prodrugs.

On January 25, 2013, we entered into a non-exclusive collaboration agreement with Janssen Pharmaceuticals, Inc., or Janssen, for the clinical evaluation of all oral direct acting antiviral, or DAA, HCV combination therapies. The combination therapies involve IDX719, our once-daily pan-genotypic NS5A inhibitor, simeprevir (TMC435), a once-daily protease inhibitor jointly developed by Janssen and Medivir AB, or Medivir, and TMC647055, a once-daily non-nucleoside polymerase inhibitor, boosted with low dose ritonavir, being developed by Janssen. Under the terms of this collaboration agreement, we will conduct the clinical trials. Clinical development plans include drug-drug interaction studies, followed by phase II studies as agreed between the companies, pending approval from regulatory authorities. The phase II program is expected to first evaluate the two-DAA combination of IDX719 and simeprevir (TMC435) plus ribavirin in treatment-naïve HCV-infected patients. Subsequently, the companies plan to evaluate a three-DAA combination of IDX719, simeprevir (TMC435), TMC647055 with low dose ritonavir, with and without ribavirin, in a broader group of HCV-infected patients.

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 May 2003, we also entered into a stockholders' agreement with Novartis, which we refer to as the stockholders' agreement. On July 31, 2012, we and Novartis materially modified our collaboration by executing a termination and revised relationship agreement, which we refer to as the termination agreement, and by amending the stockholders' agreement, which we refer to as the second amended and restated stockholders' agreement. These agreements are described more fully in Note 3.

Our drug development programs and the potential commercialization of our drug candidates will require substantial cash to fund costs that we incur in connection with preclinical studies and clinical trials, regulatory review, manufacturing and sales and marketing efforts. We have incurred losses in each year since our inception and at December 31, 2012, we had an accumulated deficit of \$708.1 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 our drug candidates. In July 2012, we filed a universal, automatically effective, well-known seasoned issuer shelf registration statement with the Securities and Exchange Commission,

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

or SEC, for the issuance, in one or more public offerings, of common stock, debt securities and other securities at prices and on terms to be determined at the time of the applicable offering. In August 2012, we issued approximately 25.3 million shares of our common stock under this shelf registration statement and received \$190.5 million in net proceeds. 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. Novartis did not participate in the August 2012 offering and its ownership of our common stock was diluted from approximately 31% prior to the offering to approximately 25% as of February 8, 2013.

We believe that our current cash and cash equivalents will be sufficient to sustain operations into at least the second half of 2014. 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.

### ***Recent Accounting Pronouncements***

In December 2011, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update No. 2011-11, *Disclosures about Offsetting Assets and Liabilities*. The amendments in this update require an entity to disclose information about offsetting and related arrangements to enable users of its financial statements to understand the effect of those arrangements on its financial position. An entity is required to apply the amendments for annual reporting periods beginning on or after January 1, 2013, and interim periods within those annual periods. An entity should provide the disclosures required by those amendments retrospectively for all comparative periods presented. We do not expect its adoption to have a material impact on our financial position or results of our operations.

### ***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

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

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, accrued expenses, 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 and receivables from related party. We invest our excess cash and cash equivalents 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, 2012 and 2011, all of our receivables from related party were due from Novartis. The receivables from related party balances at December 31, 2012 of \$7.4 million were related to Novartis' commitment under the termination agreement to reimburse us for contractual payments due by us to third-parties (Note 15). The balance at December 31, 2011 of \$1.2 million consisted of royalties associated with the sales of telbivudine (Tyzeka®/Sebivo®) under the collaborative agreement with Novartis in the normal course of business.

***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.

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

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

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, 2012 and 2011. 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, 2012 and 2011, we had \$184.0 million and \$102.6 million, respectively, invested in money market funds. 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, 2012 or 2011 and there were no gross unrealized gains or losses for the years ended December 31, 2012, 2011 and 2010.

***Intangible Asset and 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.

Our intangible asset related 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, included 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 agreed to make additional payments to UABRF equal to 20% of all royalty payments received by us from Novartis based on worldwide sales of Tyzeka<sup>®</sup>/Sebivo<sup>®</sup>, subject to minimum payment obligations aggregating \$11.0 million. Prior to the execution of the termination agreement in July 2012, we were amortizing the \$15.0 million related to this settlement payment to UAB and related entities over the life of the settlement agreement, or August 2019. Under the termination agreement with Novartis, we no longer receive royalty or milestone payments from Novartis based upon worldwide product sales of Tyzeka<sup>®</sup>/Sebivo<sup>®</sup> for the treatment of HBV. We concluded that the intangible asset was effectively abandoned on the effective date of the termination agreement since there are no future cash flows associated with its use and the intangible asset has no alternate use. As a result, we recorded an impairment charge of \$8.0 million during the year ended December 31, 2012. No significant impairment charges were recognized for the years ended December 31, 2011 or 2010.

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

***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.

***Accrued Expenses***

We accrue expenses we have incurred but 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.

***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, which: a) provides updated guidance on when multiple elements exist, how the elements in an arrangement should be separated and how the arrangement considerations should be allocated to the separate elements; b) requires an entity to allocate arrangement considerations to each element based on a selling price hierarchy, where the selling price for an element is based on vendor-specific objective evidence, or VSOE, if available, or third-party evidence, or TPE, if available and VSOE is not available, or the best estimate of selling price, or BEBP, if neither VSOE nor TPE is available; and c) eliminates the use of the residual method and requires an entity to allocate arrangement considerations using the selling price hierarchy.

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

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

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*

In May 2003, we entered into the development and commercialization agreement with Novartis which related to the worldwide development and commercialization of our drug candidates. This agreement along with several other agreements between us and Novartis constituted our collaborative arrangement with Novartis, which was treated as a single unit of accounting for revenue recognition purposes. In July 2012, the development and commercialization agreement was materially amended and the termination agreement was entered into between us and Novartis. The termination agreement is described in detail in Note 3.

*Development and Commercialization Agreement*

Prior to August 2012, under the development and commercialization agreement, we received non-refundable license fees, milestones, collaborative research and development funding and royalties. This arrangement has several joint committees in which we and Novartis participated. We participated in these committees as a means to govern or protect our interests. The committees spanned 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 attributed revenue to the development period of the drug candidates licensed under the development and commercialization agreement. We did not attribute 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, was protective. Our determination was based in part on the fact that our expertise was, and has been, the discovery and development of drugs for the treatment of human viral diseases. Novartis, on the other hand, had the considerable commercialization expertise and infrastructure necessary for the commercialization of such drug candidates. Accordingly, we believed our obligation post commercialization was inconsequential.

Prior to August 2012, we recognized non-refundable payments over the performance period of our continuing obligations. This period was estimated based on then current judgments related to the product development timeline of our licensed drug candidates and was estimated to be through May 2021. This policy is described more fully in Note 3.



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Prior to August 2012, upon the grant of options and stock awards under our 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, was recorded as a reduction of the non-refundable payments associated with the Novartis collaboration. The amount was attributed proportionately between cumulative revenue recognized through the current date and the remaining amount of deferred revenue. Novartis retains these rights under the second amended and restated stockholders' agreement that was executed in July 2012. Commencing in August 2012, the change in fair value of Novartis' stock subscription rights under the second amended and restated stockholders' agreement is accounted for as an adjustment to the revenue recognized from Novartis' non-exclusive right to conduct combination trials under the termination agreement. Novartis' stock subscription rights no longer impact deferred revenue. The fair value of the stock subscription rights was estimated using a trinomial lattice valuation model which included inputs of our per share common stock price, exercise prices of outstanding options, expected term of our options and exercise rates as well as assumptions regarding expected volatility and exercise multiples. This policy is described more fully in Note 3.

