



"In 2007, Idenix experienced a great deal of change, which enabled us to re-assess the strategic direction of our company and re-evaluate our focus. I am very pleased to report that the company continues to be grounded by a strong scientific foundation that enables us to rapidly discover novel antiviral drug candidates."

Jean-Pierre Sommadossi, Ph.D., Chairman and Chief Executive Officer of Idenix

## Dear Shareholder,

In 2007, Idenix experienced a great deal of change. Idenix began 2007 with a strong research and development group and an aspiring commercial organization, with our first approved product for the treatment of hepatitis B. We spent the better part of the year engaged in the continuing development of our commercial presence in the United States, following regulatory approval of Tyzeka® (telbivudine) at the end of 2006, and began building our commercial franchise in the European Union in anticipation of EU regulatory approval for Sebivo® (telbivudine). In the first quarter of 2007, Sebivo was approved in China, followed shortly thereafter by approval in the EU.

By the end of the second quarter of 2007, we were well on our way to achieving our corporate mission of becoming a leading antiviral franchise. Tyzeka/Sebivo was being approved by regulatory authorities around the world for the treatment of HBV and we had a robust pipeline, including a phase II drug candidate for the treatment of hepatitis C and an early-stage HIV drug candidate.

Change is a difficult thing for an organization – but what emerges on the other side of a game-changing event says a great deal about the strength of an organization's foundation. For Idenix, that game-changing event was the discontinuation of the development of valopicitabine, or NM283, in the third quarter of 2007, which had been our lead drug candidate for the treatment of hepatitis C. I am extremely proud of how our company responded to this challenge. We re-assessed the strategic direction of our company, re-evaluated our focus and implemented a strategic restructuring. As part of the restructuring, Novartis Pharma AG assumed full responsibility for the development, manufacturing and commercialization activities relating to Tyzeka/Sebivo effective October 1, 2007 in exchange for a royalty on worldwide product

sales. As a result of these changes, we reduced our workforce by approximately 100 positions, the majority of which supported the development and commercialization of Tyzeka/Sebivo in the United States and Europe. The restructuring was difficult – it was hard to part ways with very talented people who had given their all to Idenix – and on a personal level, it was one of the toughest points in my tenure as CEO.

I am very proud of the company's efforts on Tyzeka/ Sebivo – to bring a drug from an investigational new drug application (IND) to United States Food and Drug Administration approval in just over six years and have the drug approved in more than 50 countries within 12 months of U.S. approval is quite an achievement. That experience is not common among biotechnology companies; having succeeded once, I am confident that we will be able to do it again.

We are fortunate that since Idenix's beginning, we have been grounded by an exceptional scientific foundation that has enabled us to quickly discover novel antivirals. For the past two years, we have dedicated a great deal of time and energy to the discovery of drug candidates for the treatment of HCV and HIV. By year-end 2007, we had expanded our pipeline to include several novel direct-acting HCV product candidates and advanced our novel non-nucleoside reverse transcriptase inhibitor (NNRTI) development program for the treatment of HIV.

#### HIV DEVELOPMENT PROGRAM

IDX899, a non-nucleoside reverse transcriptase inhibitor, is our lead drug candidate for the treatment of HIV-1. During 2007, we filed a traditional IND for this compound and advanced IDX899 into man, first in healthy volunteers and then into a phase ib/lla proof-of-concept clinical study in HIV-infected individuals who had not been exposed to prior therapy (also known as treatment-naïve patients).



As we begin 2008 and approach the anniversary of our tenth year in business, we are a stronger, leaner organization that will devote all of our resources to the discovery and continued development of antiviral drugs for the treatment of HCV and HIV.

There are several needs that exist today within the HIV treatment market and we believe that a drug must have three key attributes to ultimately be successful:

- First, a new drug should have an excellent resistance profile. For many HIV patients today, treatment is chronic. Since resistance will build to any antiviral drug if the virus is not completely suppressed, it is important with chronic therapy that such resistance occur only after extended treatment.
   New drugs should be active against the resistant strains that emerge from previous generation therapies.
- Second, a new drug should be potent and safe to effectively treat patients as a longterm chronic therapy.
- Third, the drug should be conveniently dosed; ideally once-per-day in a low milligram formulation that could be administered as part of a single pill combination therapy.

Based on data from the studies we have conducted to date, we are very excited about the emerging profile of IDX899 as we believe it could provide advantages over currently approved and emerging NNRTIs in all of these areas.

#### HCV DISCOVERY PROGRAM

Idenix has a comprehensive HCV discovery program that began to show promise in late 2007. We are actively pursuing compounds from all three major classes of direct-acting HCV antivirals, but have focused our immediate attention on two of these classes: next-generation nucleoside/nucleotide polymerase inhibitors and protease inhibitors, as we believe that these two drug classes could be ideally suited for combination therapy.

Our HCV nucleoside polymerase inhibitor program comprises two novel nucleotide prodrugs, IDX184 and IDX102, which are based on our proprietary liver-targeting technology. Our liver-targeting technology delivers high levels of nucleoside triphosphate in the liver, potentially maximizing drug efficacy and limiting systemic side effects. Based on preclinical data, we expect to submit an IND in the United States and a CTA in Europe for at least one of these product candidates in 2008.

We also have made significant progress in our protease inhibitor discovery program, with the identification of two major chemical macrocyclic scaffolds with activity against the HCV protease. The scaffold is the master chemical structure that can be modified into a variety of different compounds. Our talented

chemists have generated a comprehensive library of potential clinical candidates that have demonstrated potent and selective antiviral activity in preclinical studies to date.

Our second-generation HCV drug candidates could offer improvements over direct-acting compounds currently in clinical development. For example, in preclinical studies, our second-generation polymerase inhibitor, IDX184, delivered multi-log viral load reductions in HCV genotype-1 infected chimpanzees in just four days – in line with the antiviral activity reported to date from protease inhibitors currently in development. We look forward to filing an IND and advancing IDX184 into the clinic in 2008 to evaluate this drug candidate in HCV-infected patients.

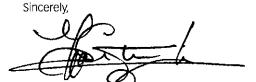
HCV nucleosides/nucleotides and HCV protease inhibitors act at different stages of HCV replication. We intend to assess the combination of these two classes given that such combination may result in a treatment more potent and durable than any one class as a stand-alone drug.

#### **CONTINUED PROGRESS**

As we begin 2008 and approach the anniversary of our tenth year in business, we are a stronger organization that will devote all of our resources to the discovery and continued development of antiviral drugs for the treatment of HCV and HIV. Within the next 12

months, we look forward to continuing the clinical development of IDX899, partnering our HIV program, and advancing our HCV nucleotide prodrug and macrocyclic protease inhibitor programs into the clinic. If the promising preclinical data generated to date are also seen in HCV-infected patients, the combination of our second-generation polymerase and protease inhibitors could lead to very exciting changes in the HCV treatment paradigm.

I would like to take this opportunity to thank our employees, board members and trusted advisors. Without them, and your continued support, Idenix could not have re-emerged from a difficult year in a position of such strength. I look forward to sharing with you our progress throughout the year.



Jean-Pierre Sommadossi, Ph.D. Chairman and Chief Executive Officer

March 31, 2008













#### **BOARD OF DIRECTORS**

Jean-Pierre Sommadossi, Ph.D. Founder, Chief Executive Officer and Chairman of the Board Idenix Pharmaceuticals, Inc.

Charles W. Cramb Vice Chairman, Chief Financial and Strategic Officer Avon Products, Inc.

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

Thomas R. Hodgson Former President and Chief Operating Officer Abbott Laboratories

Norman C. Payson, M.D. President NCP. Inc.

Robert Pelzer General Counsel and Head of Legal Services Novartis Pharma AG

Denise Pollard-Knight, Ph.D. Head of Nomura Phase4 Ventures

Emmanuel Puginier, M.D. Global Head of Marketing and Sales, General Medicines Novartis Pharma AG

Pamela Thomas-Graham Managing Director Angelo, Gordon & Co.

#### **EXECUTIVE TEAM**

Jean-Pierre Sommadossi, Ph.D. Founder, Chief Executive Officer and Chairman

Ronald C. Renaud, Jr. Chief Financial Officer and Treasurer

Paul J. Fanning Senior Vice President, Human Resources

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

David N. Standring, Ph.D. Executive Vice President, Biology

John E Weidenbruch Executive Vice President and General Counsel

#### **ANNUAL MEETING**

The Annual Meeting of the Stockholders will be held on Tuesday, June 3, 2008 at 9 a.m. Eastern Daylight Time, at the offices of Wilmer Cutler Pickering Hale and Dorr LLP, 60 State Street, Boston, Massachusetts.

#### TRANSFER AGENT

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

#### **OUTSIDE COUNSEL**

Wilmer Cutler Pickering Hale and Dorr LLP 60 State Street Boston, Massachusetts 02109

### INDEPENDENT REGISTERED **PUBLIC ACCOUNTING FIRM**

PricewaterhouseCoopers LLP 125 High Street Boston, Massachusetts 02118

#### MARKET INFORMATION

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

#### **IDENIX CONTACT**

Amy Sullivan Vice President, Corporate Communications email: sullivan.amy@idenix.com

#### **CORPORATE HEADQUARTERS**

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

#### FORM 10-K

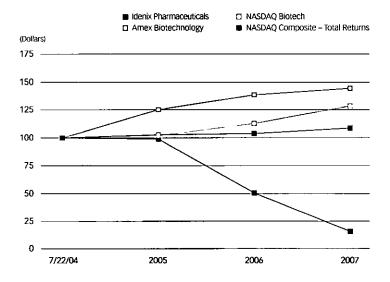
A copy of Idenix's Form 10-K for the year ended December 31, 2007 as filed with the Securities and Exchange Commission is available on http://www.sec.gov.

## COMPARATIVE STOCK PERFORMANCE GRAPH

This comparative stock performance graph compares the cumulative stockholder return on our common stock for the period from July 22, 2004 (the date our common stock began publicly trading) through December 31, 2007 with the cumulative total return on (i) the American Stock Exchange, or AMEX Biotechnology Index, (ii) the NASDAQ Stock Market (U.S. Companies), or the "NASDAQ Composite Index," and (iii) the NASDAQ Biotech Index. The graph assumes \$100 had been invested in our common stock, the AMEX Biotechnology Index, the NASDAQ Composite Index and the NASDAQ Biotech Index on July 22, 2004.

#### Comparison of 3 Year Cumulative Total Return Assumes Initial Investment of \$100

December 2007



## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## 🔏 Form 10-K

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

For the fiscal year ended December 31, 2007

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

For the transition period from

SEC Mail Processing Section

Commission file number 000-49839

harmaceuticals. Inc.

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(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or Other Jurisdiction of Incorporation or Organization)

60 Hampshire Street,

45-0478605 (I.R.S. Employer

Identification No.)

Washington, DC 100

02139 (Zip Code)

Cambridge, Massachusetts (Address of Principal Executive Offices)

(617) 995-9800

(Registrant's telephone number, including area code)

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

Common Stock, \$.001 par value

The NASDAQ Global Market

(Title of class)

(Name of exchange on which registered)

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

	Indicate	bу	check	mark	if the	registrant	IS 8	a well-known	seasoned	issuer,	as	defined	in b	Kule	405	OI	tne	Securities
t.	Yes 🗆		No ☑															
	Indicate I	by cl	neck m	ark if t	he regis	trant is not	requi	ired to file repo	orts pursuai	nt to Sec	tion	13 or 15	(d) of	f the A	Act.	Yes		No 🖾
	Indicate 1	by c	heck m	ark wł	ether ti	ne registrar	t: (1)	has filed all re	eports requ	ired to b	e fil	led by Se	ection	13 o	r 15(c	i) of	the	Securities
¢ł	hange Act	of I	934 du	ring th	e preced	ling 12 mo	nths (	or for such sho	rter period	that the	regi	strant wa	s requ	uired (	to file	suc	h гер	ports), and
t	nas been s	ubje	ct to s	uch fili	ing requ	iirements f	or the	e past 90 days.	Yes ☑	No !								

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this orm 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 porting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of e Exchange Act. (Check one):

arge 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  $\Box$ 

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant based on the last ported sale price of the common stock on the NASDAQ Global Market on June 30, 2007, was approximately \$132,000,000. For this irpose, the registrant considers its directors and officers and Novartis AG to be affiliates.

Number of shares outstanding of the registrant's class of common stock as of March 3, 2008: 56,286,241 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 eld on June 3. 2008 are incorporated by reference into Part III of this Annual Report on Form 10-K.

## Idenix Pharmaceuticals, Inc.

## Form 10-K

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## Cautionary Statement Regarding Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act, as amended, concerning our business, operations and financial condition, including statements with respect to the expected timing and results of completion of phases of development of our product candidates, the safety, efficacy and potential benefits of our product candidates, expectations with respect to development and commercialization of telbivudine and our other product candidates, the timing and results of the submission, acceptance and approval of regulatory filings, the scope of patent protection with respect to these product 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 regarding our strategy, future operations, timetables for development, regulatory approval and commercialization of product candidates, financial position, costs, prospects, plans and objectives of management are forward-looking statements. When used in this Annual Report on Form 10-K the words "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 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; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures; and uncertainties regarding necessary levels of expenditures in the future. There can be no guarantee that development of any product 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 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 and should not be relied upon as representing our expectations as of any other date. Subsequent events and developments will cause our expectations to change. However, 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.

### The Company

Idenix Pharmaceuticals, Inc. is a biopharmaceutical company engaged in the discovery and development of drugs for the treatment of human viral and other infectious diseases with operations in the United States and Europe. Our current focus is on diseases caused by hepatitis C virus, or HCV, and human immunodeficiency virus, or HIV.

References to "we," "us," "our" and similar expressions mean Idenix Pharmaceuticals, Inc. and our consolidated subsidiaries.

## 2007 Developments

#### **HBV**

Prior to October 1, 2007, we developed, commercialized and manufactured telbivudine for the treatment of patients with chronic hepatitis B. Certain of these activities were done with Novartis Pharma AG, or Novartis. Telbivudine is marketed as Tyzeka® in the United States and Sebivo® outside the United States. In April 2007, Sebivo® was approved in the European Union for the treatment of patients with chronic hepatitis B. At December 31, 2007, Tyzeka®/Sebivo® was approved in more than 50 countries world-wide, including China.

In September 2007, we entered into an amendment to the development, license and commercialization agreement dated May 8, 2003 between us and Novartis, which we refer to as the 2007 Amendment. When we refer to the development and commercialization agreement, we mean the 2003 original agreement, the 2007 Amendment and all prior amendments. We and Novartis also entered into a transition services agreement, or a TSA, as part of the 2007 Amendment. Pursuant to the 2007 Amendment, we transferred to Novartis our development, commercialization and manufacturing rights and obligations pertaining to telbivudine (Tyzeka®/Sebivo®) on a worldwide basis. Effective October 1, 2007, we began receiving royalty payments equal to a percentage of net sales of Tyzeka®/Sebivo®, with such percentage increasing according to specified tiers of net sales. The royalty percentage varies based upon the territory and the aggregate dollar amount of net sales.

In conjunction with the 2007 Amendment, we announced a restructuring of our operations and we initiated a plan to enact a workforce reduction of approximately 100 positions, the majority of which had supported the development and commercialization of Tyzeka®/Sebivo® in the United States and Europe. The restructuring was a strategic decision on our behalf to focus our resources on our HCV and HIV discovery and development programs.

In the third quarter of 2007, we also decided not to continue with the development of valtorcitabine, our other product candidate for the treatment of hepatitis B virus, or HBV.

#### **HCV**

In July 2007, we announced that the U.S. Food and Drug Administration, or FDA, had placed on clinical hold in the United States our development program of valopicitabine, or NM283, for the treatment of HCV based on the overall risk/benefit profile observed in clinical testing. We subsequently discontinued the development of valopicitabine.

Our HCV discovery program is focused on three classes of drugs for the treatment of HCV, which include nucleoside/nucleotide polymerase inhibitors, protease inhibitors and non-nucleoside polymerase inhibitors. We currently have two next-generation nucleoside/nucleotide polymerase inhibitors, IDX102 and IDX184, in late-stage preclinical development.

## HIV

In April 2007, we filed an investigational new drug application, or IND, for IDX899, our lead HIV product candidate and recently completed our first cohort in an ongoing phase I/II study in HIV-infected, treatment-naïve patients.

#### Overview

We believe that large market opportunities exist for new treatments for HCV and HIV. Chronic hepatitis C is an inflammatory liver disease associated with HCV infection. The World Health Organization has estimated that approximately 170 million people worldwide are chronically infected with HCV, including over 2.7 million people in the United States. The World Health Organization has estimated that approximately 40 million people worldwide are chronically infected with HIV, including more than 1 million people in the United States.

In May 2003, we entered into the collaboration with Novartis, relating to the worldwide development and commercialization of our product candidates. Simultaneously, Novartis purchased approximately 54% of our outstanding capital stock from our stockholders for \$255.0 million in cash, with an aggregate amount of up to \$357.0 million contingently payable to these stockholders if we achieve predetermined development milestones relating to an HCV product candidate. Including shares acquired in 2005 from its affiliate, Novartis BioVentures Ltd., and shares acquired as a result of the exercise of its stock subscription rights, as of March 3, 2008 Novartis owns approximately 56% of our outstanding common stock. In connection with its initial purchase of our common stock, Novartis agreed not to acquire additional shares of our voting stock unless a majority of our independent directors approves or requests the acquisition. These restrictions will terminate on May 8, 2008.

As part of the development and commercialization agreement between us and Novartis, Novartis has an option to license any of our development-stage product candidates, generally 90 days after early demonstration of activity and safety in a proof of concept clinical study. Novartis will have an option to license IDX899, our lead product candidate for HIV.

In July 2007, we announced that the FDA had placed on clinical hold in the United States our development program of valopicitabine. We subsequently discontinued the development of valopicitabine. As a result, we do not expect to receive any additional license fees or milestone payments for valopicitabine from Novartis. Under the development and commercialization agreement, Novartis agreed to pay us up to \$500.0 million in license fees and regulatory milestone payments for an HCV product candidate. Of this amount and prior to our discontinuation of valopicitabine, we received a \$25.0 million license payment from Novartis, an additional \$25.0 million milestone payment based upon results from our phase I clinical trial and Novartis provided clinical development funding for valopicitabine.

As a direct result of the transfer of our development, commercialization and manufacturing rights and obligations to telbivudine on a worldwide basis to Novartis, on September 28, 2007 we announced a restructuring of our operations and a workforce reduction of approximately 100 positions, including the termination of our sales force in the United States and Europe. We continue to have co-promotion and co-marketing rights with Novartis in the United States, United Kingdom, France, Germany, Italy and Spain on all other products that Novartis licenses from us that are successfully developed and approved for commercial sales. Novartis has the exclusive right to promote and market these licensed products in the rest of the world.

We have incurred significant losses since our inception in May 1998. While our operating expenses for 2008 will be considerably less than that for 2007, we expect that operating expenses for 2009 and beyond may increase as we expand our drug discovery and development efforts.

We maintain a web site with the address www.idenix.com. We are not including the information contained on our web site as part of, or incorporating by reference into, this Annual Report on Form 10-K. We make available free of charge on or through our web site our Annual Report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports as soon as practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission, or SEC. In addition, copies of our reports filed electronically with the SEC may be accessed on the SEC's web site at <a href="www.sec.gov">www.sec.gov</a>. 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 web site 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.

We are a Delaware corporation. Our principal offices are located at 60 Hampshire Street, Cambridge, Massachusetts 02139. The telephone number of our principal executive offices is 617-995-9800. Idenix is one of

our registered trademarks or service marks. All other trademarks, service marks, or tradenames referenced in this Annual Report on Form 10-K are the property of their respective owners.

In this Annual Report, all references to Tyzeka® (trade name of telbivudine in the United States), Sebivo® (trade name of telbivudine for countries other than the United States) and Tyzeka®/Sebivo® refer to telbivudine.

### **Products and Product Candidates**

We believe that our product candidates may have one or more therapeutic features that we believe will afford competitive advantages over currently approved therapies. Such therapeutic features may include efficacy, safety, resistance profile or convenience of dosing. The product candidates that we are developing are selective and specific, intended for convenient oral administration, and we believe may be used in combination with other therapeutic agents to improve clinical benefits.

#### Hepatitis C

## **HCV** Discovery Program

We have a comprehensive HCV discovery program that is focused on small molecule anti-HCV compounds from each of the three relevant drug classes: nucleoside/nucleotide polymerase inhibitors, non-nucleoside polymerase inhibitors and protease inhibitors. The key objective of our HCV discovery program is to identify and develop products that we believe will be competitive by offering significant improvements when combined with or compared to currently approved therapies with regard to safety, efficacy, resistance or convenience of dosing. Our efforts are focused on the discovery of product candidates that we expect will be active against various strains of HCV, including the genotype 1 strain of HCV, which is responsible for more than 70% of HCV infections in the United States and Japan and almost 65% of HCV infections in Europe.

Our most advanced program is next-generation nucleoside/nucleotide polymerase inhibitors. We have identified two candidates, IDX102 and IDX184, which are in late stage preclinical testing. We are in discussions with Novartis regarding the clinical development of these product candidates. With respect to IDX102 and IDX184, we expect to submit an IND in the United States and a clinical trial authorization, or CTA, in Europe for at least one of these product candidates in 2008. We have also identified several promising protease inhibitor compounds and project to file an IND and/or CTA from this program sometime during the first quarter of 2009. We believe that successful development of two or more HCV product candidates that may be used as part of a multiple-drug combination therapy would enable us to establish a franchise in this therapeutic area by offering treatments to a broad HCV population, including those patients who cannot be treated with interferon-based therapies, those for whom drug-related adverse side effects and inconvenient dosing regimens of existing therapies reduce compliance, or those for whom existing treatment regimens have been ineffective.