Prior to August 2012, royalty revenue consisted of revenue earned under our license agreement with Novartis for sales of Tyzeka<sup>®</sup>/Sebivo<sup>®</sup>, which was recognized when reported from Novartis. Royalty revenue was 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 varied based on the specified territory and the aggregate dollar amount of net sales. Under the termination agreement executed in July 2012, we no longer receive royalty or milestone payments from Novartis based upon worldwide product sales of Tyzeka<sup>®</sup>/Sebivo<sup>®</sup> for the treatment of HBV.

*Termination Agreement*

In July 2012, we and Novartis materially amended the development and commercialization agreement that was established in May 2003, which was considered a material modification under ASU No. 2009-13. Since August 2012, we recognize revenue related to the termination agreement with Novartis under ASU No. 2009-13 which: a) provides updated guidance on when multiple elements exist, how the elements in an arrangement should be separated and how the arrangement considerations should be allocated to the separate elements; b) requires an entity to allocate arrangement considerations to each element based on a selling price hierarchy, where the selling price for an element is based on VSOE, if available, or TPE, if available and VSOE is not available, or the BESP, if neither VSOE nor TPE is available; and c) eliminates the use of the residual method and requires an entity to allocate arrangement considerations using the selling price hierarchy.

We evaluated our modified arrangement with Novartis and determined that the agreements should continue to be treated as a single unit of accounting. Under the termination agreement we granted Novartis a non-exclusive license to conduct clinical trials evaluating a combination of any of our and Novartis' HCV drug candidates after the HCV drug candidates have completed dose-ranging studies, subject to meeting certain criteria. The non-exclusive license is the only revenue-generating deliverable remaining under the modified arrangement and since neither VSOE nor TPE for the non-exclusive license deliverable was available, the selling price for the non-exclusive license was established using the BESP. Prior to the execution of the termination agreement, the balance of deferred revenue, related party was \$24.7 million. We determined that the BESP of Novartis' non-exclusive license at July 31, 2012 was \$5.0 million. We recognized the excess deferred revenue over the BESP, or \$19.7 million, as collaborative revenue — related party in the third quarter of 2012. As of December 31, 2012, the remaining balance of \$4.7 million was included in deferred revenue, related party in our consolidated balance sheet and will be recognized as collaboration revenue — related party on a straight-line basis over the term of the non-exclusive license, or seven years.

In establishing BESP for the non-exclusive license, we used a discounted cash flow model and considered the likelihood of our and Novartis' drugs being commercialized, the development and commercialization

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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED**

timeline, discount rate, and probable treatment combination and associated peak sales figures which generate royalty amounts. Our key assumptions in the discounted cash flow model included the following market conditions and entity-specific factors: a) the specific rights and limitations provided under the non-exclusive license to conduct clinical trials evaluating a combination of any of our and Novartis' HCV drug candidates; b) the current stage of development of Novartis' HCV drug candidates and related risks and estimated commercialization timelines; c) the probability of successfully developing and commercializing a combination HCV drug therapy; d) the probable treatment combination; e) the market size for the probable treatment combination including the associated sales figures which generate royalty revenue; and f) the expected product life of the probable treatment combination assuming commercialization. We utilized an industry standard royalty rate in our analysis representing the mean royalty rate for phase II product licensing. We utilized a discount rate representing the risk-adjusted weighted average cost of capital derived from returns on capital for comparable companies. These assumptions involve judgment and uncertainty.

Under the termination agreement, Novartis is committed to reimburse us for contractual payments to third-parties in connection with intellectual property related to Tyzeka<sup>®</sup>/Sebivo<sup>®</sup>. Contractual payments to third-parties are described more fully in Note 15. These amounts are recorded as receivables from related party and recognized as collaboration revenue- related party as of the year ended December 31, 2012.

*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 the 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 and subsequently, the ViiV license agreement was terminated on March 15, 2012. Upon termination, ViiV relinquished all rights it had in the intellectual property licensed from us and granted 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. We will not receive any additional milestone or royalty payments under the ViiV license agreement. During the first quarter of 2012, as a result of the termination, we recognized the deferred revenue balance of \$36.1 million as other collaboration revenue which was included in the consolidated statement of operation and comprehensive loss for the year ended December 31, 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.

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*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, 2012 and 2011 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 July 2012 termination agreement, Novartis remains obligated to 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.

*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. Internal research and development expenses include costs for salaries, employee benefits, subcontractors, facility related expenses, depreciation, share-based compensation and other costs. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when payment is made.

*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.

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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED**

Share-based compensation expense is recognized based on awards ultimately expected to vest and should be reduced for estimated forfeitures. During 2012, 2011 and 2010, 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 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 and comprehensive loss.

***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.

***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

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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**

***Collaboration with Novartis***

In May 2003, we entered into the development and commercialization agreement with Novartis related to the worldwide development and commercialization of our drug candidates. In July 2012, we and Novartis materially modified our collaboration by executing the termination agreement and the second amended and restated stockholders' agreement.

The collaboration entered into in May 2003 included the following agreements and transactions which together constituted our arrangement with Novartis which was treated as a single unit of accounting for revenue recognition purposes:

- the development and commercialization agreement, under which we collaborated with Novartis to develop, manufacture and commercialize drug candidates which Novartis licensed from us;
- the manufacturing and supply agreement, under which Novartis manufactured for us the active pharmaceutical ingredient for the clinical development and, under certain circumstances, commercial supply of drug candidates Novartis licensed from us and for the finishing and packaging of licensed products;
- the stock purchase agreement, under which Novartis purchased approximately 54% of our then outstanding capital stock from certain 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 achieved predetermined milestones with respect to the development of specific HCV drug candidates;
- the stockholders' agreement, which was subsequently amended and restated in July 2004 and amended in April 2011, which provided Novartis with, among other things, registration rights, certain corporate governance rights including board representation and participation rights in future issuances of our securities; and
- a letter agreement, which was subsequently amended in January 2009 and April 2011. The letter agreement provided Novartis with rights regarding the selection, appointment and removal of our chief financial officer and other matters.

***Termination Agreement***

***Termination of Novartis' Option to License our Development Stage Drug Candidates***

Under the development and commercialization agreement, Novartis had 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 maintained at least 30% ownership of our voting stock. If Novartis licensed a drug candidate, it was obligated to fund a portion of the development expenses that we incurred in accordance with development plans agreed upon by the parties. Under the development and commercialization agreement, we granted Novartis an exclusive worldwide license to market and sell drug candidates that Novartis chose to license from us. The

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commercialization rights under the development and commercialization agreement also included our right to co-promote and co-market all licensed products in the United States, United Kingdom, France, Germany, Italy and Spain. In other countries, we would receive a royalty payment from Novartis based on net product sales.

Under the development and commercialization agreement, we granted Novartis an exclusive worldwide license to develop, market and sell Tyzeka®/Sebivo® and other compounds Novartis previously licensed from us. Under this agreement, we have received \$117.2 million of non-refundable payments from Novartis related to these drug candidates that have been recorded as deferred revenue. Through July 2012, the \$117.2 million of deferred payments were being recognized over the development period of the licensed drug candidates, which represented the period of our continuing obligations, in accordance with revenue recognition guidance that was applicable at the time the collaboration was entered into. We estimated this period to be through May 2021 based on then current judgments related to the product development timeline of our licensed drug candidates. Significant judgments and estimates were involved in determining the estimated development period and different assumptions could have yielded materially different results. Related to the deferred revenue under the development and commercialization agreement, we recognized \$1.9 million, \$3.1 million and \$4.4 million as revenue during the years ended December 31, 2012, 2011 and 2010. These amounts were impacted by Novartis' stock subscription rights described below.