Nucleoside and nucleotide inhibitors are classes of small molecule compounds that have a proven record of success as antiviral agents. Nucleosides/nucleotides are small, natural chemical compounds that function as the building blocks of human and viral genetic material, commonly referred to as deoxyribonucleic acid, or DNA, or ribonucleic acid, or RNA. Nucleoside/nucleotides inhibitors are small molecules that effectively target viral polymerases, the enzymes that replicate viral genetic information. Mimicking the role of natural nucleosides, antiviral nucleoside inhibitors 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, nucleosides and nucleotides generally offer selectivity, antiviral activity, long duration of action and convenient oral administration. As a result, nucleosides and nucleotides may be particularly well suited for the treatment of chronic viral diseases.

Viral proteases are required for viral replication. The HCV virus proteins are initially created as one long protein which is then cut into smaller proteins by the HCV protease enzyme. These smaller proteins then join together to form a replication complex to reproduce the viral genetic material. HCV protease inhibitors block the cutting of the initial large protein and thus block the formation of the replication complex preventing the virus from reproducing.

Since HCV nucleosides/nucleotides and HCV protease inhibitors act at different stages of HCV replication, the combination of these two classes may result in a potent combination treatment. Combining drugs from two different classes of HCV inhibitors could lead to a more potent blockade of HCV replication and prevent the emergence of drug resistance to either drug.

## Valopicitabine

In July 2007, we announced that the FDA had placed on clinical hold in the United States our development program for valopicitabine for the treatment of HCV, based on the overall risk/benefit profile observed in clinical testing. As a result of the clinical hold, the development of valopicitabine was discontinued.

## HIV

In addition to our HCV discovery and development program, we are also engaged in efforts to develop therapeutics for the treatment of HIV-1 from the class of compounds known as non-nucleoside reverse transcriptase inhibitors, or NNRTIs. This class of drugs is being evaluated for once-a-day oral administration. We filed an IND for IDX899 in 2007 and completed a phase I dose escalation study in healthy volunteers. The phase I study was designed to assess the safety and pharmacokinetics of IDX899 in healthy volunteers. In this study, IDX899 appeared to be well tolerated at single doses up to 1200 mg and multiple doses up to 800 mg daily over a seven day period. No serious or clinically significant adverse events were reported for the 65 IDX899-treated volunteers in this study. One healthy volunteer, after the 400 mg single dose administration of this study, experienced a single unconfirmed QTc elevation. We believe this is not a significant clinical finding as it is within the expected variability of multiple QTc measurements in a healthy volunteer study. Two volunteers discontinued from the study due to adverse events.

We are currently evaluating IDX899 in a 7-day proof of concept study in HIV-infected treatment-naïve patients. In the first dosing cohort, eight HIV-1 infected treatment-naïve patients receiving 800 mg of IDX899 oncedaily achieved a median reduction in virus level of approximately 2 logs or 99% after seven days of treatment. No serious adverse events or pattern of laboratory abnormalities were observed. No patients discontinued from the 800 mg cohort.

## Hepatitis B

#### **Telbivudine**

Transition to Novartis

On October 25, 2006, the FDA approved Tyzeka® for the treatment of patients with chronic hepatitis B in the United States. In addition, Sebivo® has been approved in more than 50 countries outside the United States, including Switzerland, China and the European Union for the treatment of patients with chronic hepatitis B. Effective October 1, 2007, we transferred to Novartis our development, commercialization and manufacturing rights and obligations related to telbivudine on a worldwide basis in exchange for royalty payments equal to a percentage of net sales, with such percentage increasing according to specified tiers of net sales. Beginning in the fourth quarter of 2007, Novartis is solely responsible for clinical trial costs and related expenditures associated with telbivudine. We also transitioned to Novartis all ongoing clinical trials and commercial activities for telbivudine.

The original worldwide marketing applications for telbivudine were based on one-year data from a two-year nternational phase III clinical trial that we refer to as the GLOBE study. The final two-year results from the GLOBE study were submitted to the FDA in December 2007 as a supplementary NDA, or sNDA, and are expected to provide additional information intended for supplemental product labeling regarding the effects of longer-term reatment with telbivudine. An additional NDA for an oral solution formulation of telbivudine was also submitted in December 2007 for the primary purpose of allowing for more appropriate dose adjustments in patients with renal mpairment.

In an effort to broaden the label to include patients with decompensated liver disease, there is an ongoing Novartis-sponsored phase III clinical trial in HBV-infected patients with decompensated liver disease. If completion and analysis of this study yields positive results, we expect that an sNDA will be submitted to the FDA.

#### Phase IIIb/IV Clinical Trials

Prior to the transfer to Novartis, we were also conducting several clinical trials to help further establish the product profile of Tyzeka®/Sebivo®. We refer to these studies as phase IIIb or phase IV trials. These trials were designed to provide additional information regarding the antiviral effects and clinical benefit of Tyzeka®/Sebivo® compared to currently available treatments for HBV, as well as to assess the potential benefit of combining Tyzeka®/Sebivo® with adefovir dipivoxil, as well as tenofivir. As a result of the 2007 Amendment, Novartis is now responsible for completion of these phase IIIb and phase IV trials.

#### Valtorcitabine

We had been developing a second HBV product candidate, valtorcitabine, as a potential combination therapy with telbivudine in a phase IIb clinical trial. Following receipt of data from this clinical trial in the third quarter of 2007, we, with Novartis, decided not to advance this combination into phase III development.

#### **Antiviral Research**

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

Our Scientists. Our scientists are engaged in drug discovery and preclinical drug development. Our scientists have expertise in the areas of medicinal chemistry, molecular virology and pharmacology, and have substantial experience in applying this expertise to the discovery and development of nucleosides/nucleotides, non-nucleosides and protease inhibitors which target enzymes of 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 inhibitors. In addition to our focused library, we have engaged with other entities to obtain rights to libraries comprised of a significant number of compounds that may have utility targeting and inhibiting viral replication.

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/nucleotide, nucleoside analog, nucleotide, and non-nucleoside and protease inhibitor libraries and those libraries to which we have access could yield a small molecule lead. The final selection is based on the probability 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 facilities enhances early progress toward lead optimization in our Cambridge, Massachusetts facilities.

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 in our Cambridge, Massachusetts facilities. 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.

#### Research and Development Expenses

Research and development expenses for the years ended December 31, 2007, 2006 and 2005, were \$85.8 million, \$96.1 million and \$86.6 million, respectively, and represented 54%, 63%, and 72%, respectively, of our total operating expenses.

### Collaborations

#### Relationship with Novartis

#### Overview

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

- the development and commercialization agreement, under which we collaborate with Novartis to develop, manufacture and commercialize our HBV product candidates and our HCV and other product candidates which they license from us;
- the supply agreement, under which Novartis manufactured for us the active pharmaceutical ingredient, or API, for the clinical development and commercial supply of product candidates it licensed from us and the finishing and packaging of licensed products for commercial sale;
- the stockholders' agreement, which was subsequently amended and restated in July 2004 in connection with the closing of our initial public offering; and
- the stock purchase transaction, under which Novartis purchased approximately 54% of our outstanding capital stock from our then existing 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 an HCV product candidate.

In each of 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 from us 5,400,000 shares of our common stock for an aggregate purchase price of \$75.6 million in connection with our July 2004 initial public offering and 3,939,131 shares of common stock in exchange 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 1,100,000 shares of common stock for a purchase price of \$.001 per share in exchange for the termination of certain stock subscription rights held by Novartis. As of March 3, 2008, Novartis owns approximately 56% of our outstanding common stock.

## Development, License and Commercialization Agreement

## **Designation of Products**

As part of the development and commercialization agreement between us and Novartis, Novartis has an option to license any of our development-stage product candidates generally 90 days after early demonstration of activity and safety in a proof of concept clinical study. To date, Novartis has exercised that option for the following products and product candidates:

- Tyzeka<sup>®</sup>/Sebivo<sup>®</sup>, which was transferred to Novartis pursuant to the 2007 Amendment;
- · valtorcitabine, our HBV product candidate, which we no longer continue to develop; and
- valopicitabine, our HCV product candidate, which was placed on clinical hold by the FDA in July 2007 based on the overall risk/benefit profile observed in clinical testing.

In September 2007, we entered into the 2007 Amendment and the TSA. The 2007 Amendment and TSA are effective October 1, 2007. Pursuant to the 2007 Amendment, we transferred to Novartis our development, commercialization and manufacturing rights and obligations related to telbivudine, our drug product for the treatment of HBV, on a worldwide basis. The royalty payments we receive will be equal to a percentage of net sales

of Tyzeka\*/Sebivo\*, with such percentage increasing according to specified tiers of net sales. The royalty percentage shall vary based upon the territory and the aggregate dollar amount of net sales. Novartis shall also be responsible for certain costs associated with the transition of third party contracts and arrangements relating to telbivudine and certain intellectual property prosecution and enforcement activities. Pursuant to the TSA, we will provide Novartis with certain services relating to telbivudine through June 2008 (or later if agreed to by the parties). We will be reimbursed by Novartis for these services.

Novartis paid us a license fee of \$75.0 million in May 2003 for Tyzeka®/Sebivo® and valtorcitabine. Novartis also provided development funding and was obligated to make milestone payments which could have totaled up to \$35.0 million upon achievement of regulatory approvals for Sebivo® and valtorcitabine in Europe and China. Of these \$35.0 million in milestone payments, we received payment on two of these regulatory milestones in 2007 totaling \$20.0 million. We do not expect to receive any additional regulatory milestones for telbivudine or valtorcitabine.

In March 2006, Novartis exercised its option to license valopicitabine, our lead HCV product candidate at that time. Under the development and commercialization agreement, Novartis agreed to pay us up to \$500.0 million in license fees and regulatory milestone payments for an HCV product candidate. Of this amount and as a result of its option exercise, Novartis paid us a license fee of \$25.0 million, paid us an additional \$25.0 million milestone payment based upon results from our phase I clinical trial and provided development funding for the product candidate. In July 2007, we announced that the FDA had placed on clinical hold in the United States our development program of valopicitabine for the treatment of HCV based on the overall risk/benefit profile observed in clinical testing. We subsequently discontinued the development of valopicitabine. As a result, we do not expect to receive any additional license fees or milestone payments for valopicitabine from Novartis.

In addition, Novartis has the exclusive option to obtain rights to other product candidates developed by us, or in some cases licensed to us, so long as Novartis maintains ownership of 51% of our voting stock and for a specified period of time thereafter.

The terms of these options, including license fees, milestone payments and payments in reimbursement of development expenses, vary according to the disease which the product candidate treats, the stage of development of the product candidate, the present value of future cash flows of the product candidate relative to those previously estimated for licensed products and product candidates, and Novartis' ownership interest in Idenix.

## Development of Products and Regulatory Activities

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

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

## **Product Commercialization**

We initially granted Novartis an exclusive, worldwide license to market and sell Tyzeka®/Sebivo®, valtorcitabine and valopicitabine, subject to our commercialization rights. Pursuant to the 2007 Amendment, we transferred all our development, commercialization and manufacturing rights to Novartis relating to telbivudine (Tyzeka®/Sebivo®). In the third quarter of 2007 we discontinued development of valtorcitabine, our HBV product candidate. Valopicitabine, our HCV product candidate, was placed on clinical hold by the FDA in July 2007 based on the

overall risk/benefit profile observed in clinical testing. As a result, we will not continue with the development of these product candidates.

In accordance with the arrangements set forth in our development and commercialization agreement with Novartis, we have the right to co-promote or co-market with Novartis in the United States, United Kingdom, France, Germany, Italy and Spain any products that Novartis licenses from us. If we co-promote or co-market, in the United States, we will act as the lead commercial party and record revenue from product sales and will share equally the resulting net benefit or net loss with Novartis from co-promotion from the date of product launch. In the United Kingdom, France, Germany, Italy and Spain, Novartis will act as the lead commercial party and record revenue from product sales. In the United Kingdom, France, Germany, Italy and Spain, the net benefit we might realize will increase incrementally during the first three years from the date of product launch, such that we will share equally with Novartis the net benefit from the co-promotion beginning in the third year from the date of product launch.

In other countries, we will effectively sell products to Novartis for their further sale to third parties. Novartis will pay us to acquire such products at a price that is determined in part by the volume of product net sales under the terms of the supply agreement described below.

## Exclusivity

Novartis has agreed that it will not market, sell or promote, or grant a license to any third party to market, sell or promote, certain competing products. However, if Novartis seeks to engage in such activities, it must first inform us of the competitive product opportunity and, at our election, enter into good faith negotiations with us concerning such opportunity. If we either do not elect to enter into negotiations with respect to such opportunity or are unable to reach agreement within a specified period, Novartis would be free to proceed with its plans with respect to such competing product. The competitive restrictions on Novartis terminate on a country-by-country basis on the earlier of May 8, 2008 or the termination of the development and commercialization agreement with respect to each particular country.

## Indemnification

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

## **Termination**

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

- · with respect to the particular product, product candidate or country to which the breach relates; or
- in its entirety, if the material breach is not limited to a particular product, product candidate or country.

Each party may also terminate the development and commercialization agreement in its entirety upon 30 days' written notice if the other party files for bankruptcy, insolvency, reorganization or the like. If Novartis terminates the development and commercialization agreement for material breach by us, or for bankruptcy, insolvency or reorganization on our part, then Novartis may elect to retain licenses to product candidates or products, in which

case it will remain obligated to make payments to us in amounts to be negotiated in good faith at the time of termination. If we terminate part or all of the development and commercialization agreement for material breach by Novartis, or for bankruptcy, insolvency or reorganization on the part of Novartis, or if Novartis terminates the development and commercialization agreement unilaterally in the absence of a breach by us, we may be obligated to make payments to Novartis in amounts to be negotiated in good faith at the time of termination.

## Master Manufacturing and Supply Agreement

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

In June 2006, after completing a competitive bid process where Novartis had the right to match the best third-party bid, we entered into a commercial manufacturing agreement with Novartis and a packaging agreement with Novartis Pharmaceuticals Corporation, an affiliate of Novartis. Under the commercial manufacturing agreement, Novartis would manufacture the commercial supply of Tyzeka® that was intended for sale in the United States. The packaging agreement provided that the supply of Tyzeka® intended for commercial sale in the United States would be packaged by Novartis Pharmaceuticals Corporation. As a result of the 2007 Amendment, the commercial manufacturing agreement and supply agreement were terminated as each related to telbivudine and we will work with Novartis to terminate our rights and obligations to the packaging agreement. Effective October 1, 2007, Novartis is solely responsible for the manufacture and supply of Tyzeka®/Sebivo® on a worldwide basis. No penalties were incurred by us as a result of the termination of these agreements.

## Stockholders' Agreement

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

- granted Novartis, together with certain other holders of our common stock, rights to cause us to register, under the Securities Act of 1933, as amended, such shares of common stock;
- agreed to use our reasonable best efforts to nominate for election as a director at least two designees of Novartis for so long as Novartis and its affiliates own at least 35% of our voting stock and at least one designee of Novartis for so long as Novartis and its affiliates own at least 19.4% of our voting stock;
- granted Novartis approval rights over a number of corporate actions that we or our subsidiaries may take as long as Novartis and its affiliates continue to own at least 19.4% of our voting stock; and
- required that, with certain limited exceptions, Novartis and its affiliates not acquire additional shares of our
  voting stock unless a majority of our independent directors approves or requests the acquisition. These
  restrictions will terminate on May 8, 2008, unless sooner terminated under the terms of the stockholders
  agreement.

## Novartis' Stock Purchase Rights

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

## **Stock Purchase Agreement**

Under the stock purchase agreement, dated March 21, 2003, which we refer to as the stock purchase agreement, among us, Novartis and substantially all holders of our capital stock as of May 8, 2003, Novartis purchased approximately 54% of our outstanding capital stock from our stockholders for \$255.0 million in cash, with an additional aggregate amount of up to \$357.0 million contingently payable to these stockholders if we achieve predetermined development milestones with respect to an HCV product candidate. The future contingent payments are payable in cash or, under certain circumstances, Novartis AG American Depository Shares. At present, Novartis owns approximately 56% of our outstanding common stock.

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 the stock purchase agreement. In the stock purchase agreement, we and our stockholders who sold shares to Novartis, which include certain of our directors and many of our officers, made numerous representations and warranties. The stock purchase agreement representations and warranties we made to Novartis regarding our HCV and HBV product 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 not true at the time we made them to Novartis, we would be in breach of this agreement. In the event of a breach by us, Novartis has the right to seek indemnification from us and, under certain circumstances, us and our stockholders who sold shares to Novartis for damages suffered by Novartis as a result of such breach. The amounts for which we could be liable to Novartis may be substantial. For additional information on such indemnification rights, see "Development, License and Commercialization Agreement," "Risk Factors — Factors Related to Our Relationship with Novartis" and "Factors Related to Patents and Licenses."

## Co-operative Laboratory Agreements

## CNRS and the University of Montpellier

In May 2003, we and Novartis entered into an amended and restated agreement with Le Centre National de la Recherche Scientifique, or CNRS, and L'Universite Montpellier II, or 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. The agreement includes provisions relating to ownership and commercialization of the technology which is discovered or obtained as part of the collaboration as well as rights regarding ownership and use of such technology, including telbivudine, which remain in effect following termination of the agreement. This agreement amended and restated an agreement that our subsidiary, Idenix SARL, the University of Montpellier and CNRS had originally entered into in January 1999. Under the terms of the agreement, we made payments to the University of Montpellier for use of the facilities, certain improvements to the facilities and for supplies consumed in connection with research activities. This cooperative agreement expired in December 2006, but we retain rights to exploit the patents derived from the collaboration.

## University of Cagliari

We have entered into two agreements with the University of Cagliari, the co-owner of the patent applications covering our HCV and certain HIV technology upon which we currently rely. One agreement covers our cooperative research program and the other agreement is an exclusive license under these patent applications to develop and sell the jointly created HCV and HIV product candidates. In May 2003, Novartis became a party to each of these agreements. The cooperative research agreement includes provisions with respect to cost sharing, ownership and commercialization of the technology which is discovered or obtained as part of the collaboration. Under the terms of the cooperative agreement, we make payments to the University of Cagliari for use of the facilities and for supplies consumed in connection with the research activities. This agreement has been amended to extend the term until January 2011.

Under the terms of the license agreement with the University of Cagliari, we have the exclusive worldwide right to make, use and sell valopicitabine and certain other HCV and HIV technology and the right to sublicense any of those rights. Under the terms of the agreement, we assume the costs and responsibility for filing, prosecuting, maintaining and defending the jointly owned patents. If we receive license fees or milestone payments with respect

to technology licensed to us by the University of Cagliari, we must provide payments to the University of Cagliari. In addition, we will be liable to the University of Cagliari for a fixed royalty payment on worldwide sales of licensed drug products. 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.

## Manufacturing

We have developed the capacity to synthesize compounds in quantities ranging from milligrams to metric tons. 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, these scientists aim to design efficient synthetic routes suitable for process chemistry scale up to the level of one-kilogram batches of the lead molecule. This material supports key preclinical studies, including proof-of-principle studies in animal models, early pharmacokinetic assays, initial toxicology studies and formulation development. The process chemistry facility we maintain in Cambridge, Massachusetts allows us to accelerate these key studies. This facility also allows us to provide non-current good manufacturing practices, or cGMP, materials in quantities up to one kilogram to support early toxicological studies and the initial development of formulations. These formulations could then be manufactured using cGMP material. We also contract with third parties, including Novartis, for the synthesis of material used in our toxicology studies and for formulation development.

We contract with third parties, including Novartis, for the synthesis of cGMP material used in our clinical trials. To reduce costs and preserve manufacturing proprietary rights, we provide these 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 product 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 product candidates are manufactured in accordance with cGMP and other domestic and foreign regulations.

The process used for the manufacture of Tyzeka®/Sebivo® was robust and had been repeated by different manufacturers on a multiple kilogram scale. We are currently pursuing the same result with respect to the other product candidates we currently have in clinical development.

We rely upon Novartis as well as other third-party manufacturers for the dosage form of our product and product candidates. We do not expect to internally manufacture material for our clinical trials or undertake the commercial-scale manufacture of our drug products.

#### Sales and Marketing

In accordance with the arrangements set forth in our development and commercialization agreement with Novartis, we have the right to co-promote or co-market with Novartis in the United States, United Kingdom, France, Germany, Italy and Spain any products that Novartis licenses from us. If we co-promote or co-market, in the markets outside of the United States, Novartis will be primarily responsible for the marketing, distribution and sale of products which it may license from us. In anticipation of the commercial launch of telbivudine, we established our own commercial organization in the United States, including marketing capabilities, a field force of sales representatives, medical scientific liaisons, and regional business managers and began building our European commercial organization. As a direct result of the transfer of all our development, commercialization and manufacturing rights to Novartis relating to telbivudine, on September 28, 2007 we announced a restructuring of our operations and a workforce reduction of approximately 100 positions, including the termination of our entire worldwide commercial organization.

#### 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.

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

## Hepatitis B Patent Portfolio and Licenses

Our hepatitis B patent portfolio includes at least 7 issued U.S. patents, at least 5 pending U.S. applications, at least 56 granted foreign patents, and at least 65 pending foreign patent applications.

Four issued U.S. patents are directed to methods of using telbivudine for the treatment of HBV. These patents, which expire in 2019, are set forth below:

- U.S. Patent No. 6,395,716 entitled "B-L-2'-Deoxy-Nucleosides for the Treatment of Hepatitis B";
- U.S. Patent No. 6,569,837 entitled "B-L-2'-Deoxy Pyrimidine Nucleosides for the Treatment of Hepatitis B";
- U.S. Patent No. 6,444,652 entitled "B-L-2'-Deoxy-Nucleosides for the Treatment of Hepatitis B"; and
- U.S. Patent No. 6,566,344, entitled "B-L-2'-Deoxy-Nucleosides for the Treatment of Hepatitis B".

Applications for patent term extensions to extend the term of either of U.S. Patent No. 6,395,716 or 6,569,837, but not both, were filed in the U.S. Patent Office. Although there is no guarantee either application will be granted by the U.S. Patent Office, if one of the applications for term extension were granted, it would extend the term to October 25, 2020. The four above-mentioned patents are co-owned by us, CNRS and University of Montpellier, and under an agreement with these entities described under the caption "Collaborations," we have the exclusive right to exploit the technology.