Pursuant to the termination agreement, Novartis' option right to license our current and future development-stage drug candidates in any therapeutic area was terminated. In exchange, we agreed to pay Novartis a royalty based on worldwide product sales of our HCV drug products, unless such drug products are prescribed in combination with Novartis' HCV drug products. The royalty percentage will vary based on our commercialized HCV drug product, but range from the high single digits to the low double digit percentages. Royalties are payable until the later to occur of: a) expiration of the last-to-expire of specified patent rights in a country; or b) ten years after the first commercial sale of a product in such country, provided that if royalties are payable on a product after the expiration of the patent rights in a country, each of the respective royalty rates for such product in such country would be reduced by one-half.

*Novartis' Non-Exclusive License to Conduct Combination Trials*

Pursuant to the termination agreement, we granted Novartis a non-exclusive license to conduct clinical trials evaluating a combination of any of our and Novartis' HCV drug candidates after the HCV drug candidates have completed dose-ranging studies, subject to meeting certain criteria. Under certain circumstances Novartis may conduct a dose-ranging study with respect to our HCV drug candidates. With respect to any combination trial, certain criteria must first be met prior to the commencement of such combination clinical trial, including, but not limited to: a) the Novartis HCV drug candidate at issue cannot be subject to any clinical hold imposed by a regulatory authority; and b) a drug-drug interaction study between the Novartis HCV drug candidate and our HCV drug candidate must be conducted by either Novartis or us. If the parties cannot agree to the initiation of a combination trial, an independent data safety monitoring board will determine whether or not the combination trial should be initiated based on the safety profile of each HCV drug candidate. We have agreed to supply Novartis with our HCV drug candidates for use in such combination trials. We and Novartis have agreed to use commercially reasonable efforts to, in good faith, enter into a supply agreement and other relevant agreements in connection with any such combination trial. Novartis' ability to initiate combination trials expires on the seven year anniversary of the execution of the termination agreement, or July 2019, although any then existing combination study commenced prior to such expiration date may continue after the expiration date.

As previously noted, since neither VSOE nor TPE for the non-exclusive license deliverable was available, the selling price for this non-exclusive license was established using the BESP. Prior to the execution of the termination agreement, the balance of deferred revenue, related party was \$24.7 million. We determined the

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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED**

BESP of the non-exclusive license at July 31, 2012 to be \$5.0 million. We recognized the excess deferred revenue over the BESP, or \$19.7 million, as collaborative revenue — related party in the three months ended September 30, 2012. The remaining deferred revenue of \$5.0 million is being recognized as revenue on a straight-line basis over the term of the non-exclusive license, or seven years. During the year ended December 31, 2012, we recognized \$0.3 million of collaboration revenue related to the non-exclusive license and as of December 31, 2012, we had a balance of \$4.7 million of deferred revenue, related party in our consolidated balance sheet.

*Treatment of Product Sales of Tyzeka®/Sebivo® for the Treatment of Hepatitis B Virus*

In 2003 under the development and commercialization agreement, Novartis licensed Tyzeka®/Sebivo® from us for the treatment of hepatitis B virus, or HBV. In September 2007, we and Novartis entered into an amendment to the development and commercialization agreement pursuant to which we transferred to Novartis worldwide development, commercialization and manufacturing rights and obligations pertaining to Tyzeka®/Sebivo®. Subsequently, we received royalty payments equal to a percentage of net sales of Tyzeka®/Sebivo® through July 31, 2012, the date of the termination agreement. We recognized \$2.9 million, \$4.5 million and \$3.8 million as royalty revenue from Novartis' sales of Tyzeka®/Sebivo® during the years ended December 31, 2012, 2011 and 2010, respectively. Royalty revenues for the year ended December 31, 2012 included royalty payments through July 31, 2012, the date of the termination agreement. Subsequent to July 31, 2012, we no longer receive royalty or milestone payments from Novartis based upon worldwide product sales of Tyzeka®/Sebivo® for the treatment of HBV.

Novartis is committed to reimburse us for contractual payments to third-parties in connection with intellectual property related to Tyzeka®/Sebivo®. We are otherwise responsible for any payments to third-parties in connection with intellectual property necessary to sell Tyzeka®/Sebivo®. Contractual payments to third-parties are described more fully in Note 15. The receivables from related party balance of \$7.4 million at December 31, 2012 consisted of the reimbursement by Novartis of the contractual payments to third-parties. The receivables from related party balance of \$1.2 million at December 31, 2011 consisted of royalties associated with product sales of Tyzeka®/Sebivo® from Novartis.

*Termination or Breach by Either Party*

If either we or Novartis materially breaches the termination agreement and does not cure such breach within 30 days, the non-breaching party may terminate this agreement in its entirety. Either party may also terminate this agreement, effective immediately, if the other party files for bankruptcy, is dissolved, or has a receiver appointed for substantially all of its property. Novartis may also terminate this agreement for convenience. If Novartis terminates this agreement either because of a material breach by us that has not been cured or because we have filed for bankruptcy, Novartis may, at its election, retain the licenses granted to it by us under the termination agreement to conduct clinical trials evaluating a combination of any of our HCV drug candidates and any of Novartis' HCV drug candidates and we would remain obligated to make royalty payments to Novartis on sales of our HCV drug products. If we terminate this agreement either because of a material breach by Novartis that has not been cured or because Novartis has filed for bankruptcy, or if Novartis terminates this agreement for convenience, the licenses granted to Novartis to conduct combination trials terminate and we would remain obligated to make royalty payments to Novartis on sales of our HCV drug products.

*Indemnification*

We have agreed to indemnify Novartis and its affiliates against losses suffered as a result of our development, manufacture and commercialization of our HCV products. We have also agreed to indemnify Novartis and its affiliates against losses suffered as a result of any breach of representations and warranties in the

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termination agreement, 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 drug candidates for the treatment of HBV and HCV, including representations regarding ownership of related inventions and discoveries. In the event of a breach of any such representation or warranty by us, Novartis has the right to seek indemnification from us and, under certain circumstances, our stockholders who sold shares to Novartis in 2003, which includes certain of our directors and officers, for damages suffered by Novartis as a result of such breach. The amounts for which we and our stockholders could be liable to Novartis could be substantial.

*Future Agreements and Possible Competition with Novartis*

Under the termination agreement, following the receipt of certain data related to a combination trial and upon Novartis' request, we and Novartis are obligated to use, in good faith, commercially reasonable efforts to negotiate a future agreement for the development, manufacture and commercialization of such combination therapy for the treatment of HCV. Any future arrangement may set forth any co-promotion and co-marketing rights we may retain and any net benefit to us and Novartis attributable to such rights. Neither party is obligated to negotiate for a period longer than 180 days. Also under the termination agreement, Novartis has a non-exclusive license to conduct clinical trials evaluating a combination of any of our HCV drug candidates and any of Novartis' HCV drug candidates after certain criteria have been met. If Novartis obtains regulatory approval to co-label a Novartis HCV drug product with one or more of our HCV drug products, Novartis could market and sell a combination that may compete with our drug candidates and/or combination products that we market and sell in the future.

*Stock Purchase Agreement*

In May 2003, Novartis purchased approximately 54% of our then outstanding capital stock from our stockholders. In connection with Novartis' purchase of stock from our stockholders, we, Novartis and substantially all of our stockholders at that time entered into the stockholders' agreement which was amended and restated in 2004 and amended in April 2011. 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. The stock purchase agreement remains unchanged and Novartis is still obligated to make such contingent payments.

*Second Amended and Restated Stockholders' Agreement*

In July 2012, we, Novartis and certain other stockholders entered into a second amended and restated stockholders' agreement which includes the terms as described below.