One issued U.S. patent is directed to valtorcitabine, as well as pharmaceutical compositions that include valtorcitabine: U.S. Patent No. 6,857,751, entitled "3'-Prodrugs of 2'-Deoxy-\u03b3-L-Nucleosides.". This patent will expire in 2021 absent a patent term extension.

In June 1998, we entered into an exclusive license agreement, which we refer to as the UAB license agreement, with the University of Alabama at Birmingham Research Foundation, or UABRF, pursuant to which we were granted an exclusive license to the rights that the University of Alabama at Birmingham, or UAB, an entity affiliated with UABRF, Emory University and CNRS, which we refer to collectively as the 1998 licensors, 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 infection. In January 2004, February 2005 and June 2005, UABRF notified us that it intended to file a U.S. continuation patent application claiming priority to the 1995 patent application, which itself is a continuation in part of a 1993 application that would purportedly enable the 1998 licensors to prosecute and seek to obtain generic patent claims generally encompassing the method of using telbivudine to treat patients infected with HBV. In July 2005, UABRF filed such a continuation patent application.

In February 2006, UABRF notified us that it and Emory University were asserting a claim that, as a result of the filing of a continuation patent application in July 2005 by UABRF, the UAB license agreement covers our telbivudine technology. UABRF contends that we are obligated to pay the 1998 licensors an aggregate of \$15.3 million comprised of 20% of the \$75 million license fee we received from Novartis in May 2003 in connection with the license of our HBV product candidates and a \$0.3 million payment in connection with the submission to the FDA of the IND pursuant to which we conducted clinical trials of telbivudine. We disagree with UABRF's contentions and advised UABRF and Emory University that we will utilize the dispute resolution procedures set forth in the UAB license agreement for resolution of this dispute. Under the terms of that agreement, if resolution cannot be achieved through negotiations between the parties or mediation, it must be decided by binding arbitration under the rules of the American Arbitration Association before a panel of three arbitrators. Pursuant to the terms of the dispute resolution procedure in the UAB license agreement, in September 2007 our

CEO and the CEO of UABRF met and agreed to begin a mediation process. While the parties participated in a joint mediation session in January 2008, no resolution of these matters has yet been reached. However, a non-binding settlement proposal has been discussed by the parties. Such settlement proposal remains subject to several terms and conditions, including a full release of all claims by UABRF and related entities. We do not believe that the matters disputed by UABRF and Emory University regarding the UAB license agreement will have any effect on either the cooperative agreement with CNRS and the University of Montpellier or the technology licenses, including the license for telbivudine, which have been granted to us pursuant to the cooperative agreement.

However, if we do not settle these disputes and it is determined that the UAB license agreement does cover our technology, we will be obligated to make payments to the 1998 licensors in the amounts and manner specified in the UAB license agreement. While we dispute the demands made by UABRF, even if liability were found to exist, UABRF's claims, in addition to those described above would likely include payments in the aggregate amount of \$1.0 million due upon achievement of regulatory milestones, a 6% royalty on annual sales up to \$50.0 million and a 3% royalty on annual sales greater than \$50.0 million made by us or an affiliate of ours. Additionally, if we sublicense our rights to any entity other than one which holds or controls at least 50% of our capital stock, or if Novartis' ownership interest in us declines below 50% of our outstanding shares of capital stock, UABRF would likely contend that we would be obligated to pay to the 1998 licensors 30% of all royalties received on sales by the sublicensee of telbivudine and 20% of all fees, milestone payments and other cash consideration received from the sublicensee with respect to telbivudine.

If we fail to perform our material obligations under the UAB license agreement, UABRF, acting for the 1998 licensors, may attempt to terminate the UAB license agreement or render the license to us non-exclusive. We do not believe that we are in default of any of the material obligations to which we are subject under the UAB license agreement. Any attempt to terminate the agreement would be subject to binding arbitration. In the event UABRF is successful in terminating the license agreement as a result of a breach by us after a period of arbitration, and the 1998 licensors obtain a valid enforceable claim that generally covers the use of telbivudine to treat HBV, it would be necessary to obtain another license from the 1998 licensors. Such license may not be available on reasonable terms, on an exclusive basis or at all. This could materially adversely affect or preclude the ability to continue to commercialize telbivudine.

If the 1998 licensors were instead to render the UAB license agreement to us non-exclusive, we would not be prohibited from commercializing telbivudine to treat HBV, but a non-exclusive license could be granted to one or more of our competitors by one or more of the 1998 licensors. In the event that the 1998 licensors exclusively or nonexclusively license any claims covering the use of telbivudine to treat HBV to a competitor, we believe that such a competitor would have to overcome substantial legal and commercial hurdles to successfully commercialize the product. For example, we have already obtained four U.S. patents covering the use of telbivudine to treat HBV, which we believe a competitor would likely infringe if it sought to commercialize telbivudine. Our patent applications are also pending or granted in Europe, Australia, Canada, and Japan, as well as numerous other countries. Additionally, since we are the first company that took telbivudine through clinical trials, we and Novartis will benefit from a five-year period of commercialization exclusivity in the United States that was granted by the FDA in October 2006 and during which the agency will not grant marketing approval to any competitor to sell telbivudine for the treatment of HBV. We also received regulatory exclusivity periods in Europe and in other countries.

If it is determined that the UAB license agreement between us and UABRF does cover our use of telbivudine to treat HBV, or we must otherwise rely upon a license agreement granted by the 1998 licensors to commercialize telbivudine, we may be in breach of certain of the representations and warranties we made to Novartis under the development and commercialization agreement and the stock purchase agreement. For a further description see "Collaborations — Relationship with Novartis — Indemnification" and "Risk Factors — Factors Related to Our Relationship with Novartis" and "Factors Related to Patents and Licenses."

In January 2007, the Board of Trustees of the University of Alabama and related entities filed a complaint in the United States District Court for the Northern District of Alabama, Southern Division against us, CNRS and the University of Montpellier. The complaint alleges that a former employee of UAB is a co-inventor of certain patents in the United States and corresponding foreign patent applications related to the use of \( \beta \-2'\)-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®/Sebivo® for the treatment of HBV. The University of Alabama has included a demand for damages under various theories in its complaint, but did not specify the amount of damages that it alleges to have incurred. In response to the complaint in March 2007, we filed a motion to dismiss based upon lack of personal jurisdiction. In September 2007, the parties agreed to stay the action and pursue mediation relating to the disputes associated with the license agreement and this litigation. As a result of a joint mediation session held in January 2008, a non-binding settlement has been proposed by the parties which could potentially require Idenix to make payments to UABRF and related entities. We have assessed this settlement proposal under the provisions of FAS 5, and recorded an expense of \$1.5 million for the quarter ended December 31, 2007. If the proposed settlement is not completed on terms acceptable to Idenix, we will resume the defense of these claims, including through the litigation process. Accruals related to the settlement proposal may be adjusted in future periods if a settlement agreement is not reached. We cannot ascertain with certainty the likelihood this or any settlement proposal will be accepted by or entered into by the parties. If we are not able to reach a settlement agreement with the parties, we will continue to vigorously defend against claims made by UABRF and related entities (see Note 2).

## Hepatitis C Patent Portfolio

Our HCV patent portfolio includes at least 10 issued U.S. patents, at least 42 pending U.S. applications, at least 38 granted foreign patents, and at least 314 pending foreign patent applications.

In the HCV patent portfolio are 8 issued United States patents: U.S. Patent No. 6,812,219; U.S. Patent No. 6,914,054; U.S. Patent No. 7,105,493; U.S. Patent No. 7,101,861; U.S. Patent No. 7,148,206; U.S. Patent No. 7,163,929; U.S. Patent No. 7,169,766 and U.S. Patent No. 7,157,441. The 8 above-mentioned United States patents will expire in 2021 absent a patent term extension. We co-own these 8 patents with the University of Cagliari, which has exclusively licensed its interest to us.

## **HIV Patent Portfolio**

Our HIV patent portfolio includes at least 3 issued U.S. patents, at least 9 pending U.S. applications, at least 4 granted foreign patents, and at least 49 pending foreign patent applications.

Of these three issued U.S. patents, U.S. Patent No. 6,635,636 will expire in 2019 and is owned by us. U.S. Patent No. 6,545,007 will expire in 2021. U.S. Patent No. 6,710,068 will expire in 2022. U.S. Patent Nos. 6,545,007 and 6,710,068 are co-owned by us with the University of Cagliari, which has exclusively licensed its rights to us.

We hold exclusive licenses from TherapX and Dr. Raymond Schinazi to one U.S. issued patent, U.S. Patent No. 5,750,493 entitled "Method to Improve the Biological and Antiviral Activity of Protease Inhibitors", and five associated non-U.S. patent filings expiring on or before 2016 that cover a method of using roxythromycin, a generic compound, to enhance the antiviral activity of protease inhibitors including for the treatment of HIV.

## Competition

Our industry is highly competitive and subject to rapid technological change. 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 and other resources. In addition, many of our competitors have significantly greater experience in testing pharmaceutical and other therapeutic product candidates and obtaining FDA and other regulatory approvals of products for use in healthcare and marketing and selling those products. Accordingly, our competitors may be more successful than we may be in obtaining FDA approval for products and achieving widespread market acceptance. We also may compete with respect to manufacturing efficiency and marketing capabilities, areas in which we have substantially less experience than our competitors.

Tyzeka®/Sebivo®, and any future products that we successfully develop, will compete with existing and future therapies. The key competitive factors affecting the commercial success of our products are likely to be efficacy, safety profile, 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 HBV, HCV and HIV. We are aware of at least three small molecule products that are currently marketed in the United States and elsewhere for the treatment of chronic hepatitis B. Such therapies are lamivudine, marketed by GlaxoSmithKline plc as Epivir-HBV®; adefovir dipoxil, marketed by Gilead Sciences, Inc., as Hepsera®; and entecavir, marketed by Bristol-Myers Squibb Company, as Baraclude®. Pegylated interferon alpha 2-a marketed by F. Hoffman-LaRoche & Co. is also approved for the treatment of chronic hepatitis B. Pegylated interferon together with ribavirin is the current standard of care for the treatment of hepatitis C. Additional companies with which we expect to compete include Abbott Laboratories, Boehringer Ingelheim International GmbH, F. Hoffman-LaRoche & Co., Johnson & Johnson, Merck & Co., Inc., Pfizer Inc., Schering-Plough Corporation, Human Genome Sciences, Inc., InterMune, Inc., Isis Pharmaceuticals, Inc., Ribapharm, Inc., a wholly-owned subsidiary of Valeant Pharmaceuticals International, SciClone Pharmaceuticals, Inc., Anadys Pharmaceuticals, Inc., Pharmasset, Ltd., and Vertex Pharmaceuticals Inc. Many of these companies and organizations, either alone or with their collaborative partners, have substantially greater financial, technical and human resources than we do. In addition, our competitors also include smaller private companies.

We believe that a significant number of drugs are currently under development and will become available in the future for the treatment of HBV, HCV and HIV. 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 product 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 product 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 U.S. 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 product candidates are approved for marketing. Adoption of new legislation could further limit reimbursement for pharmaceutical products.

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

### Regulatory Matters

In October 2006, we received approval from the FDA to market Tyzeka® in the United States. In April 2007, Sebivo® was approved in the European Union for the treatment of patients with chronic hepatitis B. To date, Sebivo® has been approved in more than 50 countries outside the United States, including China, Switzerland and the European Union. Effective October 1, 2007, we transferred to Novartis our regulatory, development, commercialization and manufacturing rights and obligations related to telbivudine (Tyzeka®/Sebivo®) on a worldwide basis in exchange for royalty payments equal to a percentage of net sales, with such percentage increasing according to specified tiers of net sales. The royalty percentage will vary based upon the territory and the aggregate dollar amount of net sales.

Currently, we are evaluating IDX899 for the treatment of HIV in phase I clinical trials. In April 2007, we filed an IND for IDX899.

## 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 to regulation 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;
- restrictions on, or prohibitions against, marketing our products, if approved for commercial sale;
- fines;
- · restrictions on importation of our products;
- · injunctions;
- · debarment;
- · civil and criminal penalties; and
- suspension of review, 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 product candidate or disease. Government regulation may delay or prevent marketing of potential product 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 product candidate. The conduct of the 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 product candidate to human subjects in the proposed clinical trial.

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

After the commencement of clinical trials, the FDA may, at any time, impose a clinical hold on ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials cannot commence or recommence without FDA authorization and then only under terms authorized 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 product 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 NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In phase I, the initial introduction of a product candidate into healthy human subjects or patients, a product candidate is tested to assess metabolism, pharmacokinetics and pharmacological actions 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 product candidate in the indication being studied.

If a product candidate is found to be effective and to have an acceptable safety profile 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 product 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 product candidates that demonstrate a significant improvement to approved products in terms of safety or efficacy in the treatment, diagnosis or prevention of serious or life-threatening conditions. The FDA's decision to grant priority review is driven solely by the data submitted and cannot be assured in advance. Under the Prescription Drug User Fee Act, or PDUFA, product candidates that are given a priority review designation have a 6-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, or, in some cases, an approvable letter followed by an approval letter. Approvable letters usually contain a number of conditions that must be met to secure final approval of the NDA. When and if those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter. The approval letter authorizes commercial marketing of the drug for specific indications. As a condition of 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 product 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 product candidates. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations 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 refuse to approve the NDA or issue a not approvable letter. The not approvable letter outlines the deficiencies in the submission and often requires additional testing or information. The FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

### Foreign Regulation of Drug Product Approval

Under the terms of our agreement with Novartis, we have primary responsibility for preparing and filing U.S. regulatory submissions with respect to any product candidate which Novartis has licensed from us. Novartis has primary responsibility for preparing and filing regulatory submissions with respect to any licensed product in all other countries in the world. Under certain circumstances, primary responsibilities for all or certain regulatory tasks in a particular country may be switched from one party to the other.

## Europe

In the European Union, which we refer to as the EU, investigational products are subject to extensive regulatory requirements. As in the United States, the marketing of medicinal products is subject to the granting of marketing authorizations by relevant regulatory agencies. The grant of these marketing authorizations can involve testing in addition to that which the FDA requires and the time required may also differ from that required for FDA approval. In the EU, approval of new pharmaceutical products can be granted either through a mutual recognition procedure and decentralized approval or through a centralized procedure. The processes are described below.

Mutual Recognition Procedure and Decentralized Approval. An applicant submits an application in one EU member state, known as the reference member state, and requests the reference member state to approve the drug. The reference member state will review the registration documents within 210 days after receipt of a valid application. With the approved dossier and the summary of product characteristics, the applicant then requests the mutual recognition in the concerned member states of the reference authorization of the reference member state. Within 90 days of receipt, the concerned member states shall approve the assessment report, summary of product characteristics, and labeling and package leaflet, and inform the reference member state accordingly. The reference member state shall record the agreement of all parties, close the procedure and inform the applicant accordingly.

Each member state in which the application has been submitted shall adopt a decision in conformity with the approved assessment report, summary of product characteristics, and the labeling and package leaflet as approved, within 50 days after acknowledgement of the agreement. If a member state cannot approve the assessment report, summary of product characteristics, and the labeling and package leaflet on the grounds of potential serious risk to public health, it will give a detailed exposition of the reasons for its position to the reference member state, the other member states concerned, and to the applicant. The points of disagreement will be referred to a coordination group for resolution. Alternatively, the applicant could implement changes in the summary of product characteristics as requested by a country.

Centralized Procedure. This procedure is currently mandatory for products developed by means of a biotechnological process and optional for certain new active substances. However beginning November 2005, medicinal products containing new active substances and for which the indication is treatment of AIDS, cancer, neurodegenerative disorder or diabetes must be submitted via the centralized process. Additionally, beginning May 2008, the centralized procedure will also be mandatory for products which contain new active substance and for which the indication is treatment of autoimmune diseases and other immune dysfunctions, and viral diseases. Our product candidates fall into the last category.

Under the centralized procedure, an application is submitted to the EMEA. Two EU 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 EU 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 EU, such as Norway and Iceland, accept EU review and approval as a basis for their own national approval.

## 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 the EU in addition to 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 U.S. NDA may 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, EU and Japan, future marketing applications in these regions will be submitted as a core global dossier known as the Common Technical Document, or CTD. While the FDA has not mandated that submissions be made in the CTD format, it has indicated that this is its preferable submission format. In the EU and Japan, the CTD is the required submission format. Electronic CTDs, or e-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, 2007, we had 219 full time employees, 162 of whom were engaged in research, development and manufacturing functions and 57 of whom were engaged in administration, finance and commercialization activities.

### 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 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. You should consider the following risks, together with all of the other information in this Annual Report on Form 10-K for the year ended December 31, 2007, before deciding to invest in our securities.

#### Factors Related to Our Business

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 since our inception in May 1998. We have generated limited revenue from the sale of telbivudine (Tyzeka®/Sebivo®) to date and are unable to make a meaningful assessment of potential future revenue associated with royalty payments of product sales. We will not be able to generate additional revenues from product sales until one of our other product candidates receives regulatory approval and we or a collaborative partner successfully introduce such product commercially. We expect to incur annual operating losses over the next several years as we expand our drug discovery and development efforts. We also expect that the net loss we will incur will fluctuate from quarter to quarter and such fluctuations may be substantial. To generate product revenue, regulatory approval for products we successfully develop must be obtained and we and /or Novartis or a future collaboration partner must effectively manufacture, market and sell such products. Even if we successfully commercialize product 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 product candidates. If we do not have or cannot raise additional capital when needed, we will be unable to develop and ultimately commercialize our product candidates successfully.

Our cash, cash equivalents and marketable securities balance was approximately \$112.0 million at December 31, 2007. We believe that this balance, any development funding we receive from Novartis relating

to licensed compounds, if any, and the anticipated royalty payments associated with product sales of Tyzeka®/Sebivo® will be sufficient to satisfy our anticipated cash needs through late 2009. However, we may need or choose to seek additional funding within this period of time. Our drug development programs and the potential commercialization of our product 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 large part on whether:

- with respect to Tyzeka®/Sebivo®, the level of royalty payments received from Novartis is significant;
- with respect to our other product candidates, Novartis exercises its option to license other product candidates, and we receive related license fees, milestone payments and development expense reimbursement payments from Novartis; and with respect to our other product candidates not licensed by Novartis, we receive related license fees, milestone payments and development expense reimbursement payments from third parties.

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

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

- the amount of revenue that we may be able to realize from commercialization and sale of product candidates, if any, which are approved for commercial sale 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 and HIV;
- the cost of obtaining, maintaining and defending patents on telbivudine, our product candidates and our processes;
- the cost, timing and outcome of regulatory reviews;
- the cost of re-establishing sales and marketing functions;
- the commercial potential of our product candidates;
- the rate of technological advances in our markets;
- the cost of acquiring or in-licensing new discovery compounds, technologies, product candidates or other business assets;
- the magnitude of our general and administrative expenses;
- · 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 INDs and/or NDAs with the FDA for our HCV and HIV product candidates as we continue development of each of these product candidates. The time and cost to complete clinical development of these product 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 its current 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 alliance or licensing arrangements that may not be favorable to us. These arrangements could result in the transfer to third parties of rights that we consider valuable.

# Our research and development efforts may not result in additional product candidates being discovered on anticipated timelines, if at all, which could limit our ability to generate revenues.

Our research and development programs, other than our program for NNRTIs for HIV, are at preclinical stages. Additional product 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 product candidates that could generate revenues for us.

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

As part of our strategy, we intend to establish a franchise in the HCV and HIV market by developing product candidates for each therapeutic indication. The success of this strategy depends upon the development and commercialization of additional product candidates that we successfully discover, license or otherwise acquire.

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

Proposing, negotiating and implementing acquisition or in-license of product 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 product candidates. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, if at all.

# Our investments are subject to general credit, liquidity, market and interest rate risks, which may be exacerbated by the volatility in the U.S. credit markets.

Our investment portfolio included municipal auction rate securities which approximated \$11.0 million as of December 31, 2007. Auction rate securities are generally debt instruments that are structured to allow for short-term interest rate resets but with contractual maturities that can be well in excess of ten years. At the end of each reset period which occurs every seven to 35 days, investors can sell or continue to hold the securities at par. The auction rate securities we held at December 31, 2007 reset in subsequent auctions in January 2008. In mid-February 2008, certain of our municipal auction rate securities experienced a failed auction. As of March 11, 2008 we had liquidated all but \$4.0 million of our auction rate securities, of which \$3.1 million was held at December 31, 2007. The liquidation of these auction rate securities did not result in any losses. Since then, the continued uncertainty in the credit markets has caused additional auctions with respect to our auction rate securities to fail, and if we had chosen to do so, would have prevented us from liquidating certain of our holdings of auction rate securities because the amount of these securities submitted for sale has exceeded the amount of purchase orders for these securities. There is a risk that auctions related to our remaining auction rate securities may fail and that there could be a decline in value of these securities or any other securities which may ultimately be deemed to be other than temporary. In the future, should we experience additional auction failures and/or determine that these declines in value of auction rate securities are other than temporary, we would recognize a loss in our consolidated statement of operations, which could be material. In addition, any future failed auctions may adversely impact the liquidity of our investments.

The condition of the credit markets remains dynamic. As a result, we may experience a reduction in value or loss of liquidity with respect to our other investments. In addition, should our other investments cease paying or reduce the amount of interest paid to us, our interest income would suffer. These market risks associated with our investment portfolio may have an adverse effect on our financial condition.

The markets which we intend to enter are subject to intense competition. If we are unable to compete effectively, products we successfully develop and our product 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 hepatitis B infection, we are aware of four other drug products, specifically, lamivudine, entecavir and adefovir dipivoxil, each nucleoside analogs, and pegylated interferon, which are approved by the FDA and commercially available in the United States or in foreign jurisdictions. These products have preceded Tyzeka®/Sebivo® into the marketplace and have gained acceptance with physicians and patients. For the treatment of chronic hepatitis C, the current standard of care is pegylated interferon in combination with ribavirin, a nucleoside analog. Currently, for the treatment of HIV infection, there are 24 antiviral therapies approved for commercial sale in the United States. Of these approved therapies, seven are nucleosides, three are non-nucleosides, 11 are protease inhibitors, one is an integrase inhibitor and two are entry inhibitors.