*Novartis' Registration Rights*

Under the second amended and restated stockholders' agreement, Novartis maintains its rights to cause us to register for resale, under the Securities Act of 1933, as amended, shares held by Novartis and/or its affiliates.

*Corporate Governance Rights*

Under the stockholders' agreement, we 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 owned at least 30% of our voting stock and at least one designee of Novartis for so long as Novartis and its affiliates owned at least 19.4% of our voting stock. Furthermore, Novartis had approval rights over a number of corporate actions that we or our



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subsidiaries may take, including the authorization or issuance of additional shares of capital stock and significant acquisitions and dispositions, as long as Novartis and its affiliates continued to own at least 19.4% of our voting stock.

Under the second amended and restated stockholders' agreement executed in July 2012, we agreed to use our reasonable best efforts to nominate for election one designee of Novartis for so long as Novartis and its affiliates own at least 15% of our voting stock. Novartis maintains its rights to appoint a non-voting observer to any committee of our board of directors. All of Novartis' other corporate governance rights, including its rights under the letter agreement, were terminated pursuant to the second amended and restated stockholders' agreement.

*Novartis' Stock Subscription Rights*

Under the stockholders' agreement, Novartis had the right to purchase, at par value of \$0.001 per share, such number of shares as was required to maintain its percentage ownership of our voting stock if we issued 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 have been terminated under the second amended and restated stockholders' agreement.

In addition to the right to purchase shares of our stock at par value as described above under the stockholders' agreement, if we issued any shares of capital stock, other than in certain situations, Novartis had 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. Under the second amended and restated stockholders' agreement executed in July 2012, if we issue any shares of our capital stock, other than in limited situations, Novartis continues to have the right to purchase such number of shares required to maintain its percentage ownership of our voting stock for either the same consideration per share paid by others acquiring our stock or, in specified situations, for a 10% premium to the consideration per share paid by others acquiring our stock.

Prior to August 2012, upon the grant of options and stock awards under our 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, was recorded as a reduction of the non-refundable payments associated with the Novartis collaboration. The amount was attributed proportionately between cumulative revenue recognized through the current date and the remaining amount of deferred revenue. Novartis retains these rights under the second amended and restated stockholders' agreement that was executed in July 2012. As of July 31, 2012, the aggregate impact of Novartis' stock subscription rights reduced the non-refundable payments by \$26.3 million, which was recorded as additional paid-in capital. Of this amount, \$6.3 million was recorded as a reduction of deferred revenue with the remaining amount of \$20.0 million recorded as a reduction of license fee revenue. For the period of January 2012 through July 2012, the impact of Novartis' stock subscription rights increased additional paid-in capital by \$3.6 million, decreased deferred revenue by \$0.9 million and decreased license fee revenue by \$2.7 million.

Commencing in August 2012, the change in fair value of Novartis' stock subscription rights under the second amended and restated stockholders' agreement is accounted for as an adjustment to the revenue recognized from Novartis' non-exclusive right to conduct combination trials under the termination agreement. Novartis' stock subscription rights no longer impact deferred revenue. The fair value of the stock subscription rights was estimated using a trinomial lattice valuation model which included inputs of our per share common stock price, exercise prices of outstanding options, expected term of our options and exercise rates as well as assumptions regarding expected volatility and exercise multiples. For the period of August 2012 through

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December 2012, using the trinomial lattice model, the impact of Novartis's stock subscription rights decreased additional paid-in capital by \$4.2 million and increased license fee revenue by \$4.2 million primarily due to the decline in our stock price.

For the year ended December 31, 2012, the impact of Novartis' stock subscription rights has reduced additional paid-in capital by \$0.6 million, decreased deferred revenue by \$0.9 million and increased license fee revenue by \$1.5 million. 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. For the year ended December 31, 2010, the impact of Novartis' stock subscription rights has 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.

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 are required. 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.

Prior to July 2012, any financing requiring the issuance of additional shares of capital stock had to first be approved by Novartis so long as Novartis owned at least 19.4% of our voting stock. This right was terminated in July 2012 under the second amended and restated stockholders' agreement with Novartis and therefore Novartis' approval was not required for the underwritten offering in August 2012. We received Novartis' approval for the following offerings:

- 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%. 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 this offering;
- 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 a 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 retained the exclusive option to obtain rights to drug candidates developed by us so long as Novartis maintained 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 would use reasonable best efforts to nominate for election as directors at least two designees of Novartis so long as Novartis maintained ownership of at least 30% of our common stock,

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rather than ownership of at least 35% as was the case prior to the amendment; and c) Novartis' consent was required for the selection, appointment and removal of our chief financial officer so long as Novartis owned 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 allowed 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.

**4. Net Loss per Common Share**

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

	<u>Years Ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>2010</u>
	(In Thousands, Except per Share Data)		
Basic and diluted net loss per common share:			
Net loss .....	\$ (32,400)	\$ (51,979)	\$ (61,555)
Basic and diluted weighted average number of common shares outstanding .....	118,755	90,831	70,715
Basic and diluted net loss per common share .....	\$ (0.27)	\$ (0.57)	\$ (0.87)

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

	<u>Years Ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>2010</u>
	(In Thousands)		
Options .....	7,556	7,579	7,032
Contingently issuable shares to related party .....	755	2,377	1,735

In addition to the contingently issuable shares to related party listed in the tables above, Novartis could be entitled to additional shares under its stock subscription rights which would be anti-dilutive in future periods based on our current stock price.

**5. Intangible Asset, Net**

Our intangible asset related to a settlement agreement entered into by and among us along with our former chief executive officer in his individual capacity, the University of Montpellier, CNRS, UAB, 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, included 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 agreed to make additional payments to UABRF equal to 20% of all royalty payments received by us from Novartis based on worldwide sales of Tyzeka®/Sebivo®, subject to minimum payment obligations aggregating \$11.0 million. Prior to the execution of the termination agreement, we were

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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED**

amortizing the \$15.0 million related to this settlement payment to UAB and related entities over the life of the settlement agreement, or August 2019. Under the termination agreement in July 2012, we no longer receive royalty or milestone payments from Novartis based upon worldwide product sales of Tyzeka®/Sebivo® for the treatment of HBV. We concluded that the intangible asset was effectively abandoned on the effective date of the termination agreement since there are no future cash flows associated with its use and the intangible asset has no alternate use. As a result, we recorded an impairment charge of \$8.0 million during the year ended December 31, 2012.

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

	December 31,	
	2012	2011
	(In Thousands)	
Beginning balance .....	\$ 8,708	\$ 9,843
Amortization expense .....	(663)	(1,135)
Intangible asset impairment .....	(8,045)	—
Ending balance .....	\$ —	\$ 8,708

As of December 31, 2011, accumulated amortization was \$6.3 million.

**6. Property and Equipment, Net**

Property and equipment consisted of the following:

	Estimated Useful Life (Years)	December 31,	
		2012	2011
		(In Thousands)	
Scientific equipment .....	7	\$ 6,920	\$ 6,584
Computer equipment and software .....	2	3,786	3,662
Enterprise software .....	5	2,599	2,599
Office furniture and equipment .....	5 - 7	731	727
Leasehold improvements .....	*	7,970	7,994
Construction-in-progress .....		128	—
		22,134	21,566
Less—accumulated depreciation .....		(18,860)	(16,870)
		\$ 3,274	\$ 4,696

\* Shorter of asset life or lease term

Depreciation and amortization expense related to property and equipment for the years ended December 31, 2012, 2011 and 2010 was \$2.4 million, \$3.1 million and \$3.4 million, respectively.