We believe that a significant number of product candidates that are currently under development may become available in the future for the treatment of HBV, HCV and HIV infections. Our competitors' products may be more effective, have fewer side effects, lower costs or be better marketed and sold, than any of our products. Additionally, products our competitors successfully develop for the treatment of HCV and HIV may be marketed prior to any HCV or HIV product we 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 product candidates that are in late-stage development; and
- · collaborative arrangements in our target markets with leading companies and research institutions.

Under certain circumstances, Novartis has the right to compete with products and product candidates developed or licensed by us. Novartis has the right under certain circumstances to market and sell products that compete with the product candidates and products that we license to it, and any competition by Novartis could have a material adverse effect on our business.

Competitive products may render our products obsolete or noncompetitive before we can recover the expenses of developing and commercializing our product 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 product candidates noncompetitive, obsolete or uneconomical.

With respect to Tyzeka®/Sebivo® and other products, if any, we may successfully develop and obtain approval to commercialize, we will face competition based on the safety and effectiveness of our products, the timing and scope of regulatory approvals, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, price, patent position and other factors. Our competitors may develop or commercialize more effective or more affordable products, or obtain more effective patent protection, than we do. Accordingly, our competitors may commercialize products more rapidly or effectively than we do, which could adversely affect our competitive position and business.

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

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

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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 product candidates, the development of our product 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, universities, 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 appropriate levels of insurance, a product liability claim against us could adversely affect our business.

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

For Tyzeka®/Sebivo®, product liability claims could be made against us based on the use of our product in people. For Tyzeka®/Sebivo® and our product candidates, product liability claims could be made against us based on the use of our product candidates in clinical trials. We have obtained product liability insurance for Tyzeka®/, Sebivo® and maintain clinical trial insurance for our product 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 product candidates. A successful product liability claim brought against us in excess of our insurance coverage, if any, 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 accounting principles generally accepted 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 disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. There can be no assurance, however, that our estimates, or the assumptions underlying them, will not change.

One of these estimates is our estimate of the development period to amortize license fee revenue from Novartis which we review on a quarterly basis. As of December 31, 2007, we have estimated that the performance period during which the development of our licensed product and product candidates will be completed is a period of approximately ten and a half years following the effective date of the development and commercialization agreement that we entered into with Novartis, or December 2013. If the estimated development period changes, we will adjust periodic revenue that is being recognized and will record the remaining unrecognized license fees and other up-front payments over the remaining development period during which our performance obligations will be completed. Significant judgments and estimates are involved in determining the estimated development period and different assumptions could yield materially different financial results. This, in turn, could adversely affect our stock price.

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

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

We have completed an assessment and will continue to review in the future our internal controls over financial reporting in an effort to ensure compliance with the Section 404 requirements. The manner by which companies implement, maintain and enhance these requirements including internal control reforms, if any, to comply with Section 404, and how registered independent public accounting firm 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 registered independent 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.

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

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

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

treatment of patients with chronic hepatitis B. Effective October 1, 2007, we transferred to Novartis all of our development, commercialization and manufacturing rights and obligations related to telbivudine (Tyzeka®/Sebivo®) on a world-wide basis in exchange for royalty payments equal to a percentage of net sales of Tyzeka®/Sebivo®, with such percentage increasing according to specified tiers of net sales. The royalty percentage will vary based upon the territory and the aggregate dollar amount of net sales. Our other product candidates are in various earlier stages of development. All of our product candidates require regulatory review and approval prior to commercialization. Approval by regulatory authorities requires, among other things, that our product candidates satisfy rigorous standards of safety, including assessments of the toxicity and carcinogenicity of the product candidates we are developing, and efficacy. To satisfy these standards, we must engage in expensive and lengthy testing. As a result of efforts to satisfy these regulatory standards, our product 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 product 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 product candidates performed satisfactorily in clinical trials in terms of both safety and efficacy have nonetheless failed to obtain approval for such product candidates. Furthermore, the FDA may request from us, and the EMEA and regulatory agencies in other jurisdictions may request from Novartis, additional information including data from additional clinical trials, which may delay significantly any approval and these regulatory agencies ultimately may not grant marketing approval for any of our product candidates. For example, in July 2007, we announced that the FDA had placed on clinical hold in the United States our development program of valopicitabine for the treatment of HCV based on the overall risk/benefit profile observed in clinical testing. We subsequently discontinued the development of valopicitabine.

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

To obtain regulatory approval for the commercial sale of our product candidates, we will be required to demonstrate through preclinical studies and clinical trials that our product candidates are safe and effective. Preclinical studies and clinical trials are lengthy and expensive and the historical rate of failure for product candidates is high. The results from preclinical studies of a product 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 product 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. As an example, in July 2007, we announced that the FDA had placed on clinical hold in the United States our development program of valopicitabine for the treatment of HCV based on the overall risk/benefit profile observed in clinical testing. We subsequently discontinued the development of valopicitabine. The observation of adverse side effects in a clinical trial may result in the FDA or foreign regulatory authorities refusing to approve a particular product candidate for any or all indications of use. Additionally, adverse or inconclusive clinical trial results concerning any of our product candidates could require us to conduct additional clinical trials, result in increased costs, significantly delay the submission of applications seeking marketing approval for such product candidates, result in a narrower indication than was originally sought or result in a decision to discontinue development of such product 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 clinical trials evaluating other investigational agents, 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 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 product candidates would delay our ability to seek and potentially obtain regulatory approvals, increase expenses associated with clinical development and likely increase the volatility of the price of our common stock.

Any of the following could suspend, terminate or delay the completion of our ongoing, or the initiation of our planned, clinical trials:

- discussions with the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- delays in obtaining, or the inability to obtain, required approvals from, or suspensions or termination by, institutional review boards or other governing entities at clinical sites selected for participation in our clinical trials;
- · delays enrolling participants into clinical trials;
- · lower than anticipated retention of participants in clinical trials;
- insufficient supply or deficient quality of product 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 ongoing or planned clinical trials for our product 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 HIV product candidate, HCV product candidates or other product candidates;
- Novartis may choose not to license our product candidates and we may not be able to enter into other collaborative arrangements for any of our other product candidates; or
- · we may not have the financial resources to continue the research and development of our product candidates.

# If our product candidates fail to obtain U.S. and/or foreign regulatory approval, we and our partners will be unable to commercialize our product candidates.

Each of our product 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 our product candidates. Before any product candidate can be approved for sale, we must demonstrate that it can be manufactured in accordance with the FDA's current good manufacturing practices, which are a rigorous set of 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 product 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 product candidate. Our 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 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 to generate revenues from a particular product candidate. Furthermore, any regulatory approval to market a product may be subject to limitations on the indicated uses for which we may market the product. These restrictions may limit the size of the market for the product. Additionally, product candidates we 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 Novartis, 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 product candidates. Any failure or delay in obtaining such marketing authorizations for our product 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 fail to comply with applicable U.S. and foreign regulations, we could lose approvals we have been granted and our business would be seriously harmed.

Even after approval, any drug product we 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 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, regulatory approvals similar to FDA approval. Any manufacturer we 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 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 product, 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 product as modified may be marketed.

If we fail to comply with applicable continuing regulatory requirements, we 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. Because of these potential sanctions, we seek to monitor compliance with these regulations.

## If we are subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, our business may be harmed.

The regulations governing drug product marketing authorization, pricing and reimbursement vary widely from country to country. Some countries require approval of the sale price of a drug-before it can be marketed. In many countries, the pricing review period begins after product marketing authorization approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we or Novartis may obtain regulatory approval for a product in a particular country, but then be subject to price regulations, which may delay the commercial launch of the product and may negatively impact the revenues we are able to derive from sales of the product in that country.

Successful commercialization of our products will also depend in part on the extent to which reimbursement for our products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Any of our commercial products may not be considered cost effective and reimbursement may not be available or sufficient to allow sale of our products on a competitive basis. We may need to conduct expensive pharmacoeconomic studies to demonstrate to third-party payers the cost effectiveness of our product candidates. Sales of prescription drugs depend on the availability and level of reimbursement from third-party payers, such as government and private insurance plans. These third-party payers frequently require that drug companies provide predetermined discounts from list prices, and third-party payers are increasingly challenging the prices charged for medical products. If the reimbursement we receive for any of our products is inadequate in light of development and other costs, our profitability could be adversely affected.

We believe that the efforts of governments and third-party payers to contain or reduce the cost of healthcare will increase pressure on drug pricing and continue to affect the business and financial condition of pharmaceutical and biopharmaceutical companies. If we fail to obtain adequate reimbursement for respective current or future products, healthcare providers may limit how much or under what circumstances they will prescribe or administer them, which could reduce the demand for and use of our products or cause us to reduce the price of our products.

If we fail to comply with ongoing regulatory requirements after receipt of approval to commercialize a product, we may be subject to significant sanctions imposed by the FDA, EMEA or other U.S. and foreign regulatory authorities.

The research, testing, manufacturing and marketing of product candidates and products are subject to extensive regulation by numerous regulatory authorities in the United States and other countries. Failure to comply with FDA or other applicable U.S. and foreign regulatory 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 could have a material adverse effect on our business.

# If we violate healthcare statutes such as fraud and abuse laws, we could be subject to significant penalties and expenses.

Commercialization efforts in which we expect at a future time period to engage in the United States are subject to various federal and state laws pertaining to pharmaceutical promotion and healthcare fraud and abuse, including the Food, Drug and Cosmetic Act, the Prescription Drug Marketing Act, federal and state anti-kickback laws and false claims laws. Our future efforts to comply with these laws will be time consuming and expensive.

Anti-kickback laws make it illegal for any prescription drug manufacturer to offer or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. The federal government has published regulations that identify specific safe harbors or exemptions for types of payment arrangements that do not violate the anti-kickback statutes. We intend to align our commercialization activities to

such safe harbors, however, there can be no assurance that such activities will not be subject to scrutiny by government or private authorities. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third-party payers (including Medicare and Medicaid), claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services.

The activities in which we expect to engage relating to the sale and marketing of products, if any, that are approved for commercialization will be subject to scrutiny under these laws and regulations. Violations may be punishable by significant criminal and/or civil fines and other penalties, as well as the possibility of exclusion of the approved product from governmental healthcare programs (including Medicare and Medicaid). If the government were to allege against or convict us or any of our employees of violating these laws, there could be a material adverse effect on our business, including our stock price.

Our activities could be subject to challenge for many reasons, including the broad scope and complexity of these laws and regulations and the high degree of prosecutorial resources and attention being devoted to the sales practices of pharmaceutical companies by law enforcement authorities. During the last few years, several companies have agreed to enter into corporate integrity agreements and have paid multi-million dollar fines and settlements for alleged violation of these laws, and other companies are under active investigation.

We have limited marketing and sales experience, and we cannot assure you that we or our employees, directors or agents are or will be or will act in compliance with all applicable laws and regulations. If we fail to comply with any of these laws or regulations, various negative consequences could result, including the termination of clinical trials, the failure to gain regulatory approval of a product candidate, restrictions on our products or manufacturing processes, withdrawal of the approved product from the market, exclusion of the approved product from governmental healthcare programs (including Medicare and Medicaid), significant criminal and/or civil fines or other penalties, and costly litigation.

Additionally, Novartis has the right to terminate the development and commercialization agreement due to our uncured material breach, which could include our failure to comply with applicable laws and regulations relating to our efforts to commercialize products that we successfully develop and receive approval to commercialize.

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

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

## Factors Related to Our Relationship with Novartis

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

As of December 31, 2007, Novartis owned approximately 56% of our outstanding common stock. For so long as Novartis owns at least a majority of our outstanding common stock, in addition to its contractual approval rights, Novartis has the ability to delay or prevent a change in control of Idenix that may be favored by other stockholders

and otherwise exercise substantial control over all corporate actions requiring stockholder approval irrespective of how our other stockholders may vote, including:

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

Novartis has the right to exercise control over certain corporate actions that may not otherwise require stockholder approval as long as it holds at least 19.4% of our voting stock.

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

- the authorization or issuance of additional shares of our capital stock or the capital stock of our subsidiaries, except for a limited number of specified issuances;
- any change or modification to the structure of our board of directors or a similar governing body of any of our subsidiaries:
- · any amendment or modification to any of our organizational documents or those of our subsidiaries;
- the adoption of a three-year strategic plan;
- the adoption of an annual operating plan and budget, if there is no approved strategic plan;
- any decision that would result in a variance of total annual expenditures, capital or expense, in excess of 20% from the approved three-year strategic plan;
- any decision that would result in a variance in excess of the greater of \$10 million or 20% of our profit or loss target in the strategic plan or annual operating plan;
- the acquisition of stock or assets of another entity that exceeds 10% of our consolidated net revenue, net income or net assets;
- the sale, lease, license or other disposition of any assets or business which exceeds 10% of our net revenue, net income or net assets;
- the incurrence of any indebtedness by us or our subsidiaries for borrowed money in excess of \$2 million;
- any material change in the nature of our business or that of any of our subsidiaries;
- · any change in control of Idenix or any subsidiary; and
- any dissolution or liquidation of Idenix or any subsidiary, or the commencement by us or any subsidiary of any action under applicable bankruptcy, insolvency, reorganization or liquidation laws.

Pursuant to the amended and restated stockholders' agreement, dated July 27, 2004, among us, Novartis and certain of our stockholders, which we refer to as the stockholders' agreement, we are obligated to use our reasonable best efforts to nominate for election as a director at least two designees of Novartis for so long as Novartis and its affiliates own at least 35% of our voting stock and at least one designee of Novartis for so long as Novartis and its affiliates own at least 19.4% of our voting stock.

Additionally, until such time as Novartis and its affiliates own less than 50% of our voting stock, Novartis' consent is required for the selection and appointment of our chief financial officer. If in Novartis' reasonable judgment our chief financial officer is not satisfactorily performing his duties, we are required to terminate the employment of our chief financial officer.

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

Under the stockholders' agreement, voting stock means our outstanding securities entitled to vote in the election of directors, but does not include:

- securities issued in connection with our acquisition of all of the capital stock or all or substantially all of the
  assets of another entity; and
- shares of common stock issued upon exercise of stock options or stock awards pursuant to compensation and equity incentive plans. Notwithstanding the foregoing, voting stock includes up to 1,399,106 shares that were reserved as of May 8, 2003 for issuance under our 1998 equity incentive plan.

Novartis has the ability to exercise substantial control over our strategic direction, our research and development focus and other material business decisions. In connection with its initial purchase of our common stock, Novartis agreed not to acquire additional shares of our voting stock unless a majority of our independent directors approves or requests the acquisition. These restrictions will terminate on May 8, 2008.

We currently depend on Novartis for substantially all our revenues and for the commercialization of Tyzeka®/Sebivo® and for support in the development of product candidates Novartis has licensed from us. If our development, license and commercialization agreement with Novartis terminates, our business and, in particular, the development of our product candidates and the commercialization of any products that we successfully develop could be harmed.

In May 2003, we received a \$75.0 million license fee from Novartis in connection with the license to Novartis of our then HBV product candidates, telbivudine and valtorcitabine. In April 2007, we received a \$10.0 million milestone payment for regulatory approval of Sebivo® in China and in June 2007 we received an additional \$10.0 million milestone payment for regulatory approval of Sebivo® in the European Union. Pursuant to the development and commercialization agreement, as amended, Novartis also acquired options to license valopicitabine and additional product candidates from us. In March 2006, Novartis exercised its option and acquired a license to valopicitabine. In exchange we received a \$25.0 million license fee from Novartis and the right to receive up to an additional \$45.0 million in license fee payments upon advancement of an HCV product candidate into phase III clinical trials. Assuming we continue to successfully develop and commercialize our product candidates (other than valopicitabine), under the terms of the development and commercialization agreement, we are entitled to receive reimbursement of expenses we incur in connection with the development of these product candidates and additional milestone payments from Novartis. Additionally, if any of the product candidates we have licensed to Novartis are approved for commercialization, we anticipate receiving proceeds in connection with the sales of such products. If Novartis exercises the option to license with respect to other product candidates that we discover, or in some cases, acquire, we are entitled to receive license fees and milestone payments as well as reimbursement of expenses we incur in the development of such product candidates in accordance with development plans mutually agreed with Novartis.

Under the existing terms of the development and commercialization agreement, we have the right to co-promote and co-market with Novartis in the United States, United Kingdom, Germany, Italy, France and Spain any products licensed by Novartis, including Tyzeka®/Sebivo®. For Tyzeka®/Sebivo®, we acted as lead commercial party in the United States. On September 28, 2007 we entered into an amendment to the development and commercialization agreement and a transition services agreement, both of which became effective on October 1, 2007, whereby we transferred to Novartis all of our development, commercialization and manufacturing rights and obligations related to telbivudine (Tyzeka®/Sebivo®) on a world-wide basis in exchange for royalty payments equal to a percentage of net sales of Tyzeka®/Sebivo®, with such percentage increasing according to specified tiers of net sales. The royalty percentage will vary based upon the territory and the aggregate dollar amount of net sales.

Novartis is responsible for development and commercialization expenses relating to telbivudine after October 1, 2007 and is also responsible for certain costs associated with the transition of third party contracts and arrangements relating to telbivudine and certain intellectual property prosecution and enforcement activities. Pursuant to the transition services agreement, we will provide Novartis with certain services relating to telbivudine through June 2008 (or later if agreed to by the parties). We will be reimbursed for these services at an agreed upon rate.

As a result of the amendment to the development and commercialization agreement discussed above, our master manufacturing and supply agreement, dated May 2003, and our commercial manufacturing agreement, dated June 2006, between us and Novartis, were terminated without penalty as each related to telbivudine.

Novartis may terminate the development and commercialization agreement in any country or with respect to any product or product candidate licensed under the development and commercialization agreement for any reason with six months written notice. If the development and commercialization agreement is terminated in whole or in part and we are unable to enter similar arrangements with other collaborators or partners, our business would be materially adversely affected.

Novartis has the option to license from us product candidates we discover, or in some cases, acquire. If Novartis does not exercise its option with respect to a product candidate, our development, manufacture and/or commercialization of such product candidate may be substantially delayed or limited.

Our drug development programs and potential commercialization of our product candidates will require substantial additional funding. In addition to its license of Tyzeka®/Sebivo®, valtorcitabine and valopicitabine, Novartis has the option under the development and commercialization agreement to license our other product candidates. If Novartis elects not to exercise such option, we may be required to seek other collaboration arrangements to provide funds necessary to enable us to develop such product candidates.

If we are not successful in efforts to enter into a collaboration arrangement with respect to a product candidate not licensed by Novartis, we may not have sufficient funds to develop such product candidate internally. As a result, our business would be adversely affected. In addition, the negotiation of a collaborative agreement is time consuming, and could, even if successful, delay the development, manufacture and/or commercialization of a product candidate and the terms of the collaboration agreements may not be favorable to us.

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

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

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

Novartis could also suffer losses in connection with any amounts we become obligated to pay relating to or under the terms of any license agreement, including the UAB license agreement, or other arrangements we may be required to enter into with UAB, Emory University and CNRS, each licensors under the UAB license agreement, to commercialize telbivudine. Novartis may seek to recover from us, and, under certain circumstances, us and those of our officers, directors and other stockholders who sold shares to Novartis, such losses and other losses it suffers as a result of any breach of the representations and warranties we made relating to our HBV product candidates.

If we are required to rely upon the UAB license agreement to commercialize telbivudine, we will be obligated to make certain payments to UABRF and the other licensors. Such amounts would include payments in the aggregate amount of \$1.3 million due upon the achievement of regulatory milestones, a 6% royalty on annual sales up to \$50.0 million and a 3% royalty on annual sales greater than \$50.0 million made by us or an affiliate of ours. Additionally, if we sublicense our rights to a non-affiliate sublicensee, which is defined as any entity other than one which holds or controls at least 50% of our capital stock, or if Novartis's ownership interest in us declines below 50% of our outstanding shares of capital stock, we could be obligated to pay to UABRF 30% of all royalties received by us from sales by the sublicensee of telbivudine and 20% of all fees, milestone payments and other cash consideration we receive from the sublicensee with respect to telbivudine.

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

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

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

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

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

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

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

Novartis' right to purchase shares includes a right to purchase securities that are convertible into, or exchangeable for, our common stock, provided that Novartis' right to purchase stock in connection with options or other convertible securities issued to any of our directors, officers, employees or consultants pursuant to any stock compensation or equity incentive plan will not be triggered until the underlying equity security has been issued to the director, officer, employee or consultant.

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

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

In addition, Novartis has the right to terminate the development and commercialization agreement with respect to any product, product candidate or country with six months written notice to us. If Novartis were to breach or terminate this agreement with us, the development or commercialization of the affected product 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 product candidate, and we may not be successful in entering into a collaboration with another third party.

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

Novartis has agreed that, other than as set forth in the development and commercialization agreement, it will not market, sell or promote certain competitive products except that:

- this agreement not to compete extends only until May 2008;
- as to any country, the agreement not to compete would terminate if Novartis terminates the development and commercialization agreement with respect to that country; and
- if Novartis wishes to market, sell, promote or license a competitive product, it is required to inform us of the
  competitive product opportunity and, at our election, enter into good faith negotiations with us concerning
  such opportunity. If we either do not elect to enter into negotiations with respect to such opportunity or are

unable to reach agreement within a specified period, Novartis would be free to proceed with its plans with respect to such competing product.

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

## Factors Related to Our Dependence on Third Parties

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

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

If we do not have sufficient funds to develop our product candidates, we will not be able to bring these product 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 product 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 product candidate to commercialization;
- · revenue from product sales could be delayed; or
- we may elect not to develop or commercialize the product candidate.

## If any collaborative partner terminates or fails to perform its obligations under agreements with us, the development and commercialization of our product candidates could be delayed or terminated.

We have entered into the development and commercialization agreement with Novartis and we may enter into additional collaborative arrangements in the future. If collaborative partners do not devote sufficient time and resources to any collaboration arrangement with us, we may not realize the potential commercial benefits of the arrangement, and our results of operations may be adversely affected. In addition, if Novartis or future collaboration partners were to breach or terminate their arrangements with us, the development and commercialization of the affected product candidate could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue development and commercialization of such product candidate.

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

We work with chemists and biologists at academic and other institutions that assist us in our research and development efforts. Telbivudine, valtorcitabine and valopicitabine 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 product 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, if at all. We also expect to rely upon other 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 current good manufacturing practice regulations. Any failure by us or our third-party manufacturers to comply with current good manufacturing practices 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 product 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 product 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.

We may not have identified all patents, published applications or published literature that affect our business either by blocking our ability to commercialize our product candidates, by preventing the patentability of our product candidates to us or our licensors or co-owners, or by covering the same or similar technologies that may invalidate our patents, limit the scope of our future patent claims or adversely affect our ability to market our product candidates. For example, patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U.S. Patent and Trademark Office, which we refer to as the U.S. Patent Office, for the entire time prior to issuance of a U.S. patent. Patent applications filed in countries outside the United States are not typically published until at least 18 months from their first filing date. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we or our licensors or co-owners were the first to invent, or the first to file, patent applications on our product or product candidates or for their uses. In the event that a third

party has also filed a U.S. patent application covering our product or product candidates or a similar invention, we may have to participate in an adversarial proceeding, known as an interference, declared by the U.S. Patent Office to determine priority of invention in the United States. The costs of these proceedings could be substantial and it is possible that our efforts could be unsuccessful, resulting in a loss of our U.S. patent position. The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed.

Since our HBV product, telbivudine, was a known compound before the filing of our patent applications covering the use of this product candidate to treat HBV infection, 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 hepatitis B infection.

Pursuant to the UAB license agreement, we were granted an exclusive license to the rights that the 1998 licensors 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 infection.

In February 2006, UABRF notified us that it and Emory University were asserting a claim that, as a result of the filing of a continuation patent application in July 2005 by UABRF, the UAB license agreement covers our telbivudine technology. UABRF contends that we are obligated to pay the 1998 licensors an aggregate of \$15.3 million comprised of 20% of the \$75.0 million license fee we received from Novartis in May 2003 in connection with the license of our HBV product candidates and a \$0.3 million payment in connection with the submission to the FDA of the IND pursuant to which we conducted clinical trials of telbivudine. We disagree with UABRF's contentions and advised UABRF and Emory University that we will utilize the dispute resolution procedures set forth in the UAB license agreement for resolution of this dispute. Under the terms of that agreement, if resolution cannot be achieved through negotiations between the parties or mediation, it must be decided by binding arbitration under the rules of the American Arbitration Association before a panel of three arbitrators. Pursuant to the terms of the dispute resolutions procedure in the UAB license agreement, in September 2007 the CEOs of UABRF and Idenix met and agreed to begin a process of mediation. While the parties participated in a joint mediation session in January 2008, no resolution of these matters has yet been reached. However, a non-binding settlement proposal has been discussed by the parties. Such settlement proposal remains subject to several terms and conditions, including a full release of all claims by UABRF and related entities.

If we do not settle these disputes and it is determined that the UAB license agreement does cover our use of telbivudine to treat HBV, we will be obligated to make payments to the 1998 licensors in the amounts and manner specified in the UAB license agreement. While we dispute the demands made by UABRF, even if liability were found to exist, UABRF's claims, in addition to those described above would likely include payments in the aggregate amount of \$1.0 million due upon achievement of regulatory milestones, a 6% royalty on annual sales up to \$50.0 million and a 3% royalty on annual sales greater than \$50.0 million made by us or an affiliate of ours. Additionally, if we sublicense our rights to any entity other than one which holds or controls at least 50% of our capital stock, or if Novartis' ownership interest in us declines below 50% of our outstanding shares of capital stock, UABRF would likely contend that we would be obligated to pay to the 1998 licensors 30% of all royalties received on sales by the sublicensee of telbivudine and 20% of all fees, milestone payments and other cash consideration received from the sublicensee with respect to telbivudine.

If we fail to perform our material obligations under the UAB license agreement, UABRF, acting for the 1998 licensors, may attempt to terminate the UAB license agreement or render the license to us non-exclusive. We do not believe that we are in default of any of the material obligations to which we are subject under the UAB license agreement. Any attempt to terminate the agreement would be subject to binding arbitration. In the event UABRF is successful in terminating the license agreement as a result of a breach by us after a period of arbitration, and the 1998 licensors obtain a valid enforceable claim that generally covers the use of telbivudine to treat hepatitis B, it may be necessary for us to obtain another license from the 1998 licensors. Such license may not be available to us on reasonable terms, on an exclusive basis or at all. This could materially adversely affect or preclude the commercialization of telbivudine.

If the 1998 licensors were instead to render the UAB license agreement to us non-exclusive, we would not be prohibited from using telbivudine to treat hepatitis B, but a non-exclusive license could be granted to one or more of our competitors by one or more of the 1998 licensors. In the event that the 1998 licensors exclusively or non-exclusively license any claims covering the use of telbivudine to treat HBV to a competitor, we believe that such a competitor would have to overcome substantial legal and commercial hurdles to successfully commercialize the product. For example, we have four U.S. patents covering the use of telbivudine to treat HBV, which we believe a competitor would likely infringe if it sought to commercialize telbivudine. Patent applications covering the use of telbivudine to treat HBV are also pending or have already been granted in numerous other countries. The FDA granted approval for the commercial use of Tyzeka® on October 25, 2006 and also granted five years of marketing exclusivity, during which period the FDA will not approve the applications of any competitors who seek approval of telbivudine for the treatment of hepatitis B. We may also receive regulatory exclusivity periods in Europe and in other countries.

If it is determined that the UAB license agreement does cover our use of telbivudine to treat HBV, or we must otherwise rely upon a license agreement granted by the 1998 licensors to commercialize telbivudine, we may be in breach of certain of the representations and warranties we made to Novartis under the development and commercialization agreement and the stock purchase agreement. Pursuant to the terms of the development and commercialization agreement and the stock purchase agreement, if there is a breach Novartis has the right to seek indemnification from us, and, under certain circumstances, us and our stockholders who sold shares to Novartis, for the losses Novartis incurs as a result of the breach. The amounts for which we could be liable to Novartis may be substantial.

In January 2007, the Board of Trustees of the University of Alabama and related entities filed a complaint in the United States District Court for the Northern District of Alabama, Southern Division against us, CNRS and the University of Montpellier. The complaint alleges that a former employee of UAB is a co-inventor of certain patents in the United States and corresponding foreign patent applications related to the use of \( \beta \text{L-2'-deoxy-nucleosides} \) for the treatment of HBV; assigned to one or more of us, CNRS and the University of Montpellier and which cover the use of Tyzeka®/Sebivo®.

If the Board of Trustees of the University of Alabama and related entities are successful in the lawsuit against us, CNRS and the University of Montpellier, then UAB could obtain rights in certain patents in the United States and corresponding foreign patent applications related to the use of \( \beta \text{-L-2'-deoxy-nucleosides} \) for the treatment of HBV currently assigned to one or more of us, CNRS and the University of Montpellier and which cover the use of Tyzeka®/ Sebivo. The University of Alabama has included a demand for damages under various theories in its complaint, but did not specify the amount of damages that it alleges to have incurred. In response to the complaint, in March 2007, we filed a motion to dismiss based upon lack of personal jurisdiction. In September 2007, the parties agreed to stay the action and pursue mediation relating to the disputes associated with the license agreement and this litigation. As a result of a joint mediation session held in January 2008, a non-binding settlement has been proposed by the parties which could potentially require Idenix to make payments to UABRF and related entities. We have assessed this settlement proposal under the provisions of FAS 5, and recorded an expense of \$1.5 million for the quarter ended December 31, 2007. If the proposed settlement is not completed on terms acceptable to Idenix, we will resume the defense of these claims, including through the litigation process. Accruals related to the settlement proposal may be adjusted in future periods if a settlement agreement is not reached. We cannot ascertain with certainty the likelihood this or any settlement proposal will be accepted by or entered into by the parties. If we are not able to reach a settlement agreement with the parties, we will continue to vigorously defend against claims made by UABRF and related entities (see Note 2).

Our initial HCV clinical product candidate, valopicitabine, is a prodrug of the active molecule NM107, which is converted into biologically active NM107 in the body. We believe that valopicitabine may be a new compound, and therefore we are prosecuting patent applications directed to valopicitabine itself, as well as a method to treat HCV infection with valopicitabine. NM107 was a known compound at the time that the patent applications covering the use of this active form of valopicitabine to treat HCV infection were filed. We have been granted U.S. patents claiming methods of treatment using NM107, each directed to treating HCV infection specifically to treating flavivirus and pestivirus infection. We have a pending U.S. patent application covering the compound valopicitabine. We cannot, however, obtain patent protection on the compound NM107.

Despite the fact that NM107 is a known compound, we are aware that a number of companies have filed patent applications attempting to cover NM107 specifically as a compound, as well as valopicitabine, as members of broad classes of compounds. Companies have also filed patent applications covering the use of NM107, specifically, and valopicitabine, generically, to treat HCV infection, or infection by any member of the Flaviviridae virus family to which the HCV virus belongs. These companies include Merck & Co., Inc. together with Isis Pharmaceuticals, Inc., Ribapharm, Inc., a wholly-owned subsidiary of Valeant Pharmaceuticals International, Genelabs Technologies, Inc. and Biota, Inc., a subsidiary of Biota Holdings Ltd., or Biota. We believe that we were the first to file patent applications covering the use of these product candidates to treat HCV infection. Because patents in countries outside the United States are awarded to the first to file a patent application covering an invention, we believe that we are entitled to patent protection in these countries. Notwithstanding this, a foreign country may grant patent rights covering our product candidates to one or more other companies, either because it is not aware of our patent filings or because the country does not interpret our patent filing as a bar to issuance of a patent to the other company in that country. If that occurs, we may need to challenge the third-party patent to enforce our proprietary rights, and if we do not or are not successful, we will need to obtain a license that may not be available at all or on commercially reasonable terms. In the United States, a patent is awarded to the first to invent the subject matter. The U.S. Patent Office could initiate an interference between us and any or all of Merck/Isis, Ribapharm, Genelabs, Biota or another company to determine the priority of invention of the use of these compounds to treat HCV infection. If such an interference is initiated and it is determined that we were not the first to invent the use of these compounds in methods for treating HCV or other viral infection under U.S. law, we would need to obtain a license that may not be available on commercially reasonable terms or at all.

A number of companies have filed patent applications and have obtained patents covering general methods for the treatment of HBV, HCV and HIV infections that could materially affect the ability to develop and commercialize Tyzeka®/Sebivo®, and other product candidates we may develop in the future. For example, we are aware that Chiron Corporation, now a subsidiary of Novartis, and Apath, LLC have 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 product 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 product candidates.

If we find that any product 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 the third-party patents 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 product candidates to market and harm our ability to operate. Such litigation could take place in the United States in a federal court or in the U.S. Patent Office. The litigation could also take place in a foreign country, in either the court 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 coowned by us or licensed to us, which cover products we successfully develop. Proceedings involving our patents or patent applications could result in adverse decisions regarding:

- · ownership of patents and patent applications;
- · the patentability of our inventions relating to our product candidates; and/or

the enforceability, validity or scope of protection offered by our patents relating to our product candidates.

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

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

Under the terms of the settlement agreement, we agreed to make a \$2.0 million initial payment to UABRF, as well as other potential contingent payments based upon the commercial launch of other HCV products discovered or invented by Dr. Sommadossi during his sabbatical and unpaid leave. In addition, UAB and UABRF have each agreed that neither of them has any right, title or ownership interest in these inventions and discoveries. Under the development and commercialization agreement and stock purchase agreement, we made numerous representations and warranties to Novartis regarding valopicitabine and our HCV program, including representations regarding our ownership of the inventions and discoveries. If one or more of our representations or warranties were not true at the time we made them to Novartis, we would be in breach of these agreements. In the event of a breach by us, Novartis has the right to seek indemnification from us and, under certain circumstances, us and our stockholders who sold shares to Novartis, which include many of our directors and officers, for damages suffered by Novartis as a result of such breach. The amounts for which we could be liable to Novartis may 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, 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 product candidates to market; and/or
- be precluded from participating in the manufacture, use or sale of our product 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 proprietary 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 product candidates are terminated, we and/or Novartis may be unable to develop or commercialize our product candidates.

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

agreements with the Universita degli Studi di Cagliari, which we refer to as the University of Cagliari, the co-owner of the patents and patent applications covering our HCV product candidates and certain HIV preclinical product 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 the jointly created HCV and HIV product candidates. Under the amended and restated agreement with CNRS and the University of Montpellier and the license agreement, as amended, with the University of Cagliari, we obtained from our co-owners the exclusive right to exploit these product candidates. Subject to certain rights afforded to Novartis, 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 product candidate or selling a product. In addition, these agreements provide that we pay the 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 our co-owned product candidates without the permission of the co-owners. 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 U.S. 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, we may not be able to exploit, license or otherwise convey to Novartis or other third parties our rights in our product candidates for a desired commercial purpose without the consent of the co-owner, which could materially affect our business and prevent us from developing our product candidates and selling our products.

Under U.S. law, a co-owner has the right to prevent the other 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 product 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.

## If our cooperative research agreement with the University of Cagliari is terminated, we may be unable to utilize research results arising out of that work prior to the termination.

Our cooperative research agreement with the University of Cagliari, as amended, grants us the exclusive right to directly or indirectly use or license to Novartis or other third parties the results of research obtained from the cooperative effort, in exchange for a fixed royalty. If the cooperative research agreement is terminated, our exclusive right to use the research results will also terminate, unless those rights are also granted under a separate license agreement. Our cooperative agreement with the University of Cagliari currently expires in January 2011 and can only be renewed by the written consent of both parties. If the agreement is not renewed, there is no guarantee that the University of Cagliari will agree to transfer rights to any of the research results into a separate license agreement on termination of the research program, or that it will agree to do so on reasonable commercial terms.

#### Factors Related to 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 March 3, 2008, we had 56,286,241 shares of common stock issued and outstanding, together with outstanding

options to purchase approximately 6,357,788 shares of common stock with a weighted average exercise price of \$9.14 per share.

Novartis and other holders of an aggregate of approximately 37,137,061 shares of common stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders.

## Fluctuation of our quarterly results may cause our stock price to decline, resulting in losses to you.

Our quarterly operating results have fluctuated in the past and are likely to fluctuate in the future. A number of factors, many of which are not within our control, could subject our operating results and stock price to volatility, including:

- realization of license fees and achievement of milestones under our development and commercialization agreement with Novartis and, to the extent applicable, other licensing and collaborative agreements;
- reductions in proceeds associated with Novartis' right to maintain its percentage ownership of our voting stock when we issue shares at a price below fair market value;
- adverse developments regarding the safety and efficacy of Tyzeka®/Sebivo®; or our product candidates;
- the results of ongoing and planned clinical trials of our product candidates;
- developments in the market with respect to competing products or more generally the treatment of HBV, HCV or HIV;
- the results of regulatory reviews relating to the approval of our product candidates;
- the timing and success of the launch of products, if any, we successfully develop;
- future royalty payments received by us associated with sales of Tyzeka®/Sebivo®;
- the initiation or conclusion of litigation to enforce or defend any of our assets; and
- general and industry-specific economic conditions that may affect our research and development expenditures.

Due to the possibility of significant fluctuations, we do not believe that quarterly comparisons of our operating results will necessarily be indicative of our future operating performance. If our quarterly operating results fail to meet the expectations of stock market analysts and investors, the price of our common stock may decline, resulting in losses to you.

## 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 announcements regarding:

- · our collaboration with Novartis;
- the results of discovery, preclinical studies and clinical trials by us or our competitors;
- the acquisition of technologies, product candidates or products by us or our competitors;
- the development of new technologies, product candidates or products by us or our competitors;
- regulatory actions with respect to our product candidates or products or those of our competitors, including those relating to our clinical trials, marketing authorizations, pricing and reimbursement;
- the timing and success of launches of any product we successfully develop;

- future royalty payments received by us associated with sales of Tyzeka®/Sebivo®;
- · the market acceptance of any products we successfully develop;
- · significant changes to our existing business model;
- the initiation or conclusion of litigation to enforce or defend any of our assets; 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 it 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 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.

We lease approximately 130,000 square feet of office and laboratory space. Our major leased properties are described below:

Property Location	Approximate Square Feet	Use	Lease Expiration Date
Cambridge, MA	49,912 sq ft 39,014 sq ft	Office Headquarters Office and Laboratory	March 2010 December 2013
Montpellier, France	35,215 sq ft	Office and Laboratory	April 2017

#### Item 3. Legal Proceedings.

We are currently a party to one legal proceeding, where on January 12, 2007, the Board of Trustees of the University of Alabama and related entities filed a complaint in the United States District Court for the Northern District of Alabama, Southern Division against us, CNRS and the University of Montpellier. The complaint alleges that a former employee of UAB is a co-inventor of certain patents in the United States and corresponding foreign patent applications related to the use of \( \textit{B-L-2'-deoxy-nucleosides} \) for the treatment of HBV, assigned to one or more of us, CNRS and the University of Montpellier and which cover the use of Tyzeka®/Sebivo® for the treatment of HBV. The University of Alabama has included a demand for damages under various theories in its complaint, but did not specify the amount of damages that it alleges to have incurred. In response to the complaint in March 2007, we filed a motion to dismiss based upon lack of personal jurisdiction. In September 2007, the parties agreed to stay the action and pursue mediation relating to the disputes associated with the license agreement and this litigation. As a result of a joint mediation session held in January 2008, a non-binding settlement has been proposed by the parties

which could potentially require Idenix to make payments to UABRF and related entities. We have assessed the settlement proposal under the provisions of FAS 5, and recorded an expense of \$1.5 million for the quarter ended December 31, 2007. If the proposed settlement is not completed on terms acceptable to Idenix, we will resume the defense of these claims, including through the litigation process. Accruals related to the settlement proposal may be adjusted in future periods if a settlement agreement is not reached. We cannot ascertain with certainty the likelihood this or any settlement proposal will be accepted by or entered into by the parties. If we are not able to reach a settlement agreement with the parties, we will continue to vigorously defend against claims made by UABRF and related entities (see Note 2).

### Item 4. Submission of Matters to a Vote of Security Holders.

None.

#### 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 March 3, 2008 the closing price of our common stock, as reported on the NASDAQ Global Market, \$5.22 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 and, prior to July 1, 2006, the NASDAQ National Market.

	High	Low
2006		
First quarter	\$23.87	\$13.17
Second quarter	\$13.76	\$ 7.50
Third quarter	\$11.21	\$ 8.56
Fourth quarter	\$10.49	\$ 8.05
2007		
First quarter	\$10.83	\$ 7.18
Second quarter	\$ 8.24	\$ 5.76
Third quarter	\$ 6.07	\$ 2.29
Fourth quarter	\$ 3.30	\$ 2.10

#### Stockholders

On March 3, 2008, we had approximately 71 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 financial statements. The consolidated statement of operations data for the years ended December 31, 2007, 2006 and 2005 and the consolidated balance sheet data as of December 31, 2007 and 2006 have been derived from our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. 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.

2007	2006	2005	2004	2003
	(In thousan	ds, except per	share data)	
* ***		<b>*</b> < 4.710	A 05 300	A 00 570
\$ 68,028	\$ 67,377	\$ 64,718	\$ 95,389	\$ 29,570
2,001	62	_	_	_
85,839	96,080	86,590	79,979	51,477
	56,954	33,657	23,603	20,193
<del></del>				
				<u>71,670</u>
	(85,719)	(55,529)		(42,100)
· ·	9,487	4,038	1,383	404
	1,145	714	566	(184)
		(50,777)	(6,244)	(41,880)
(,,	(,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	( , - ,	( , ,	, , ,
				(29,074)
\$ (82,515)	<u>\$(75,087)</u>	<u>\$ (50,777)</u>	\$ (6,244)	<u>\$(70,954</u> )
\$ (1.47)	\$ (1.34)	\$ (1.03)	\$ (0.15)	\$ (2.70)
56,169	56,005	49,395	41,369	26,232
2007				2003
		(In thousands)	1	
	•	•		\$ 43,485
72,985	110,159	167,069	70,123	30,399
160,540	228,465	277,657	187,118	67,090
	_	_	<del></del>	107
4,272	4,272	4,272	4,272	4,272
8,372	13,490	9,695	9,695	10,756
41,861	40,471	29,089	38,779	54,239
	2,251	2,792	3,691	4,849
	(355,941)	(280,854)	(230,077)	(223,833)
• • •	142,025	206,887	109,058	(27,731)
	\$ 68,028  2,001 85,839 63,348 8,744 159,932 (91,904) 6,387 3,500 (498) (82,515) \$ (1.47) 56,169  2007  \$ 48,260 72,985 160,540 4,272 8,372 41,861 13,172 (438,756)	2007         2006 (In thousand)           \$ 68,028         \$ 67,377           2,001         62           85,839         96,080           63,348         56,954           8,744         —           159,932         153,096           (91,904)         (85,719)           6,387         9,487           3,500         —           (498)         1,145           (82,515)         \$ (75,087)           \$ (1.47)         \$ (1.34)           56,169         56,005           As         2007           2006         As           2007         2006           \$ 48,260         \$ 55,892           72,985         110,159           160,540         228,465           —         4,272           8,372         13,490           41,861         40,471           13,172         2,251           (438,756)         (355,941)	2007   2006   2005   (In thousands, except per   \$ 68,028   \$ 67,377   \$ 64,718	Company   Comp

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

This report contains "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. For this purpose, any statements contained herein regarding our strategy, future operations, financial position, future revenues, projected costs and expenses, prospects, plans and objectives of management, other than statements of historical facts, are forward-looking statements. The words "anticipate," "believes," "estimates," "intends," "may," "plans," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such statements reflect our current views with respect to future events. We cannot guarantee that we actually will achieve the plans, intentions, or expectations disclosed in our forward-looking statements. There are a number of important factors that could cause actual results or events to differ materially from those disclosed in the expressed or implied forward-looking statements we make. These important factors include our "critical accounting policies and estimates" and the risk factors set forth below in Part II, Item IA — Risk Factors. Although we may elect to update forward-looking statements in the future, we specifically disclaim any obligation to do so, even if our estimates change, readers should not rely on those forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report.