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**7. Accrued Expenses**

Accrued expenses consisted of the following:

	December 31,	
	2012	2011
	(In Thousands)	
Research and development contract costs . . . . .	\$2,686	\$2,425
Payroll and benefits . . . . .	2,946	3,267
Professional fees . . . . .	1,204	592
Short-term portion of accrued settlement payment . . . . .	976	874
Other . . . . .	1,481	1,255
	\$9,293	\$8,413

**8. Restructuring Charges**

In 2010, we recorded charges of \$2.2 million for employee severance costs related the reduction of our workforce in the United States and France. All significant severance amounts were paid in 2010. There were no restructuring charges in 2012 or 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.

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.

In June 2012, we adopted the 2012 stock incentive plan, or 2012 plan. The 2012 plan allows for the granting of incentive stock options, non-qualified stock options, stock appreciation rights, performance share awards, restricted stock awards and restricted stock unit awards, or awards. Up to 10.0 million shares of our common stock may be issued pursuant to awards granted under the 2012 plan, plus an additional amount up to 0.5 million

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shares of our common stock previously authorized for issuance under our 2005 plan. The 2012 plan replaced our 2005 plan and we will not make new grants under the 2005 plan although all outstanding options granted through June 7, 2012 under the 2005 plan will remain in effect.

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:

	<b>Years Ended December 31,</b>		
	<b>2012</b>	<b>2011</b>	<b>2010</b>
	<b>(In Thousands)</b>		
Research and development .....	\$1,810	\$1,066	\$1,214
General and administrative .....	3,026	1,357	5,203
Total share-based compensation expense .....	\$4,836	\$2,423	\$6,417

Share-based compensation expense is based on awards ultimately expected to vest. During the years ended December 31, 2012, 2011 and 2010, 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:

	<b>Years Ended December 31,</b>		
	<b>2012</b>	<b>2011</b>	<b>2010</b>
Weighted average fair value of options .....	\$7.40	\$2.15	\$2.03
Risk-free interest rate .....	0.86%	2.07%	1.97%
Expected dividend yield .....	0%	0%	0%
Expected option term (in years) .....	5.32	5.20	5.14
Expected volatility .....	79.4%	75.0%	70.9%

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.

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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 (In Thousands)</u>
Options outstanding at December 31, 2011 . . . . .	7,578,612	\$ 6.25		
Granted . . . . .	1,658,075	\$11.48		
Cancelled . . . . .	(326,756)	\$11.25		
Exercised . . . . .	<u>(1,354,333)</u>	\$ 3.95		
Options outstanding at December 31, 2012 . . . . .	<u>7,555,598</u>	\$ 7.60	5.65	\$3,699
Options exercisable at December 31, 2012 . . . . .	5,409,055	\$ 7.42	4.45	\$2,417
Options vested and expected to vest at December 31, 2012 . . . . .	7,490,806	\$ 7.59	5.62	\$3,650

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, 2012, based on the closing price of our common stock of \$4.85 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 2012, 2011 and 2010 was \$10.0 million, \$1.2 million and \$0.5 million, respectively. The increase in the 2012 intrinsic value of stock options exercised as compared to 2011 was primarily due the increase of stock options exercised.

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 \$10.8 million of share-based compensation expense as of December 31, 2012 remaining to be amortized over a weighted average expected term of 2.5 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>2012</u>	<u>2011</u>	<u>2010</u>
Federal statutory rate benefit . . . . .	(34)%	(34)%	(34)%
State tax benefit, net of federal expense (benefit) . . . . .	(6)	3	(2)
Permanent items . . . . .	(1)	1	1
Other . . . . .	0	1	1
Valuation allowance . . . . .	<u>41</u>	<u>29</u>	<u>34</u>
Effective income tax rate . . . . .	<u>0%</u>	<u>0%</u>	<u>0%</u>

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The components of our net deferred taxes were as follows:

	December 31,	
	2012	2011
	(In Thousands)	
Depreciation . . . . .	\$ 2,739	\$ 1,667
Development contracts . . . . .	897	1,065
Nonqualified stock options . . . . .	5,700	7,628
Deferred licensing income . . . . .	1,847	25,724
Accrued expenses and other . . . . .	6,454	3,425
Capitalized research costs . . . . .	78,734	64,185
Research and development credits . . . . .	10,712	10,532
Foreign tax credit carryforward . . . . .	877	877
Net operating carryforwards . . . . .	110,330	89,798
Valuation allowance . . . . .	(218,290)	(204,901)
Deferred tax asset . . . . .	\$ —	\$ —

As of December 31, 2012, we had United States federal and state net operating loss carryforwards of \$312.5 million and \$76.8 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 began expiring 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 \$3.6 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 \$218.3 million has been established at December 31, 2012.

There were no significant changes to the balance of unrecognized tax benefits in 2012 or 2011 as compared to 2007 when we adopted FASB guidance related to unrecognized tax benefits. The total amount of unrecognized tax benefits was \$1.3 million at December 31, 2012. Of this amount, \$0.3 million will impact the effective tax rate if ultimately realized and \$1.0 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, 2012, we have accrued \$0.4 million related to interest and penalties for uncertain tax positions. Of this amount, less than \$0.1 million was included in other income, net for the year ended December 31, 2010. There were no amounts included in other income, net for the years ended December 31, 2012 and 2011.

The open tax years by major jurisdiction are: a) the years ended December 31, 2009 through 2011 for the United States; and b) the years ended December 31, 2010 and 2011 for France.



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**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 50% of employee contributions up to 6% of participants' annual compensation. We made contributions to the 401(k) plan of \$0.2 million during the year ended December 31, 2012 and \$0.1 million during each of the years ended December 31, 2011 and 2010.

We are required by statute to maintain a defined benefit plan for our employees in France. We have recorded \$0.5 million in other long-term liabilities related to this benefit plan as of December 31, 2012 and 2011.

**12. Related Party Transactions**

In connection with the collaboration with Novartis, we have generated revenues from Novartis related to royalty revenue associated with the sale of Tyzeka®/Sebivo®, license payments and reimbursements of royalties in the amount of \$33.6 million, \$4.3 million and \$6.2 million for the years ended December 31, 2012, 2011 and 2010, respectively. We recognized \$2.9 million, \$4.5 million and \$3.8 million as royalty revenue from Novartis' sales of Tyzeka®/Sebivo® during the years ended December 31, 2012, 2011 and 2010, respectively. Royalty revenues for the year ended December 31, 2012 included royalty payments through July 31, 2012, the date of the termination agreement.

The receivables from related party balance of \$7.4 million at December 31, 2012 consisted of \$7.2 million for the reimbursement by Novartis of the contractual payments to UAB which have been recorded as collaboration revenue – related party in our consolidated statement of operations and comprehensive loss for the year ended December 31, 2012. The remaining balance of \$0.2 million was related to the reimbursement by Novartis of the contractual payments to CNRS that are subject to our assignment to Novartis of our patent rights under the amended and restated agreement with CNRS and the University of Montpellier related to Tyzeka®/Sebivo®. Until the assignment of such patent rights to Novartis is effective, payments from Novartis to reimburse us for our contractual payments to CNRS of \$0.2 million were recorded as a deferred payment obligation as of December 31, 2012. The receivables from related party balance of \$1.2 million at December 31, 2011 consisted of royalties associated with product sales of Tyzeka®/Sebivo® from Novartis.

We also included \$4.7 million and \$27.3 million as deferred revenue, related party, as of December 31, 2012 and 2011, 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:

	December 31,	
	2012	2011
	(In Thousands)	
United States .....	\$2,102	\$3,389
France .....	1,172	1,307
	\$3,274	\$4,696

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**14. Collaborative Agreements and License Agreements**

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

***Janssen Pharmaceuticals, Inc. Collaboration***

In January 2013, we entered into a non-exclusive collaboration agreement with Janssen for the clinical evaluation of all oral DAA HCV combination therapies. The combination therapies involve IDX719, our once-daily pan-genotypic NS5A inhibitor, simeprevir (TMC435), a once-daily protease inhibitor jointly developed by Janssen and Medivir, and TMC647055, a once-daily non-nucleoside polymerase inhibitor, boosted with low dose ritonavir, being developed by Janssen.

Under the terms of this collaboration agreement, we will conduct the clinical trials. Clinical development plans include drug-drug interaction studies, followed by phase II studies as agreed between the companies, pending approval from regulatory authorities. The phase II program is expected to first evaluate the two-DAA combination of IDX719 and simeprevir (TMC435) plus ribavirin in treatment-naïve HCV-infected patients. Subsequently, the companies plan to evaluate a three-DAA combination of IDX719, simeprevir (TMC435), TMC647055 with low dose ritonavir, with and without ribavirin, in a broader group of HCV-infected patients.

The clinical trials will be conducted under an arrangement whereby Janssen provides us with clinical supply of simeprevir (TMC435) and TMC647055 at no cost. Neither party will receive any milestone or royalty payments from the other party under this agreement. Both companies retain all rights to their respective compounds under this agreement. The parties have no obligation to conduct additional clinical trials beyond those described here. Neither party has licensed any commercial rights to the other party.

This collaboration agreement may be terminated by either party in certain circumstances. This collaboration agreement will terminate if the parties do not agree to proceed with a two-DAA combination clinical trial of IDX719 and simeprevir (TMC435) plus ribavirin in treatment-naïve HCV-infected patients within a certain period of time following the drug-drug interaction study involving these two compounds. Janssen may terminate the collaboration agreement, in its sole discretion, by providing us with 30 days written notice. If Janssen terminates the collaboration agreement in such instance, it shall reimburse us for certain of our costs associated with the collaboration. Janssen may also terminate the collaboration agreement if we fail to meet certain formulation requirements.

If either us or Janssen materially breaches the collaboration agreement and does not cure such breach within a specified time period, the non-breaching party may terminate the collaboration agreement in its entirety. Either party may also terminate the collaboration agreement, effective immediately, if the other party files for bankruptcy, is dissolved or has a receiver appointed for substantially all of its property. Either party may also terminate the collaboration agreement to protect the safety, health or welfare of subjects in the trials. We may terminate the collaboration agreement prior to the commencement of certain activities if Janssen's research development and license agreement with Medivir is terminated.

***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 GlaxoSmithKline, or 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 \$26.5 million in milestone payments related to the achievement of a preclinical operational milestone and the initiation of a phase IIb clinical study of '761.

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.

In February 2011, ViiV informed us that the FDA placed '761 on clinical hold and subsequently, the ViiV license agreement was terminated on March 15, 2012. Upon termination, ViiV relinquished all rights it had in the intellectual property licensed from us and granted 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. We will not receive any additional milestone or royalty payments under the ViiV license agreement. We had \$36.1 million of deferred revenue recorded as of December 31, 2011 related to payments received from ViiV. During the first quarter of 2012, as a result of the termination, we recognized the deferred revenue balance of \$36.1 million as other collaboration revenue. We recognized \$36.1 million, \$2.6 million and \$4.0 million of collaboration revenue for the years ended December 31, 2012, 2011 and 2010, respectively.

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.

***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. 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, milestone payments or any other payments in connection with a sublicense by us of technology covered by the agreements between the University of Cagliari and us.

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

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, 2012 and 2011 representing amounts received from Sumitomo that have 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 July 2012 termination agreement, Novartis remains obligated to 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**

**15. Commitments and Contingencies**

***Lease Arrangements***

We lease our facilities and certain equipment under operating leases. Our lease arrangements have terms through the year 2020. Total rent expense under our operating leases was \$1.9 million, \$3.4 million and \$3.3 million for the years ended December 31, 2012, 2011 and 2010, respectively. Future minimum payments under lease arrangements at December 31, 2012 were as follows:

<u>Years Ending December 31,</u>	<u>Operating Leases</u>
	<u>(In Thousands)</u>
2013 .....	\$ 2,899
2014 .....	3,329
2015 .....	3,406
2016 .....	3,485
2017 .....	3,071
2018 and thereafter .....	6,849
Total .....	<u>\$23,039</u>

In October 2003, we entered into an operating lease commitment for our current office and laboratory space at 60 Hampshire Street in Cambridge, Massachusetts. The term of the lease was 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 remaining 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 which has been recorded as restricted cash in our consolidated balance sheets as of December 31, 2012 and 2011. The letter of credit expires in December 2013. In September 2012, in connection with entering into a new lease which is described below, we negotiated a revision to this lease which accelerated the termination date to be on or about April 30, 2013.

In September 2012, we entered into a seven year lease agreement for 46,418 square feet of office and laboratory space located at 320 Bent Street in Cambridge, Massachusetts beginning on or about April 1, 2013. The square footage of the leased property includes 5,596 square feet of office space located on the premises that will become available to us on or prior to February 28, 2014. We have an option to extend the term of this lease agreement for an additional five years beyond the original lease term. In connection with this operating lease commitment, a commercial bank issued a letter of credit in September 2012 for \$1.4 million collateralized by cash held with that bank which has been recorded as restricted cash in our consolidated balance sheet as of December 31, 2012. The letter of credit expires in September 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 had 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

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

commercial bank issued a letter of credit in May 2005 for \$0.4 million collateralized by cash we had on deposit with that bank and was 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.

***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. Such payments would be due even in the instance where we licensed such technology to a third-party. Currently, there are no such HCV products approved and therefore there was no related liability recorded as of December 31, 2012.

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, milestone payments or any other payments with respect to such technology from a collaborator or other third-party.

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 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 agreed to make additional payments to UABRF equal to 20% of all royalty payments received by us from Novartis from worldwide sales of Tyzeka<sup>®</sup>/Sebivo<sup>®</sup>, 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. Included in the consolidated balance sheet as of December 31, 2012 was a \$7.2 million liability related to this settlement agreement. Under the termination agreement executed in July 2012 with Novartis, we no longer receive royalty or milestone payments from Novartis based upon worldwide product sales of Tyzeka<sup>®</sup>/Sebivo<sup>®</sup> for the treatment of HBV in connection with our intellectual property related to Tyzeka<sup>®</sup>/Sebivo<sup>®</sup>. Novartis is required to reimburse us for our contractual payments to UABRF in connection with our intellectual property related to Tyzeka<sup>®</sup>/Sebivo<sup>®</sup>. Included in receivables from related party was \$7.2 million for the reimbursement from Novartis for these contractual payments which have been recorded as collaboration revenue – related party in our consolidated statement of operations and comprehensive loss for the year ended December 31, 2012.

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

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, including products for HBV, HCV and HIV. Such payments would be due even in the instance where we licensed such patents to a third-party. Under the termination agreement, we no longer receive royalty or milestone payments from Novartis based upon worldwide product sales of Tyzeka®/Sebivo® for the treatment of HBV. Novartis is required to reimburse us for our contractual payments to CNRS and the University of Montpellier, subject to our assignment to Novartis of our patent rights under the amended and restated agreement with CNRS and the University of Montpellier within 12 months of the execution of the termination agreement, in connection with our intellectual property related to Tyzeka®/Sebivo®. Until the assignment of such patents rights to Novartis is effective, payments from Novartis to reimburse us for our contractual payments to CNRS will be recorded as a deferred payment obligation on our consolidated balance sheet and we will continue to charge payments we make to CNRS to cost of revenues on our consolidated statement of operations and comprehensive loss. We are in the process of assigning these patent rights to Novartis.

***Legal Contingencies***

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. In June 2012, the License Commission granted an extension of the July 2010 variance until the end of our original lease term, or December 31, 2013. 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 at this time therefore we have not recorded a liability associated with this potential contingent matter.