#### Overview

Idenix is a biopharmaceutical company engaged in the discovery and development of drugs for the treatment of human viral and other infectious diseases, with operations in the United States and Europe. Our current focus is on diseases caused by hepatitis C virus, or HCV, and human immunodeficiency virus, or HIV.

Prior to October 1, 2007, we developed, commercialized and manufactured telbivudine for the treatment of patients with chronic hepatitis B. Certain of these activities were done with Novartis Pharma AG, or Novartis. Telbivudine is marketed as Tyzeka® in the United States and Sebivo® outside the United States. In April 2007, Sebivo® was approved in the European Union for the treatment of patients with chronic hepatitis B. At December 31, 2007, Tyzeka®/Sebivo® was approved in more than 50 countries world-wide, including China.

In September 2007, we entered into an amendment to the development and commercialization agreement, which we refer to as the 2007 Amendment. When we refer to the development and commercialization agreement, we mean the 2003 original agreement, 2007 Amendment and all prior amendments. We and Novartis also entered into a transition services agreement, or a TSA, as part of the 2007 Amendment. Pursuant to the 2007 Amendment, we transferred to Novartis our development, commercialization and manufacturing rights and obligations pertaining to telbivudine (Tyzeka®/Sebivo®) on a worldwide basis. Effective October 1, 2007, we began receiving royalty payments equal to a percentage of net sales of Tyzeka®/Sebivo®, with such percentage increasing according to specified tiers of net sales. The royalty percentage varies based upon the territory and the aggregate dollar amount of net sales.

In conjunction with the 2007 Amendment, we announced a restructuring of our operations in which we enacted a workforce reduction of approximately 100 positions, the majority of which had supported the development and commercialization of Tyzeka®/Sebivo® in the United States and Europe. The restructuring was a strategic decision on our behalf to focus our resources on our HCV and HIV discovery and development programs. In connection with the restructuring, we recorded restructuring and impairment charges of \$8.7 million in 2007, including \$6.6 million for employee severance, benefits and related costs and \$2.1 million for the impairment of certain assets. We also incurred additional charges in 2007 of \$2.8 million due to accelerating depreciation on certain assets whose useful lives were shortened due to the restructuring. We estimate that this restructuring will result in annual cost savings of \$40.0 million to \$45.0 million, including associated third party and marketing costs.

The following table summarizes key information regarding Tyzeka®/Sebivo® and our pipeline of product candidates:

Indication	Product/Product Candidates/Programs	Description
HBV	Tyzeka*/Sebivo** (telbivudine) (L- nucleoside)	Effective October 1, 2007, we transferred to Novartis all of our development, commercialization and manufacturing rights and obligations related to telbivudine (Tyzeka®/Sebivo®) on a worldwide basis in exchange for royalty payments equal to a percentage of net sales of Tyzeka®/Sebivo®. Beginning in the fourth quarter of 2007, Novartis is solely responsible for clinical trial costs and related expenditures associated with telbivudine. We have transitioned to Novartis all ongoing clinical trials and commercial activities related to telbivudine.
	valtorcitabine (L-nucleoside)	During the third quarter of 2007, we discontinued development of valtorcitabine.
HCV	valopicitabine (NM283) (Nucleoside analog)	In July 2007, this program was placed on clinical hold by the FDA and development of the program was discontinued.
	discovery program	Preclinical evaluation of compounds from the HCV discovery program is in progress. This program is focused on the three primary classes of drugs for the treatment of HCV, which include nucleoside/nucleotide polymerase inhibitors, protease inhibitors and non-nucleoside polymerase inhibitors.
·	<ul> <li>Nucleoside/nucleotide polymerase inhibitors (IDX184 and IDX102)</li> </ul>	The most advanced of these efforts is our research in next-generation nucleoside/ nucleotide polymerase inhibitors. IDX184 and IDX102 are in late stage preclinical development. We expect to submit an IND in the United States and a CTA in Europe for at least one of these product candidates in 2008.
	Protease inhibitors	We are evaluating multiple scaffolds in our protease inhibitor discovery program. Clinical candidates from this program have been selected and IND-enabling pharmacology and toxicology studies are ongoing.
	Non-nucleoside polymerase inhibitors	We have an ongoing discovery effort in non-nucleoside polymerase inhibitors.

Indication

Product/Product Candidates/Programs

HIV

IDX899 (Non-nucleoside reverse transcriptase inhibitor or NNRTI)

#### Description

In addition to our HCV discovery and development program, we are also engaged in efforts to develop therapeutics for the treatment of HIV-1 from the class of compounds known as non-nucleoside reverse transcriptase inhibitors, or NNRTIs. This class of drugs is being evaluated for once-a-day oral administration. We filed an IND for IDX899 in 2007 and completed a phase I dose escalation study in healthy volunteers. The phase I study was designed to assess the safety pharmacokinetics of IDX899 in healthy volunteers. In this study, IDX899 appeared to be well tolerated at single doses up to 1200 mg and multiple doses up to 800 mg daily over a seven day period. No serious or clinically significant adverse events were reported for the 65 IDX899-treated volunteers in this study. One healthy volunteer, after the 400 mg single dose administration of this study, experienced a single unconfirmed QTc elevation. believe this is not a significant clinical finding as it is within the expected variability of multiple QTc measurements a healthy volunteer study. Two volunteers discontinued from the study due to adverse events.

In May 2003, we entered into a collaboration with Novartis relating to the worldwide development and commercialization of our product candidates. The collaboration includes the development, license and commercialization agreement, as amended and the master manufacturing and supply agreement between us and Novartis. Under the collaboration, Novartis paid us a license fee of \$75.0 million for our HBV product and product candidate, Tyzeka®/Sebivo® and valtorcitabine, respectively, provided development funding for Tyzeka®/Sebivo® and valtorcitabine and was obligated to make milestone payments, which could have totaled up to \$35.0 million upon the achievement of specific regulatory approvals.

Of the \$35.0 million in regulatory milestone payments, we received payment on two of these regulatory milestones in 2007. We achieved one of these regulatory milestones for \$10.0 million in the first quarter of 2007 with the regulatory approval of Sebivo® in China. We recognized this regulatory milestone payment in collaboration revenue from Novartis in 2007 as the milestone was deemed substantive. A second of these regulatory milestones for \$10.0 million was achieved in April 2007 with the regulatory approval of Sebivo® in the European Union. This milestone was deemed not to be substantive and we recognized \$4.8 million as revenue in 2007, representing the portion of the development period that has passed, with the remaining \$5.2 million recorded as deferred revenue and recognized as revenue over the remaining development period of our licensed product candidates. We do not expect to receive any additional regulatory milestones for telbivudine or valtorcitabine.

In March 2006, Novartis exercised its option to license valopicitabine, our lead HCV product candidate at that time. Under the development and commercialization agreement, Novartis agreed to pay us up to \$500.0 million in license fees and regulatory milestone payments for an HCV product candidate. Of this amount and in connection with its option exercise, Novartis paid us a license fee of \$25.0 million, paid us an additional \$25.0 million payment based upon results from our phase I clinical trial and provided development funding for the product candidate. In July 2007, we announced that the FDA had placed on clinical hold in the United States our development program of valopicitabine for the treatment of HCV based on the overall risk/benefit profile observed in clinical testing. We

subsequently discontinued the development of valopicitabine. As a result, we do not expect to receive any additional license fees or milestone payments for valopicitabine from Novartis.

We initially planned to co-promote or co-market with Novartis in the United States, United Kingdom, France, Germany, Italy and Spain all products Novartis licenses from us that are successfully developed and approved for commercial sales, including Tyzeka®/Sebivo®. Effective October 1, 2007, we transferred to Novartis our development, commercialization and manufacturing rights and obligations related to telbivudine (Tyzeka®/Sebivo®) on a world-wide basis in exchange for royalty payments equal to a percentage of net sales, with such percentage increasing according to specified tiers of net sales. The royalty percentage will vary based upon the territory and the aggregate dollar amount of net sales. We continue to have co-promotion and co-marketing rights with Novartis in the United States, United Kingdom, France, Germany, Italy and Spain on all other products, with the exception of Tyzeka®/Sebivo®, that Novartis licenses from us that are successfully developed and approved for commercial sales. Novartis has the exclusive right to promote and market these licensed products in the rest of the world.

Pursuant to the supply agreement, Novartis was appointed to finish and package licensed products for commercial sale. Novartis was also afforded the opportunity to manufacture active pharmaceutical ingredients for the commercial supply of licensed products if certain conditions and criteria were satisfied. In June 2006, after completing a competitive bid process where Novartis had the right to match the best third-party bid, we entered into a commercial manufacturing agreement with Novartis and a packaging agreement with Novartis Pharmaceuticals Corporation, an affiliate of Novartis. Under the commercial manufacturing agreement, Novartis would manufacture the commercial supply of Tyzeka® that was intended for sale in the United States. The packaging agreement provided that the supply of Tyzeka® intended for commercial sale in the United States would be packaged by Novartis Pharmaceuticals Corporation. As a result of the 2007 Amendment, the commercial manufacturing agreement and supply agreement were terminated as each related to telbivudine and we will work with Novartis to terminate our rights and obligations to the packaging agreement. Effective October 1, 2007, Novartis is solely responsible for the manufacture and supply of Tyzeka®/Sebivo® on a worldwide basis. No penalties were incurred by us as a result of the termination of these agreements.

In addition to the collaboration described above, Novartis purchased approximately 54% of our outstanding capital stock in May 2003 from our then existing stockholders for \$255.0 million in cash, with an additional aggregate amount of up to \$357.0 million contingently payable to these stockholders if we achieve predetermined development milestones relating to an HCV product candidate. The future contingent payments are payable in cash or, under certain circumstances, Novartis AG American Depository Shares. At present, Novartis owns approximately 56% of our outstanding common stock.

All of our product candidates are currently in preclinical development or clinical development. To commercialize any of our product candidates, we will be required to obtain marketing authorization approvals after successfully completing preclinical studies and clinical trials of such product candidates. Currently, Tyzeka®/Sebivo® has received regulatory approval for the treatment of patients with chronic hepatitis B in more than 50 countries around the world, including the United States, China, Switzerland and the European Union.

We started recognizing revenue from product sales associated with Tyzeka® in the United States during the fourth quarter of 2006. To date, our revenues have been derived from: license fees and milestone payments, development expense reimbursements received from Novartis, Tyzeka® product sales in the United States prior to October 1, 2007, amounts associated with Sebivo® product sales outside of the United States prior to October 1, 2007, royalty payments associated with sales of Tyzeka®/Sebivo®, and government grants. Effective October 1, 2007 with the recent transfer to Novartis of our development and commercial rights to telbivudine, we no longer recognize revenue from product sales of Tyzeka® and instead we recognize royalty income associated with product sales of Tyzeka®/Sebivo®. We derived substantially all of our total revenues from Novartis in 2007, 2006 and 2005. We anticipate recognizing additional revenues from our collaboration with Novartis. These revenues include additional development expense funding for our HCV product candidate and other product candidates that Novartis may elect to subsequently license from us, as well as, regulatory milestones and, if products are approved for sale, commercialization milestones and revenues derived from sales by us or Novartis of our licensed product candidates.

We have incurred significant losses since our inception in May 1998 and expect such losses to continue in the foreseeable future. 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 operating losses for the foreseeable future. We expect our near-term sources of funding to consist principally of the reimbursement of expenses we may incur in connection with the development of our licensed product and product candidates; potential license and other fees we may receive in connection with license agreements with third parties; and anticipated royalty payments associated with product sales of Tyzeka®/Sebivo®.

Our research and development expenses consist primarily of salaries and payroll-related expenses for research and development personnel, including stock-based compensation, fees paid to clinical research organizations and other professional service providers in conjunction with our clinical trials, fees paid to research organizations in conjunction with animal studies, costs of material used in research and development, costs of contract manufacturing consultants, occupancy costs associated with the use of our research facilities and equipment, consulting and license fees paid to third parties, and depreciation of property and equipment related to research and development. We incur the majority of our research and development spending on clinical, preclinical and manufacturing activity with third-party contractors relating to the development of our product candidates. We expense internal and external research and development costs as incurred. We expect our research and development expenses to increase from our base level as of January 1, 2008 as we continue to engage in research activities, further develop our potential product candidates and advance our clinical trials.

Set forth below are the direct third-party research and development expenses incurred during the period from May 1, 1998 through December 31, 2003, and the years ended December 31, 2004, 2005, 2006 and 2007 in connection with our preclinical studies and clinical trials of Tyzeka\*/Sebivo\*, valtorcitabine and valopicitabine.

Period from

Disease	Product/Product	May 1, 1998 (Inception) Through		Year	s Ended Decem	ber 31,	
Indication	<u>Candidate</u>	December 31, 2003	2004	2005	2006	2007	Total
		(Dollars in	thousands)	•			
HBV	Tyzeka®/Sebivo®	\$41,519	\$43,483	\$46,447	\$36,310	\$24,147	\$191,906
HBV	Valtorcitabine	8,338	8,673	3,770	3,726	1,515	26,022
HCV	Valopicitabine	8,947	7,096	12,140	11,489	6,196	45,868
		\$58,804	\$59,252	<u>\$62,357</u>	<u>\$51,525</u>	\$31,858	<u>\$263,796</u>

We anticipate that we will incur significant additional direct third-party research and development expenses prior to the commercial launch of our HCV product candidates. We expect such amounts to approximate those set forth below:

Vetimeted Additional

Product Candidate	Current Stage of Development	Amount of Direct/Third-Party Research and Development Expenses Expected to be Incurred Prior to Commercial Launch of a Drug	
IDX102 and IDX184	preclinical	\$200 to \$500 million	
Protease Inhibitor Program	preclinical	\$200 to \$500 million	
IDX899	clinical	\$200 to \$300 million	

Our current estimates of additional direct or 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 product candidates on a project-by-project basis.

Pursuant to our development and commercialization agreement with Novartis, after it licenses a product candidate, Novartis is obligated to fund development expenses that we incur in accordance with development plans agreed upon by us and Novartis. The option we have granted to Novartis with respect to its exclusive right to license our product candidates generally requires that Novartis exercise the option for each such product candidate generally 90 days after early demonstration of activity and safety in a proof of concept clinical study. The expenses associated with phase III clinical trials generally are the most costly component in the development of a successful new product.

## **Results of Operations**

## Comparison of Years Ended December 31, 2007 and 2006

#### Revenues

Revenues for the years ended December 31, 2007 and 2006 were as follows:

	Years Ended December 31,		
	2007	2006	
	(In thou	isands)	
Collaboration revenue — related party	•		
Reimbursement of research and development costs	\$41,933	\$54,858	
License fee revenue	13,535	12,049	
Milestone revenue	10,000	_	
Royalty revenue	617	_	
Product revenue — rest of world	46	_	
Profit-sharing to related party	(1,380)	(183)	
•	64,751	66,724	
Product sales, net	3,187	424	
Government grants	90	229	
Total revenues	\$68,028	<u>\$67,377</u>	

Collaboration revenue-related party consists of revenue associated with our collaboration with Novartis for the worldwide development and commercialization of our product candidates. Effective October 1, 2007, as a result of the 2007 Amendment, collaboration revenue-related party is comprised of the following:

- reimbursement by Novartis for expenses we incur in connection with the development and registration of our licensed products and product candidates, net of certain qualifying costs incurred by Novartis;
- license and other fees received from Novartis for the license of HBV and HCV product candidates, net of
  reductions for Novartis stock subscription rights, which is being recognized over the development period of
  the licensed product candidates;
- milestone amounts from Novartis upon achievement of regulatory filings, certain marketing authorization approvals and other milestone payments; and
- royalty payments associated with product sales of Tyzeka®/Sebivo® made by Novartis.

Prior to October 1, 2007, collaboration revenue-related party that we have recognized from Novartis also included the following:

- product revenue rest of world which is comprised of amounts that Novartis would pay us for the supply of licensed products in countries outside of the United States, United Kingdom, Germany, France, Spain and Italy. These amounts were recorded as revenue at a percentage of net sales; and
- profit sharing to related party which represents the net benefit amount paid to Novartis on licensed product sales in the United States in which we acted as the lead commercialization party. The net benefit, defined as

net sales less cost of goods sold, was shared equally with Novartis on product sales in the United States. These amounts due to Novartis were recorded as a reduction of collaboration revenue.

Collaboration revenue — related party decreased \$2.0 million to \$64.8 million in 2007. Reimbursements of research and development costs from Novartis declined by \$12.9 million in 2007 as clinical studies and clinical trial activity came to a close in advance of the commercial launch of Tyzeka®/Sebivo® in November 2006 and as a result of the discontinuation of our valtorcitabine and valopicitabine development activities in 2007. The lower research and development reimbursements were offset by: (i) recognition of a \$10.0 million regulatory milestone payment received from Novartis upon achievement of marketing authorization of Sebivo® in China in the first quarter of 2007 which was deemed substantive; (ii) increased license fee revenue due to recognition of \$4.8 million of revenue relating to a \$10.0 million milestone payment received upon achievement of regulatory approval of Sebivo® in the European Union in April 2007, offset by amounts relating to changes in the estimated development period; and (iii) \$0.6 million of royalty revenue primarily associated with product sales of Tyzeka®/Sebivo® made by Novartis.

The increase in product sales of \$2.8 million in 2007 was due to increased market acceptance of Tyzeka® in the United States following its launch in November 2006 and to the inclusion of a nine-month sales period in 2007 versus a two-month sales period in 2006. As a result of the amendment of our agreement with Novartis in September 2007, effective October 1, 2007, we no longer record product sales as revenue.

## Cost of Sales

Cost of sales were \$2.0 million in 2007 as compared with \$0.1 million in 2006. The increase of \$1.9 million is primarily related to \$1.5 million related to the non-binding settlement proposal with UABRF and related entities.

## Research and Development Expenses

Research and development expenses were \$85.8 million in 2007 as compared with \$96.1 million in 2006. The decrease of \$10.3 million in 2007 was primarily due to a decrease in expenses for third party contractors, primarily related to clinical trials of Tyzeka\*/Sebivo\*. These expenses decreased due to the commercial launch of Tyzeka\*/Sebivo\* in November 2006 and discontinuation of our development of valtorcitabine and valopicitabine in 2007. The decrease was partially offset by increases to expand other research and development activities, primarily an increase of salary and payroll-related expenses associated with hiring additional employees and laboratory operating expenses.

While our operating expenses for 2008 will be considerably less than that for 2007, we expect that operating expenses for 2009 and beyond may increase as we expand our drug discovery and development efforts. We continue to devote substantial resources to our research and development activities, expand our research pipeline, engage in future development activities as we continue to advance our product candidates and explore collaborations with other entities that we believe will create shareholder value.

## Selling, General and Administrative Expenses

Selling, general and administrative expenses were \$63.3 million in 2007 as compared to \$57.0 million in 2006. The increase of \$6.3 million was primarily due to an increase in professional fees; salary and other payroll-related expenses related to the hiring of sales and marketing personnel in the United States in mid-2006 and in Europe in early 2007 in connection with the commercialization of Tyzeka®/Sebivo®; and accelerated depreciation of \$2.8 million related to enterprise software that was no longer needed with the transition of commercialization and development activities to Novartis effective October 1, 2007.

We expect our selling, general and administrative expenses to decrease in 2008 due to the recent transfer to Novartis of our commercialization rights to telbivudine and to the related restructuring.

#### Restructuring and Impairment Charges

As described above, as a result of the 2007 Amendment, we announced a restructuring of our operations and enacted a workforce reduction of approximately 100 positions, the majority of which had supported the development and commercialization of Tyzeka\*/Sebivo\* in the United States and Europe. In connection with the

restructuring, we recorded restructuring and impairment charges of \$8.7 million in 2007, including \$6.6 million for employee severance, benefits and related costs and \$2.1 million for the impairment of certain assets.

## Investment and Other Income, Net

Net investment income was \$6.4 million in 2007 as compared with \$9.5 million in 2006. The decrease in 2007 resulted from lower average cash and marketable securities balances held in 2007 due to the use of cash for operations, and a result of lower average interest rates. Additionally, \$0.4 million of the decrease related to recording interest and penalties related to an uncertain international tax position recorded in 2007.

## Gain on Sale of Equity Securities

In October 2007, we sold the equity securities we held in Pharmasset, Inc., or Pharmasset, for net proceeds of \$4.0 million and realized a gain of \$3.5 million on the sale.

#### Income Taxes

The income tax expense was approximately \$0.5 million in 2007 as compared with a tax benefit of approximately \$1.1 million in 2006. During the fourth quarter of 2007, we re-assessed an uncertain tax position related to our international operations. As a result, we recorded \$1.8 million of expense associated with this uncertain tax position including \$1.3 million associated with prior years which consisted of expense, interest and penalties. Of the total charge recorded, \$0.4 million was classified as investment and other income, net consistent with our policy for the classification of interest and penalties. We determined that the amount related to prior years was not material to our 2007 results. If our estimates related to this matter change, this amount may be adjusted accordingly in future periods. We also incurred a \$0.3 million increase in our accumulated deficit due to the adoption of Financial Accounting Standards Board Interpretation, or FIN No. 48, "Accounting for Uncertain Tax Positions".

## Comparison of Years Ended December 31, 2006 and 2005

#### Revenues

Revenues for the years ended December 31, 2006 and 2005 were as follows:

	2006	2005
	(In thousands)	
Collaboration revenue — related party		
Reimbursement of research and development costs	\$54,858	\$54,718
License fee revenue	12,049	9,700
Substantive milestone revenue	_	_
Profit-sharing to related party	(183)	
	66,724	64,418
Product sales, net	424	_
Government grants	229	300
Total revenues	<u>\$67,377</u>	<u>\$64,718</u>

The increase in revenues of \$2.7 million in 2006 as compared with 2005 was primarily due to an increase in license fee revenue from Novartis as a result of the licensing by Novartis of valopicitabine in March 2006.