In February 2012, an interference was declared by the United States Patent and Trademark Office, or the USPTO, concerning a patent application co-owned by us and a patent owned by Gilead Pharmasset LLC. Both the application and patent claim certain nucleoside compounds useful in treating HCV. While we cannot predict whether we will prevail, we intend to vigorously defend these actions and any others like it brought by any third-party. We do not believe our co-owned application at issue in the interference is relevant to any compounds we currently have under development. An interference is based upon complex specialized U.S. patent law. In the event we do not prevail in the interference, certain or all claims in our application may not be issued. In the event we do not prevail, we do not believe we will be required to make any payments to any third-parties and therefore we have not recorded a liability associated with this potential contingent matter.

In June 2012, Gilead Sciences, Inc. filed suit against us in Canadian Federal Court seeking to invalidate one of our issued Canadian patents. Our patent, which is the subject of the Canadian litigation, covers similar subject matter to that patent application at issue in the U.S. interference. In September 2012, Gilead Sciences, Ltd. filed

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

suit against us in the Norway District Court of Oslo seeking to invalidate one of our issued Norwegian patents. Our patent at issue in the potential Norwegian litigation covers similar subject matter to that patent application at issue in the U.S. interference. In January 2013, Gilead Sciences Australia Pty Ltd. commenced proceedings in the Federal Court of Australia seeking a declaration that certain claims of one of our issued Australian patents, covering similar subject matter to that patent application at issue in the U.S. interference, are invalid and an order that such claims be revoked. We do not believe the respective patents at issue in these cases are relevant to any compounds we currently have under development. Gilead Sciences, Inc. may make similar claims or bring additional legal proceedings in the U.S. other jurisdictions where we have granted patents. While we cannot predict whether we will prevail, we intend to vigorously defend these actions and any others like it brought by any third-party. In the event we do not prevail, we do not believe we will be required to make any payments to any third-parties 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 the development, manufacture and commercialization of our HCV products. We have also agreed to indemnify Novartis and its affiliates against losses suffered as a result of any breach of representations and warranties in the termination agreement, 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 drug candidates for the treatment of HBV and HCV, including representations regarding ownership of related inventions and discoveries. In the event of a breach of any such representation or warranty by us, Novartis has the right to seek indemnification from us, and, under certain circumstances, from our stockholders who sold shares to Novartis in 2003 (including certain of our current and former directors and officers), for damages suffered by Novartis as a result of such breach. The amounts for which we and our stockholders could be liable to Novartis could be substantial. 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, 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 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.

Under the Janssen collaboration agreement, we agreed to indemnify Janssen against losses suffered as a result of its breach of representations and warranties in the agreement and/or any injury to a subject in a clinical trial under the collaboration agreement caused by the use or manufacture of IDX719. We made numerous representations and warranties to Janssen. If one or more of these representations or warranties were not true at the time they were made, we would be in breach of the agreement. In the event of a breach by us or in the event of injury to a subject in a clinical trial under the collaboration agreement caused by the use or manufacture of IDX719, Janssen has the right to seek indemnification from us for damages suffered as a result of such breach or subject injury. The amounts for which we could be liable to Janssen under these circumstances may be substantial. In the instance where a subject in a clinical trial suffers injury or death and it is not determinable which compound caused the injury or death, each party shall be responsible for defending any third-party claims alleged against the party after the application of our clinical trial insurance, to the extent applicable.



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

**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>2012</b>					
Total revenues	\$35,645	\$ 1,438	\$ 32,253	\$ 327	\$ 69,663
Total operating expenses	24,537	27,026	28,187	25,294	105,044
Net income (loss)	11,449	(25,395)	4,271	(22,725)	(32,400)
Basic net income (loss) per common share	0.11	(0.23)	0.03	(0.17)	(0.27)
Diluted net (loss) per common share	0.10	(0.23)	0.03	(0.17)	(0.27)
<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)

In the first quarter of 2012, we recorded \$36.1 million of collaboration revenue related to the termination of the ViiV license agreement which is described more fully in Note 14.

In the third quarter of 2012, we recorded \$27.1 million of collaboration revenue-related party in connection with the termination agreement entered into with Novartis which is described more fully in Note 3.

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: February 25, 2013

/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)	February 25, 2013
<u>/s/ Daniella Beckman</u> Daniella Beckman	Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	February 25, 2013
<u>/s/ Wayne Hockmeyer</u> Wayne Hockmeyer	Director	February 25, 2013
<u>/s/ Thomas Hodgson</u> Thomas Hodgson	Director	February 25, 2013
<u>/s/ Tamar Howson</u> Tamar Howson	Director	February 25, 2013
<u>/s/ Denise Pollard-Knight</u> Denise Pollard-Knight	Director	February 25, 2013
<u>/s/ Anthony Rosenberg</u> Anthony Rosenberg	Director	February 25, 2013
<u>/s/ Michael Wyzga</u> Michael Wyzga	Director	February 25, 2013

## 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	Second Amended and Restated By-Laws	8-K	3.1	9/19/2012	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 September 25, 2012, by and between the Registrant and BMR-Rogers Street LLC	8-K	10.1	9/28/2012	000-49839
10.2	Termination Agreement, dated September 25, 2012, by and between the Registrant and BMR-Hampshire LLC, as successor-in-interest to BHX. LLC, as trustee of 205 Broadway Realty Trust	8-K	10.2	9/28/2012	000-49839
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
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

Exhibit Number	Description	Incorporated by Reference to			
		Form	Exhibit No.	Filing Date	SEC File Number
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	10-K for 12/31/11	10.12	3/2/2012	000-49839
	<b><i>Material contracts with Third-Parties</i></b>				
10.13+	Termination and Revised Relationship Agreement, dated July 31, 2012, between the Registrant, Idenix (Cayman) Limited and Novartis Pharma AG	10-Q	10.4	8/8/2012	000-49839
10.14+	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
10.15	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
10.16+	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
10.17+	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
10.18	Second Amended and Restated Stockholders' Agreement, dated July 31, 2012, by and among the Registrant, Novartis Pharma AG and the stockholders identified on the signature pages thereto	8-K	10.1	7/31/2012	000-49839

Exhibit Number	Description	Incorporated by Reference to			
		Form	Exhibit No.	Filing Date	SEC File Number
10.19	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
10.20+	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
10.21	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
10.22	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
10.23	Stock Purchase Agreement, dated February 4, 2009, between the Registrant and SmithKline Beecham Corporate	8-K	10.1	2/6/2009	000-49839
10.24+	Clinical Trial Collaboration Agreement, dated January 25, 2013 by and between the Registrant and Janssen Pharmaceuticals, Inc. <i>University of Cagliari</i>	*			
10.25+	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
10.26+	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
10.27+	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
10.28+	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
10.29	Collaborative Activities	S-1	10.18.2	7/6/2004	333-111157
10.30+	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>					
10.31	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
10.32+	Master Services Agreement, dated February 25, 2003, by and between the Registrant and Quintiles, Inc.	S-1	10.21	12/15/2003	333-111157
10.33	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
10.34	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
10.35	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
10.36+	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
<i>Material contracts — management contracts and compensatory plans</i>					
10.37#	Form of Incentive Stock Option Agreement for awards granted pursuant to the 2012 Stock Incentive Plan	10-Q	10.2	8/8/2012	000-49839
10.38#	Form of Non-Statutory Stock Option Agreement for awards granted pursuant to the 2012 Stock Incentive Plan	10-Q	10.3	8/8/2012	000-49839
10.39#	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
10.40#	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