#### Research and Development Expenses

Research and development expenses were \$96.1 million in 2006 as compared with \$86.6 million in 2005. The increase of \$9.5 million was primarily due to increases of \$5.2 million for HCV and HIV collaborations with third parties; \$2.4 million in salary and other payroll-related expenses associated with the hiring of additional employees for expanded research and development activities; and \$2.2 million in stock-based compensation with the adoption

of the Statement of Financial Accounting Standard, or SFAS No. 123(R), "Share-Based Payment," or SFAS No. 123(R), on January 1, 2006. These increases were partially offset by a decrease of \$3.2 million in expenses for third party contractors, primarily related to lower clinical trial activity as a result of nearing completion of our GLOBE study and certain phase IIIb clinical trials for telbivudine.

## Selling, General and Administrative Expenses

Selling, general and administrative expenses were \$57.0 million in 2006 as compared with \$33.7 million in 2005. The increase of \$23.3 million was primarily due to increases in selling and marketing expenses in preparation of and for the commercial launch of Tyzeka\*/Sebivo\* and an increase of \$5.1 million in stock-based compensation with the adoption of SFAS No. 123(R).

#### Investment and Other Income, Net

Net investment income was \$9.5 million in 2006 as compared with \$4.0 million in 2005. The increase was primarily the result of higher average cash and marketable securities balances held during 2006 and to higher interest rates in 2006. Higher average cash balances in 2006 were due to the receipt of proceeds from our public offering in October 2005 and the license payment received from Novartis in March 2006.

#### Income Taxes

The income tax benefit was \$1.1 million in 2006 compared with \$0.7 million in 2005. The increase in the income tax benefit was primarily due to higher research and development costs incurred by our French subsidiary in 2006 that were eligible for the research and development credit.

## 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, reimbursements from Novartis for costs we have incurred subsequent to May 8, 2003 in connection with the development of Tyzeka®/Sebivo®, valtorcitabine and valopicitabine, net proceeds from Sumitomo for reimbursement of development costs, collections on sales of Tyzeka® in the United States, net proceeds from private placements of our convertible preferred stock, net proceeds from public offerings and concurrent private placements of our common stock in July 2004 and in October 2005 and proceeds from the exercise of stock options granted pursuant to our equity compensation plans. As a result of the clinical hold the FDA placed on our development program of valopicitabine, we discontinued the development of valopicitabine. Therefore, we will not receive any additional license fees or other milestone payments for valopicitabine from Novartis. As a result of the transfer to Novartis of our development and commercial rights to telbivudine in October 2007, we will no longer recognize revenue from product sales of Tyzeka®/Sebivo®. During the third quarter of 2007, we discontinued development of valtorcitabine. As a result, we will not receive any future payments for valtorcitabine from Novartis.

We had \$48.3 million and \$55.9 million in cash and cash equivalents as of December 31, 2007 and 2006, respectively. We invest our excess cash balances in short-term and long-term marketable debt securities. All of our marketable securities are classified as available-for-sale. Our investments have an effective maturity not greater than 24 months and investments with maturities greater than 12 months are classified as non-current marketable securities. As of December 31, 2007, we had \$39.9 million in current marketable securities and \$23.9 million in non-current marketable securities and \$59.2 million in non-current marketable securities.

We invest our cash in instruments that meet high credit quality standards, as specified in our investment policy. Our investment policy also limits the amount of our credit exposure to any one issue or issuer and seeks to manage these assets to achieve our goals of preserving principal, maintaining adequate liquidity at all times, and maximizing returns subject to our investment policy.

As of March 13, 2008, the fair value of cash and other investments held at Bear, Stearns Securities Corp., or BSSC was \$39.9 million. BSSC is a separately capitalized broker/dealer subsidiary of Bear, Stearns and Co. Inc., or Bear Stearns. On March 14, 2008, Bear Stearns announced that it had received funding from outside parties, including the Federal Reserve Bank of New York, for a limited period of time in order to manage an ongoing deterioration of its liquidity position. We do not believe Bear Stearns' liquidity position will affect our access to or the fair value of our cash and other investments held at BSSC.

We held approximately \$11.0 million in municipal auction rate securities at December 31, 2007. Our investments in auction rate securities consist solely of municipal debt securities and none of the auction rate securities in our portfolio are mortgage-backed. The auction rate securities we held at December 31, 2007 reset is subsequent auctions in January 2008. In mid-February 2008, certain of our municipal auction rate securities experienced failed auctions. As of March 11, 2008 we had liquidated all but \$4.0 million of our auction rate securities, of which \$3.1 million was held at December 31, 2007. The liquidation of these auction rate securities did not result in any losses. Since then, the continued uncertainty in the credit markets has caused additional auctions with respect to our auction rate securities to fail, which prevented us from liquidating certain of our holdings of auction rate securities. Based on our ability to access our cash and other short-term investments, our expected operating cash flows, and our other sources of cash, we do not anticipate the current lack of liquidity on these investments to have a material impact on our financial condition or results of operation. However, due to the current lack of liquidity in these investments, we do not intend to invest in auction rate securities in the future.

Net cash used in operating activities was \$70.7 million, \$48.8 million and \$56.3 million in 2007, 2006 and 2005, respectively, due primarily to the net losses for the periods, excluding stock-based compensation and other non-cash charges adjusted for changes in working capital. The increase in cash used in operating activities in 2007 compared to 2006 was due primarily to the increase in operating expenses associated with the commercialization of Tyzeka®/Sebivo® and to payments made in connection with the restructuring plan put in place in September 2007. The decrease in cash used in operating activities in 2006 compared to 2005 was due primarily to the receipt of a \$25.0 million license payment from Novartis in March 2006 offset by an increase in operating expenses.

Net cash provided by investing activities was \$63.0 million and \$19.9 million in 2007 and 2006, respectively, due primarily to net transfers of \$66.3 million and \$29.5 million, respectively, from our investment portfolio to finance operating activities. The sale of our investment in the equity securities of Pharmasset provided an additional \$4.0 million of cash in 2007. The \$49.1 million of net cash used in investing activities in 2005 was principally due to the investment of a portion of the net proceeds from our public offering completed in October 2005, net of \$113.8 million in sales of marketable securities. Capital expenditures in 2007, 2006 and 2005 primarily relate to leasehold improvements in Cambridge, Massachusetts and Montpellier, France and the implementation of computer systems projects.

Net cash provided by financing activities was \$0.2 million, \$1.0 million and \$147.5 million in 2007, 2006 and 2005, respectively. The net cash provided by financing activities in 2007 and 2006 was primarily due to the exercise of stock options by employees. The net cash provided by financing activities in 2005 was due to the net proceeds from our public offering and concurrent private placement completed in October 2005 and the exercise of stock options held by employees.

A summary of restructuring activity at December 31, 2007 is as follows:

	Year En	ded December 31, 2007	Current Liability at December 31,	
	Charge	Payments/Settlements (In thousands)	2007	
Employee severance, benefits and related costs	\$6,492	\$(4,654)	\$1,838	
Contract termination and other costs	139	(139)		
Total	\$6,631	<u>\$(4,793</u> )	<u>\$1,838</u>	

In connection with the restructuring, we recorded impairment charges of \$2.1 million in 2007 related to enterprise software that was no longer needed with the transfer of telbivudine related commercialization and development activities to Novartis.

Set forth below is a description of our contractual obligations as of December 31, 2007:

	Payments Due by Period					
Contractual Obligations	Total	Less Than One Year	One to Three Years	Three to Five Years	After Five Years	
Operating leases	\$17,355	\$3,228	\$5,654	\$4,141	\$4,332	
Consulting and other agreements	5,810	2,345	3,428	37		
Total contractual obligations	\$23,165	\$5,573	\$9,082	<u>\$4,178</u>	\$4,332	

In connection with certain of our operating leases, we have two letters of credit with a commercial bank totaling \$1.2 million which expire at varying dates through December 31, 2013.

We have certain potential payment obligations relating to our HBV and HCV product and product candidates. These obligations are excluded from the contractual obligations table above, as further described below.

Pursuant to the license agreement, between us and UABRF, or the UAB license agreement, we were granted an exclusive license to the rights that UABRF, Emory University and Le Centre Nationale de la Recherche Scientifique, or CNRS, collectively the 1998 licensors, 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 infection.

In February 2006, UABRF notified us that it and Emory University were asserting a claim that, as a result of the filing of a continuation patent application in July 2005 by UABRF, the UAB license agreement covers our telbivudine technology. UABRF contended that we are obligated to pay the 1998 licensors an aggregate of \$15.3 million comprised of 20% of the \$75.0 million license fee we received from Novartis in May 2003 in connection with the license of our HBV product candidates and a \$0.3 million payment in connection with the submission to the FDA of the IND pursuant to which we have conducted clinical trials of telbivudine. We disagree with UABRF's contentions and advised UABRF and Emory University that we will utilize the dispute resolution procedures set forth in the UAB license agreement for resolution of this dispute. Under the terms of that agreement, if resolution cannot be achieved through negotiations between the parties or mediation, it must be decided by binding arbitration under the rules of the American Arbitration Association before a panel of three arbitrators. Pursuant to the terms of the dispute resolution procedure in the UAB license agreement, in September 2007 our CEO and the CEO of UABRF met and agreed to begin a mediation process. While the parties participated in a joint mediation session in January 2008, no resolution of these matters has yet been reached. However, a non-binding settlement proposal has been discussed by the parties. Such settlement proposal remains subject to several terms and conditions, including a full release of all claims by UABRF and related entities. We do not believe that the matters disputed by UABRF and Emory University regarding the UAB license agreement will have any effect on either the cooperative agreement with CNRS and the University of Montpellier or the technology licenses, including the license for telbivudine, which have been granted to us pursuant to the cooperative agreement.

However, if we do not settle these disputes and it were determined that the UAB license agreement does cover our technology, we will become obligated to make payments to the 1998 licensors in the amounts and manner specified in the UAB license agreement. While we dispute the demands made by UABRF, if a liability were found to exist, UABRF's claims, in addition to those described above would likely include payments in the aggregate amount of \$1.0 million due upon achievement of regulatory milestones, a 6% royalty on annual sales up to \$50 million and a 3% royalty on annual sales greater than \$50 million made by us or an affiliate of ours. Additionally, if we sublicense our rights to any entity other than one which holds or controls at least 50% of our capital stock, or if Novartis' ownership interest in us declines below 50% of our outstanding shares of capital stock, UABRF would likely contend that we would be obligated to pay to the 1998 licensors 30% of all royalties received by us from sales by the sublicensee of telbivudine and 20% of all fees, milestone payments and other cash consideration we receive from the sublicensee with respect to telbivudine.

If it were determined that the UAB license agreement between us and UABRF does cover our use of telbivudine to treat HBV, or we must otherwise rely upon a license agreement granted by the 1998 licensors to

commercialize telbivudine, we may be in breach of certain of the representations and warranties we made in the development and commercialization agreement and the stock purchase agreement. For a further description see "Collaborations — Relationship with Novartis — Indemnification" and "Risk Factors — Factors Related to Our Relationship with Novartis" and "Factors Related to Patents and Licenses."

Separately, we had a research collaboration with CNRS, one of the 1998 licensors. In May 2003, we and Novartis entered into an amended and restated cooperative agreement with CNRS and L'Universite Montpellier, or 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. The agreement included provisions relating to the ownership and commercialization of the technology, which is discovered or obtained as part of the collaboration as well as rights regarding ownership or use of such technology upon termination of the agreement. This cooperative agreement expired in December 2006. We do not believe that the matters disputed by UABRF and Emory University regarding the UAB license agreement will have any effect on either our cooperative agreement with CNRS and the University of Montpellier or the technology licenses, including the license for telbivudine, which have been granted to us pursuant to the cooperative agreement.

In January 2007, the Board of Trustees of the University of Alabama and related entities filed a complaint in the United States District Court for the Northern District of Alabama, Southern Division against us, CNRS and the University of Montpellier. The complaint alleges that a former employee of UAB is a co-inventor of certain patents in the United States and corresponding foreign patent applications related to the use of β-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®/Sebivo® for the treatment of HBV. The University of Alabama has included a demand for damages under various theories in its complaint, but did not specify the amount of damages that it alleges to have incurred. In response to the complaint in March 2007, we filed a motion to dismiss based upon lack of personal jurisdiction. In September 2007, the parties agreed to stay the action and pursue mediation relating to the disputes associated with the license agreement and this litigation. As a result of a joint mediation session held in January 2008, a non-binding settlement has been proposed by the parties which could potentially require Idenix to make payments to UABRF and related entities. We have assessed this settlement proposal under the provisions of FAS 5, and recorded an expense of \$1.5 million for the quarter ended December 31, 2007. If the proposed settlement is not completed on terms acceptable to Idenix, we will resume the defense of these claims, including through the litigation process. Accruals related to the settlement proposal may be adjusted in future periods if a settlement agreement is not reached. We cannot ascertain with certainty the likelihood this or any settlement proposal will be accepted by or entered into by the parties. If we are not able to reach a settlement agreement with the parties, we will continue to vigorously defend against claims made by UABRF and related entities (see Note 2).

Additionally, in connection with the resolution of matters relating to certain of our HCV product candidates we entered into a settlement agreement with UABRF which provides for a milestone payment of \$1.0 million to UABRF upon receipt of regulatory approval in the United States to market and sell certain HCV products invented or discovered by our chief executive officer during the period from November 1, 1999 to November 1, 2000. This settlement agreement also allows for payments in 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.

Further, 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 valopicitabine and certain other HCV and HIV technology. We are liable for certain payments to the University of Cagliari if we receive from Novartis or another collaborator license fees or milestone payments with respect to such technology.

In March 2003, we entered into a final settlement agreement with Sumitomo Pharmaceuticals Corporation 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. 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.

In October 2006, we entered into a two-year research collaboration agreement with Metabasis Therapeutics, Inc. or Metabasis. Under the terms of the agreement, Metabasis' proprietary liver-targeted technology would have

been applied to certain of our compounds to develop second-generation nucleoside analog product candidates for the treatment of HCV. In July 2007, we notified Metabasis that we would exercise our option to terminate the research collaboration on the first anniversary of the agreement in October 2007. Prior to the termination of the agreement, Metabasis asserted that a certain scientific milestone was met and thus a \$1.0 million payment under the collaboration agreement came due. We do not agree with Metabasis' assessment that the scientific milestone has been met and therefore do not believe that we have any liability for this payment and have so notified Metabasis.

We believe that our current cash and cash equivalents and marketable securities together with anticipated royalty payments associated with product sales of Tyzeka®/Sebivo® will be sufficient to satisfy our cash needs through late 2009. We also estimate that we will generate annual cost savings of \$40.0 million to \$45.0 million as a result of our restructuring. At any time, it is possible that we may seek additional financing. We may seek such financing through a combination of public or private financing, collaborative relationships and other arrangements. 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. Moreover, any debt financing, if available, may involve restrictive covenants that would not be favorable to us. Our failure to obtain financing when needed may harm our business and operating results.

## **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 accounting principles generally accepted in the United States of America. 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 collaborative research and development revenue recognition, accrued expenses and stock-based compensation. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements included in this document, we believe the following accounting policies to be the most critical in understanding the judgments and estimates we use in preparing our financial statements:

#### Collaborative Research and Development Revenue

We recognize revenues relating to our collaborative research and development arrangements in accordance with the SEC's Staff Accounting Bulletin No. 104, "Revenue Recognition in Financial Statements," or SAB 104, Revenues under such collaborative research and development arrangements may include non-refundable license fees, milestones, royalties and research and development payments from collaborative partners.

Where we have continuing performance obligations under the terms of a collaborative arrangement, we recognize non-refundable license fees as revenue over the specified development period during which we complete our performance obligations. When our level of effort is relatively constant over the performance period, the revenue is recognized on a straight-line basis. The determination of the performance period involves judgment on the part of our management. If this estimated performance period changes, then we will adjust the periodic revenue we are recognizing and will record the remaining unrecognized non-refundable license fees over the remaining period during which our performance obligations will be completed. Significant judgments and estimates are involved in determining the estimated development period and different assumptions could yield materially different results.

To date, we have received from Novartis a \$25.0 million license fee for valopicitabine, a \$75.0 million license fee for Tyzeka®/Sebivo® and valtorcitabine, and a \$5.0 million reimbursement for reacquiring product rights from

Sumitomo to develop and commercialize Sebivo® in certain markets in Asia. We included this reimbursement as part of the license fee for accounting purposes because Novartis required the repurchase of these rights as a condition to entering into the development and commercialization agreement. We also incurred approximately \$2.2 million in costs associated with the development of valopicitabine prior to Novartis licensing valopicitabine in March 2006 for which Novartis has reimbursed us. We have included the \$10.0 million milestone payment for the regulatory approval of Sebivo® in the European Union as part of the license fee for accounting purposes as the milestone was deemed not to be substantive. The sum of these non-refundable payments received from Novartis, totaling \$117.2 million, has been recorded as license fees and is being recognized over the development period of the licensed product candidates.

We review our assessment and judgment on a quarterly basis with respect to the expected duration of the development period of our licensed product candidates. We have estimated that the performance period during which the development of our licensed product and product candidates will be completed is a period of approximately ten and a half years following the effective date of the development and commercialization agreement that we entered into with Novartis, or December 2013. We are recognizing revenue on the license fee payments over this period. If the estimated performance period changes, we will adjust the periodic revenue that is being recognized and will record the remaining unrecognized license fee payments over the remaining development period during which our performance obligations will be completed. Significant judgments and estimates are involved in determining the estimated development period and different assumptions could yield materially different results.

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

Additionally, if we issue any shares of our capital stock, other than in certain situations, Novartis has the right to purchase such number of shares required to maintain its percentage ownership of our voting stock for the same consideration per share paid by others acquiring our stock. Subject to certain exceptions, upon the grant of options and stock awards under stock incentive plans, other than the 1998 Equity Incentive Plan, we record, as a reduction of the license fees and payments received from Novartis, the fair value of our common stock that would be issuable to Novartis, less the exercise price, if any, payable by the option or award holder. The amount is attributed proportionately between cumulative revenue recognized as of that date and the remaining amount of deferred revenue. These amounts are adjusted through the date that either, Novartis elects to exercise its stock subscription rights or the right expires. These adjustments will also be attributed proportionately between cumulative revenue recognized through the measurement date and the remaining deferred revenue.

In connection with the closing of our initial public offering in July 2004, Novartis terminated a common stock subscription right with respect to 1,399,106 shares of common stock issuable pursuant to the 1998 Equity Incentive Plan in connection with the exercise of stock options granted after May 8, 2003. In exchange for Novartis' termination of such right, we issued 1,100,000 shares of our 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 to Novartis of these shares, Novartis' rights to purchase additional shares as a result of future option grants and stock issuances under the 1998 Equity Incentive Plan were terminated and no additional adjustments to revenue and deferred revenue will be required for options exercised under this plan. Prior to the termination of the stock subscription rights under the 1998 Equity Incentive Plan, as we granted options that were subject to Novartis' 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 license fee and payments received from Novartis in May 2003. We are still subject to potential revenue adjustments relating to future grants of options and stock awards under our 2005 Stock Incentive Plan and other equity plans that our board of directors may approve and stockholders adopt.

As of December 31, 2007, the cumulative license fee has been reduced by \$15.6 million and has been reclassified to additional paid-in capital. Of this amount, \$6.3 million has been recorded as a reduction of deferred revenue as of December 31, 2007 with the remaining amount of \$9.3 million recorded as a reduction of revenue.

The collaboration arrangement with Novartis contemplates several joint committees in which we and Novartis participate. We participate in these committees as a means to govern or protect our interests. The committees span the period from early development through commercialization of product candidates licensed by Novartis.

As a result of applying the provisions of SAB 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 product candidates licensed under the development and commercialization agreement. We have not attributed revenue to our involvement in the committees following the commercialization of the licensed products as we have determined that our participation on the committees as such participation relates to the commercialization of product candidates is protective. Our determination is based in part on the fact that our expertise is, and has been, the discovery and development of drugs for the treatment of human viral and other infectious diseases. Novartis, on the other hand, has and continues to possess the considerable commercialization expertise and infrastructure necessary for the commercialization of such drug candidates. Accordingly, we believe our obligation post commercialization is inconsequential.

In March 2003, we entered into a final settlement agreement with Sumitomo Pharmaceuticals Corporation 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 in deferred revenue on our consolidated balance sheet at December 31, 2006 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 upon the first commercial sale of telbivudine 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. 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.

We recognize payments received from collaborative partners for research and development efforts that we perform or others perform on our behalf as revenue as the related costs are incurred. We recognize such revenue only if we believe that collection of these amounts is reasonably assured. This assessment involves judgment on our part. If we do not believe that collection of amounts billed, or amounts to be billed to our collaborators, is reasonably assured, then we defer revenue recognition.

We recognize revenues from milestones related to arrangements under which we have continuing performance obligations upon achievement of the milestone if the milestone is deemed substantive. Milestones are considered substantive if all of the following conditions are met:

- the milestone is non-refundable;
- achievement of the milestone was not reasonably assured at the inception of the arrangement;
- · substantive effort is involved to achieve the milestone; and
- the amount of the milestone appears reasonable in relation to the effort expended, the other milestones in the arrangement and the related risk associated with the achievement of the milestone.

In 2007, we achieved a regulatory milestone for \$10.0 million during the three months ended March 31, 2007 with the regulatory approval of Sebivo® in China. We recognized this regulatory milestone in collaboration revenue from Novartis in association with this milestone as the milestone was deemed substantive. A second regulatory milestones of \$10.0 million was achieved in April 2007 with the regulatory approval of Sebivo® in the European Union. This milestone was deemed not to be substantive and we recognized \$4.8 million as revenue in 2007, representing the portion of the development period that has passed, with the remaining \$5.2 million recorded as

deferred revenue and recognized as revenue over the remaining development period of our licensed product candidates.

Where we have no continuing involvement 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, and we record milestones when we receive appropriate notification from the collaborative partner of achievement of the milestones.

In November 2002, the Emerging Issues Task Force, or EITF, reached a consensus on EITF No. 00-21, "Accounting for Revenue Arrangements with Multiple Deliverables," or EITF No. 00-21 EITF No. 00-21 provides guidance on how to account for arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. The provisions of EITF No. 00-21 apply to revenue arrangements entered into on or after July 1, 2003.