Exhibit Number	Description	Incorporated by Reference to			
		Form	Exhibit No.	Filing Date	SEC File Number
10.41#	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
10.42#	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
10.43#	2012 Stock Incentive Plan	10-Q	10.1	8/8/2012	000-49839
10.44#	2005 Stock Incentive Plan, as amended	10-Q for 6/30/2010	10.1	7/27/2010	000-49839
10.45#	2004 Stock Incentive Plan	S-1 Amendment 2	10.32	5/28/2004	333-111157
10.46#	Amended and Restated 1998 Equity Incentive Plan	S-1 Amendment 2	10.1	6/1/2004	333-111157
10.47#	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
10.48#	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
10.49#	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
10.50#	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
10.51#	Employment Letter, dated November 30, 2010, by and between the Registrant and Maria Stahl	10-K	10.62	3/7/2011	000-49839
10.52#	Employment Letter, dated June 20, 2011, by and between the Registrant and Daniella Beckman	8-K	10.1	6/24/2011	000-49839
<b>Additional Exhibits</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	*			

Exhibit Number	Description	Incorporated by Reference to			
		Form	Exhibit No.	Filing Date	SEC File Number
31.2	Certification of 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 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



## Subsidiaries of the Company

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

\*\* Wholly-owned by Idenix (Cayman) Limited

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, 333-167330 and 333-182049) and Form S-3 (File Nos. 333-127710, 333-129213, 333-153471, 333-159716, 333-173374, 333-177167 and 333-182953) of Idenix Pharmaceuticals, Inc. of our report dated February 25, 2013 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  
February 25, 2013

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: February 25, 2013

/s/ RONALD C. RENAUD, JR.

Ronald C. Renaud, Jr.  
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: February 25, 2013

/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 year ended December 31, 2012 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Ronald C. Renaud, Jr., 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: February 25, 2013

/s/ RONALD C. RENAUD, JR.

Ronald C. Renaud, Jr.  
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 year ended December 31, 2012 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: February 25, 2013

/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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**BOARD OF DIRECTORS**

**Ronald C. Renaud, Jr.**  
*President and Chief Executive Officer  
of Idenix Pharmaceuticals, Inc.*

**Wayne T. Hockmeyer, Ph.D.**  
*Former Chairman of the Board of Directors  
of MedImmune, Inc.*

**Thomas R. Hodgson**  
*Chairman of the Board of Directors  
Former President and Chief Operating Officer  
of Abbott Laboratories*

**Tamar Howson**  
*Former Interim Chief Executive Officer of S\*Bio*

**Denise Pollard-Knight, Ph.D.**  
*Managing Partner of Phase4 Ventures*

**Anthony Rosenberg**  
*Head of Partnering & Emerging Businesses,  
Novartis Pharma AG*

**Michael Wyzga**  
*President and Chief Executive Officer  
Radius Health, Inc.*

**EXECUTIVE TEAM**

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

**Daniella Beckman**  
*Senior Vice President  
and Chief Financial Officer*

**Paul J. Fanning**  
*Senior Vice President, Human Resources*

**Douglas L. Mayers, M.D.**  
*Executive Vice President  
and Chief Medical Officer*

**Maria Stahl**  
*Senior Vice President and General Counsel*

**David N. Standing, Ph.D.**  
*Executive Vice President  
and Chief Scientific Officer*

**ANNUAL MEETING**

The Annual Meeting of Stockholders will be held on Thursday, June 6th at 9 a.m. Eastern Daylight Time at the offices of Wilmer Hale, 60 State Street, Boston, Massachusetts.

**TRANSFER AGENT**

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

**OUTSIDE COUNSEL**

Wilmer Hale  
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.

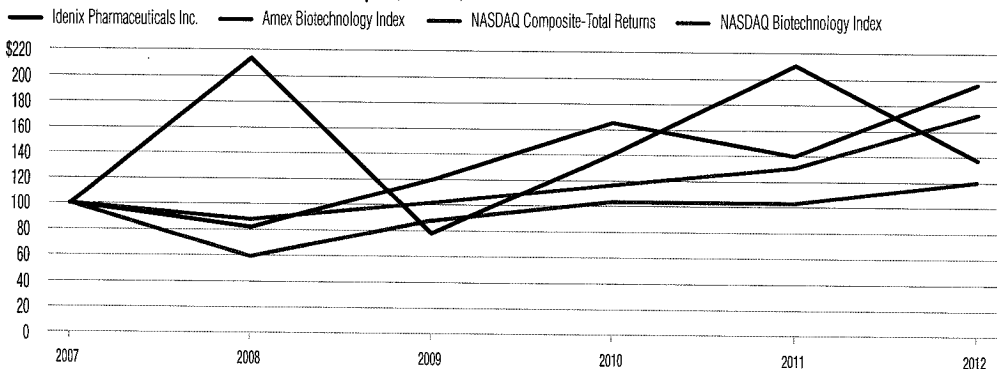
**IDENIX CONTACT**

Teri Dahlman  
Director  
Corporate Communications  
investor@idenix.com

**CORPORATE HEADQUARTERS**

Idenix Pharmaceuticals, Inc.  
320 Bent Street  
Cambridge, Massachusetts 02141

**Comparison Stock Performance Graph** (in dollars)



**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.  
Prepared by Zacks Investment Research, Inc. Used with permission. All rights reserved. Copyright 1980-2012.  
Index Data: Copyright NASDAQ OMX, Inc. Used with permission. All rights reserved.

**CAUTIONARY STATEMENTS REGARDING FORWARD-LOOKING STATEMENTS**

This annual report contains "forward-looking statements" for purposes of the safe harbor provisions of The Private Securities Litigation Reform Act of 1995, including but not limited to the statements regarding the Company's future business and financial performance. For this purpose, any statements contained herein that are not statements of historical fact may be deemed forward-looking statements. Without limiting the foregoing, the words "expect," "plans," "anticipates," "intends," "will," and similar expressions are also intended to identify forward-looking statements, as are expressed or implied statements with respect to the Company's potential pipeline candidates, including any expressed or implied statements regarding the efficacy and safety of IDX719 or any other drug candidate; the successful development of novel combinations of direct-acting antivirals for the treatment of HCV; the likelihood and success of any future clinical trials involving IDX719 or our other drug candidates; and expectations with respect to funding of operations and future cash balances. Actual results may differ materially from those indicated by such forward-looking statements as a result of risks and uncertainties, including but not limited to the following: there can be no guarantees that the Company will advance any clinical product candidate or other component of its potential pipeline to the clinic, to the regulatory process or to commercialization; management's expectations could be affected by unexpected regulatory actions or delays; uncertainties relating to, or unsuccessful results of, clinical trials, including additional data relating to the ongoing clinical trials evaluating its product candidates; the Company's ability to obtain additional funding required to conduct its research, development and commercialization activities; the Company's expectations regarding the benefits of the restructuring of its collaboration with Novartis; changes in the Company's business plan or objectives; the ability of the Company to attract and retain qualified personnel; competition in general; and the Company's ability to obtain, maintain and enforce patent and other intellectual property protection for its product candidates and its discoveries. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. These and other risks which may impact management's expectations are described in greater detail under the heading "Risk Factors" in the Company's annual report on Form 10-K for the year ended December 31, 2011, and the quarterly report on Form 10-Q for the quarter ended September 30, 2012, each as filed with the Securities and Exchange Commission (SEC) and in any subsequent periodic or current report that the Company files with the SEC. All forward-looking statements reflect the Company's estimates only as of the date of this release (unless another date is indicated) and should not be relied upon as reflecting the Company's views, expectations or beliefs at any date subsequent to the date of this release. While Idenix may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so, even if the Company's estimates change.



IDENIX PHARMACEUTICALS, INC.  
320 BENT STREET  
CAMBRIDGE, MASSACHUSETTS 02141  
[WWW.IDENIX.COM](http://WWW.IDENIX.COM)