## Valuation and Impairment of Investments and/or Marketable Securities

The fair value of our investments and/or marketable securities is generally determined from quoted market prices received from pricing services based upon market transactions at fair value. We also have investments in auction rate securities that consist entirely of municipal debt securities, recorded at fair value at December 31, 2007, which approximates cost due to their variable interest rates, which typically reset through an auction process every seven to 35 days. This auction mechanism generally allows existing investors to roll over their holdings and continue to own their securities or liquidate their holdings by selling their securities at par value. Because of these short intervals between interest reset dates, we monitor the auctions to ensure they are successful, which provides evidence of their approximate fair values. To the extent an auction were to fail such that the securities were deemed not to be liquid, we would need to seek other alternatives to determine the fair value of these securities, which may not be based on quoted market transactions. Due to the current lack of liquidity in auction rate securities, we do not intend to invest in auction rate securities in the future.

Investments and marketable securities are considered to be impaired when a decline in fair value below cost basis is determined to be other than temporary. We periodically evaluate whether a decline in fair value below cost basis is other than temporary by considering available evidence regarding these investments including, among other factors,

- the duration of the period that, and the 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; and
- · overall market conditions and trends.

Once a decline in fair value is determined to be other than temporary, a write-down is recorded and a new cost basis in the security is established. Assessing the above factors involves inherent uncertainty. Write-downs, if recorded, could be materially different from the actual market performance of investments and marketable securities in our portfolio, if, among other things, relevant information related to our investments and marketable securities was not publicly available or other factors not considered by us would have been relevant to the determination of impairment.

## Accrued Expenses

As part of the process of preparing our financial statements, we are required to estimate accrued expenses. This process involves identifying services that third parties have performed on our behalf and estimating the level of service performed and the associated cost incurred on these services as of each balance sheet date in our financial statements. Examples of estimated accrued expenses include contract service fees, such as amounts due to clinical research organizations, professional service fees, such as attorneys and accountants, and investigators in conjunction with preclinical and clinical trials, fees paid to contract manufacturers in conjunction with the production of materials related to our product candidates and third party expenses relating to marketing efforts associated with commercialization of our product and product candidates. 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. In the event that we do not identify certain costs that have been incurred or we under or over-estimate the level of services or the costs of such services, our reported expenses for a reporting period could be overstated or understated. 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 and account for these estimates in accordance with accounting principles involving accrued expenses and income tax liabilities generally accepted in the United States.

#### Stock-Based Compensation

In December 2004, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standard No. 123 (revised 2004), "Share-Based Payment" or SFAS No. 123(R). This Statement replaces SFAS No. 123, "Accounting for Stock-Based Compensation," and supersedes Accounting Principles Board, an APB, Opinion No. 25, "Accounting for Stock Issued to Employees," or APB No. 25. SFAS No. 123(R) requires share- based transactions for employees and directors to be accounted for using a fair value based method resulting in expense being recognized in our financial statements.

We adopted SFAS No. 123(R) on January 1, 2006. We applied the modified prospective method at adoption in which stock compensation expense was determined based on fair value using the Black-Scholes method at grant dates for stock options. Accordingly, financial statement amounts for the periods prior to the adoption of SFAS No. 123(R) including the year ended December 31, 2005 have not been restated to reflect the fair value method of expensing required by SFAS No. 123(R). Prior to January 1, 2006, we accounted for stock-based awards to employees and directors using the intrinsic value method prescribed in APB No. 25 and related interpretations.

In November 2005, the FASB issued FASB Staff Position FAS 123(R)-3, "Transition Election Related to Accounting for Tax Effects of Share-based Payment Awards," or FSP FAS 123(R)-3. In accordance with FSP FAS 123(R)-3, entities can choose to follow either the transitional guidance of SFAS 123(R) or the alternative transition method described in FSP FAS 123(R)-3. Effective in the fourth quarter of 2006, we elected to adopt the alternative transition method for calculating the tax effects of stock-based compensation pursuant to SFAS 123(R). The alternative transition method includes simplified methods to establish the beginning balance of the additional paid-in capital pool, or APIC pool or windfall, related to the tax effects of employee stock-based compensation, and to determine the subsequent impact on the APIC pool and consolidated statements of cash flows of the tax effects of employee-stock based compensation awards that are outstanding upon adoption of SFAS 123(R). The adoption of the alternative transition method resulted in no impact on our financial statements.

For purposes of estimating the fair value of stock options granted in 2007 and 2006 using the Black-Scholes method, we have made assumptions for the inputs in the model regarding expected dividend yield, risk-free interest rate, expected option term and expected volatility. The amounts recognized for stock-based compensation expense could vary depending upon changes in assumptions in the model.

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 U.S. Treasury securities consistent with the expected life of the option (4.35% in 2007 and 4.78% in 2006). The expected option term (5.1 years in 2007 and 5.0 years in 2006) and expected volatility (59.5% in 2007 and 63% in 2006) were determined by examining the expected option term and volatility of our own stock as well as the expected terms and volatilities of similarly sized biotechnology companies.

As share-based compensation expense recognized in the consolidated statements of operations in 2007 and 2006 are based on awards ultimately expected to vest, it should be reduced for estimated forfeitures. SFAS No. 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods as options vest, if actual forfeitures differ from those estimates. During 2007 and 2006, because substantially all of the Company's stock option grants vest monthly, no forfeiture assumption was applied. In our pro forma information required under SFAS No. 123 for the periods prior to fiscal 2006, we accounted for forfeitures as they occurred.

We recognize compensation expense for restricted stock sold and stock options granted to non-employees in accordance with the requirements of SFAS No. 123(R) and EITF Issue No. 96-18, "Accounting for Equity Instruments that Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services," or EITF 96-18 requires such equity instruments to be recorded at their fair value at the measurement date, which is generally the vesting date of the instruments. Therefore, the measurement of stock-based compensation is subject to periodic adjustments as the underlying equity instruments vest.

Our equity incentive plans are administered by the compensation committee of our 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 employees at an exercise price per share 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 common stock) and with a term not to exceed ten years from the 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 stock-based awards on terms and conditions it may determine. These equity incentive plans are described more fully in Note 12 to the Consolidated Financial Statements.

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

### **Recent Accounting Pronouncements**

In September 2006, FASB Statement No. 157, "Fair Value Measurements," or SFAS 157, was issued. This statement defines fair value, establishes a framework for measuring fair value in accounting principles generally accepted in the United States, or GAAP, and expands disclosures about fair value measurements. This statement applies under other accounting pronouncements that require or permit fair value measurements, the FASB having previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Accordingly, this statement does not require any new fair value measurements. However, for some entities, the application of this Statement will change current practice. The Statement is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. We are currently evaluating the impact, if any, that this standard will have on our financial statements.

In February 2008, the FASB issued FASB Staff Position No. FAS 157-2, "Effective Date of FASB Statement No. 157" or FSP FAS 157-2. FSP FAS 157-2 defers the effective date provision of SFAS 157 for certain non-financial assets and liabilities until fiscal years beginning after November 15, 2008. We are currently evaluating the impact of adopting SFAS 157 on our financial statements.

In February 2007, FASB Statement No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities," or SFAS No. 159, was issued. SFAS No. 159 includes an amendment of FASB Statement No. 115, "Accounting for Certain Investments in Debt and Equity Securities," and permits entities to choose, at specified election dates, to measure eligible items at fair value and requires unrealized gains and losses on items for which the fair value option has been elected to be reported in earnings. This statement is effective for fiscal years beginning after November 15, 2007. We are currently evaluating the impact, if any, that this standard will have on our financial statements.

In June 2007, EITF Issue No. 07-03, "Accounting for Nonrefundable Advance Payment for Goods and Services Received for Use in Future Research and Development Activities," or EITF 07-03 was issued. EITF 07-03 provides guidance on whether nonrefundable advance payments for goods and services that will be used in research and development activities should be expensed when the advance payment is made or when the research and development activity has been performed. EITF 07-03 is effective for fiscal years beginning after December 15, 2007. We are currently evaluating the impact, if any, that this standard will have on our financial statements.

On December 12, 2007, EITF Issue No. 07-01, "Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property", or EITF 07-01, was issued. EITF- 07-01 prescribes the accounting for collaborations. It requires certain transactions between collaborators to be recorded in the income statement on either a gross or net basis within expenses when certain characteristics exist in the collaboration relationship. EITF 07-01 is effective for all of our collaborations existing after January 1, 2009. We are evaluating the impact this standard will have on our financial statements.

### Item 7A. Quantitative and Qualitative Disclosure about Market Risk.

Market risk represents the risk of loss that may impact our financial position, operating results or cash flows due to changes in interest rates. 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 excess cash in high quality financial instruments, primarily money market funds, U.S. government guaranteed debt obligations, repurchase agreements with major financial institutions and certain corporate debt securities with the dollar weighted average effective maturity of the portfolio less than 12 months and no security with an effective maturity in excess of 24 months. Since our investments are short term in duration and the investments are denominated in U.S. dollars, we believe that we are not subject to any material credit, market or foreign exchange risk exposure. We do not have any derivative financial instruments.

In addition, the fair value of our marketable securities is subject to change as a result of potential changes in market interest rates. The potential change in fair value for interest rate sensitive instruments has been assessed on a hypothetical 100 basis point adverse movement across all maturities. We estimate that such hypothetical adverse 100 basis point movement would result in a hypothetical loss in fair value of approximately \$0.6 million to our interest rate sensitive instruments.

We place our cash investments in instruments that meet high credit quality standards, as specified in our investment policy. Our investment policy also limits the amount of our credit exposure to any one issue or issuer and seeks to manage these assets to achieve our goals of preserving principal, maintaining adequate liquidity at all times, and maximizing returns subject to our investment policy.

Our investments in auction rate securities consist solely of municipal debt securities and none of the auction rate securities in our portfolio are mortgage-backed. The auction rate securities we held at December 31, 2007 reset is subsequent auctions in January 2008. In mid-February 2008, certain of our municipal auction rate securities experienced failed auctions. We held approximately \$11.0 million in municipal auction rate securities at December 31, 2007. As of March 11, 2008 we had liquidated all but \$4.0 million of our auction rate securities, of which \$3.1 million was held at December 31, 2007. The liquidation of these auction rate securities did not result in any losses. Since then, the continued uncertainty in the credit markets has caused additional auctions with respect to our auction rate securities to fail, which prevented us from liquidating certain of our holdings of auction rate securities. Based on our ability to access our cash and other short-term investments, our expected operating cash flows, and our other sources of cash, we do not anticipate the current lack of liquidity on these investments to have a material impact on our financial condition or results of operation. However, due to the current lack of liquidity in these investments, we do not intend to invest in auction rate securities in the future.

### 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 Ac	ccounting and	l Financial Disclosure.
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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, 2007. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the 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 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, 2007 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 Idenix's assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that receipts and expenditures of Idenix 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 Idenix'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. 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, 2007. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in *Internal Control-Integrated Framework*.

Based on our assessment, management concluded that, as of December 31, 2007, 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, 2007 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, 2007 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 2008 Annual Meeting of Stockholders (the "2008 Proxy Statement") under the captions "Proposal 1 — Election of Directors", "Corporate Governance", "Compensation of Directors" and "Sections 16(a) Beneficial Ownership Reporting and Compliance."

### Codes of Business Conduct

We have adopted a Code of Business Conduct and Ethics that applies to all of our 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 web site, www.idenix.com, and is available in print to any shareholder upon request. Information regarding any amendments to the Code of Business Conduct and Ethics will also be posted on our web site.

### Item 11. Executive Compensation

The response to this Item is incorporated herein by reference to our 2008 Proxy Statement under the captions 'Compensation of Executive Officers', "Compensation Interlocks and Insider Participation" and "Compensation Committee Report."

The "Compensation Committee Report" contained in the Proxy Statement under the caption "Executive Compensation" shall not be deemed "soliciting material" or "filed" with the SEC or otherwise subject to the liabilities of Section 18 of the Securities Exchange Act of 1934, as amended, or 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 he Exchange Act.

### tem 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 2008 Proxy Statement under the captions Stock Ownership of Certain Beneficial Owners and Management" and "Compensation of Executive Officers—Equity Compensation Plan Information."

### tem 13. Certain Relationships, Related Transactions and Director Independence

The response to this Item is incorporated herein by reference to our 2008 Proxy Statement under the captions Certain Relationships and Related Transaction," "Employment Agreements" and "Corporate Governance — Director Independence."

### tem 14. Principal Accountant Fees and Services

The response to this Item is incorporated herein by reference to our 2008 Proxy Statement under the captions Audit Fees," "Audit-Related Fees," "All Other Fees" and "Pre-Approval Policies."

### 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:

	Page
Report of Independent Registered Public Accounting Firm	73
Consolidated Balance Sheets at December 31, 2007 and 2006	74
Consolidated Statements of Operations for the Years Ended December 31, 2007, 2006 and 2005	75
Consolidated Statements of Stockholders' Equity and Comprehensive Loss for the Years Ended  December 31, 2007, 2006 and 2005	76
Consolidated Statements of Cash Flows for the Years Ended December 31, 2007, 2006 and 2005	77
Notes to the Consolidated Financial Statements	78

(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 Shareholders of Idenix Pharmaceuticals, Inc.:

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of shareholders equity and comprehensive loss and of cash flows present fairly, in all material respects, the financial position of Idenix Pharmaceuticals, Inc. and its subsidiaries at December 31, 2007 and 2006, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2007 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, 2007, 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.

As discussed in Note 12 to the consolidated financial statements, the Company changed the manner in which it accounts for share-based compensation in 2006. As discussed in Note 14 to the consolidated financial statements, the Company changed the manner in which it accounts for income tax contingencies in 2007.

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

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

s/ PricewaterhouseCoopers LLP

Boston, Massachusetts March 14, 2008

## IDENIX PHARMACEUTICALS, INC. CONSOLIDATED BALANCE SHEETS

	Decem	ber 31,
	2007	2006
	(In tho	
ACCETC	except sh	are data)
ASSETS		
Current assets:	f 40.200	¢ 55.000
Cash and cash equivalents	\$ 48,260	\$ 55,892
Restricted cash	411	411
Marketable securities	39,862	71,251
Accounts receivable, net		509
Receivables from related party	11,196	12,035
Income taxes receivable	224	201
Inventory		400
Prepaid expenses and other current assets	3,766	6,906
Total current assets	103,719	147,605
Intangible asset, net	13,548	_
Property and equipment, net	15,460	17,448
Restricted cash, non-current	750	750
Marketable securities, non-current	23,882	59,208
Income taxes receivable, non-current	2,296	2,060
Investment	_	500
Other assets	885	894
Total assets	\$ 160,540	\$ 228,465
	<u> </u>	=======================================
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 5,372	\$ 6.811
	16,437	15,679
Accrued expenses	10,437	939
Payables to related party	338	338
Deferred revenue, selected porty		
Deferred revenue, related party	8,372	13,490
Income taxes payable	215	189
Total current liabilities	30,734	37,446
Long-term obligations	13,172	2,251
Deferred rent, net of current portion	1,663	2,000
Deferred revenue	4,272	4,272
Deferred revenue, related party, net of current portion	41,861	40,471
Total liabilities	91,702	86,440
Commitments and contingencies (Note 13 and 19)	,	,
Stockholders' equity:		
Common stock, \$0.001 par value; 125,000,000 and 75,000,000 shares authorized at		
December 31, 2007 and 2006; 56,189,467 and 56,091,632 shares issued and outstanding at		l
December 31, 2007 and 2006, respectively	56	56
Additional paid-in capital	506,800	497,778
Deferred compensation	_	(106)
Accumulated other comprehensive income	738	238
Accumulated deficit	(438,756)	(355,941)
Total stockholders' equity	68,838	142,025
Total liabilities and stockholders' equity	\$ 160,540	\$ 228,465
Total machines and stockholders equity	<u> </u>	Ψ 220,70J

### CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31, 2007 2006 2005					
	2007	2005				
	(In thousan	ds, except per	share data)			
Revenues:						
License fees and collaborative research and development - related						
party	\$ 64,751	\$ 66,724	\$ 64,418			
Product sales, net	3,187	424	_			
Government research grants	90	229	300			
Total revenues	68,028	67,377	64,718			
Operating expenses:		٠				
Cost of sales	2,001	62	_			
Research and development	85,839	96,080	86,590			
Selling, general and administrative	63,348	56,954	33,657			
Restructuring and impairment charges	8,744					
Total operating expenses	159,932	153,096	120,247			
Loss from operations	(91,904)	(85,719)	(55,529)			
Investment and other income, net	6,387	9,487	4,038			
Gain on sale of equity securities	3,500					
Loss before income taxes	(82,017)	(76,232)	(51,491)			
Income tax (expense) benefit	(498)	1,145	<u>714</u>			
Net loss	<u>\$(82,515</u> )	<u>\$(75,087)</u>	<u>\$(50,777)</u>			
Basic and diluted net loss per common share	<u>\$ (1.47)</u>	<u>\$ (1.34)</u>	\$ (1.03)			
Shares used in computing basic and diluted net loss per common share	56,169	56,005	49,395			

# CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS For the Years Ended December 31, 2007, 2006, 2005

Comprehensive	Loss									\$(50.777)	(	119	(280)	\$(51,248)								\$(75,087) 191	382	\$(74,514)					(87 515)	*(92,515) (62)	562	\$(82,015)	
Total Stockholders'	Equity	\$109,058	64.248	81,185	86	2,018	255	1	1,282	(50,777)	`	119	(230)		\$206,887	60%	4	54	30	8,607	25	(75,087) 191	382		\$142,025	205	8,731	192	(300)	(62)	295		\$ 68,838
Accumulated	Deficit data)	\$(230,077)	ļ		ļ	1	l	I	ŀ	(50.777)		1	!		\$(280,854)		1	1	I	ļ	{	(75,087)	1	1	\$(355,941)		1	1 600	(300)	(515,28)	1		\$(438,756)
Accumulated Other Comprehensive	pensation Income (Loss) 1 (In thousands, except share data)	\$ 136	1		1	1	1	1	1			119	(280)		\$(335)		,	1	1	1	I	l <u>6</u> 1	382		\$ 238		1		[ !	(62)	<b>2</b> 95		\$ 738
Deferred	Compensation (In thousar	\$(1,987)	ļ	1		I	I	385	1,282			I	I	1	\$ (320)			I	ı	214	I	1		1	(901) \$		106	1			1	1	₩
Additional Paid-in	Capital	\$340,938	64.245	81,181	86	2,017	255	(382)	Įŝ	<u> </u>		1	1	1	\$488,340	802	4	54	30	8,393	25	1 1	1	1	\$497,778	205	8,625	192			I		\$506,800
Stock	Amount	\$48	m	4	l	_	I	l	]			l	1	1	\$56			1	1	1	l	1 1	1	Ιį	\$56		1	†			I	1	\$56
Common Stock	Shares	47,857,887	3.338.889	3,939,131	1	590,618	86,750		l			I	l	.  .	55,813,275	260.612	14,442	3,303	,	I		1	1		56,091,632	97,835	j	1	<b>\</b>				56,189,467
		Balance at December 31, 2004	expenses and underwriting discounts of \$4.567	Issuance of common stock in follow-on public offering, with related party.	Compensation related to modification of employee stock options	Issuance of common stock upon exercise of stock options	Issuance of common stock upon vesting of stock options	Forfeiture of common stock under stock option plans	Amortization of deferred compensation	Antiditution snares contingently Issuable to related party	Net change in unrealized holding gains on marketable securities, net of	tax	Cumulative translation adjustment	Comprehensive loss	Balance at December 31, 2005	Issuance of common stock mon exercise of stock outions	Issuance of common stock upon vesting of stock options	Issuance of common stock with related party	Stock-based compensation for non-employees	Amortization of deferred compensation	Antidilution shares contingently issuable to related party	Net loss  Net change in unrealized holding gains on marketable securities.	Cumulative translation adjustment	Comprehensive loss	Balance at December 31, 2006	Issuance of common stock upon exercise of stock options	Amortization of deferred compensation	Antidilution shares contingently issuable to related party	Cumulative effect adjustment from adoption of FIN 48	Net change in unrealized holding loss on marketable securities, net of tax	Cumulative translation adjustment	Comprehensive loss	Balance at December 31, 2007

### CONSOLIDATED STATEMENTS OF CASH FLOWS

2004         2005         2005           Cash flows from operating activities:           Net loss         \$(82,515)         \$(75,087)         \$(50,777)           Adjustments to reconcile net loss to net cash used in operating activities:         8,955         3,463         2,066           Stock-based compensation expense         8,731         8,637         1,388           Impairment charges         2,113         6,637         -6           Gain on sale of equity securities         338         1,139         (991)           Other         128         12         9           Account interest on marketable securities         309         1,688         2,520           Other         128         1,688         2,520           Accounts receivables.         509         5,699         7           Receivables from related party         839         1,688         2,520           Income taxes receivables         82         1,134         2,50           Income taxes receivable         82         1,134         2,50           Other assets         1,146         1,146         1,146           Accounts payable         1,146         1,146         1,146           Accounts p		Years	Ended Decemb	er 31,
(Sas.) flows from operating activities:         Net loss.         (\$15,087)         \$ (\$50,777)           Adjustments to reconcile net loss to net cash used in operating activities:         Depreciation and amortization.         8,955         3,463         2,066           Stock-based compensation expense         8,731         8,637         1,388           Impairment charges         2,113         —         —           Gain on sale of equity securities         (3,500)         —         —           Accrued interest on marketable securities         138         (1,319)         (991)           Other         128         12         3           Changes in operating assets and liabilities:         509         (509)         —           Accounts receivables.         509         (509)         —           Receivables from related party.         839         1,688         2,520           Inventory.         400         (400)         —           Prepaid expenses and other current assets         3,311         (753)         (2,992)           Income taxes receivable         (82)         (1,347)         (376)         (362)         1,718           Accude dexpenses.         3(38)         (38)         (28)         1,		2007	2006	2005
Net loss			(In thousands)	
Adjustments to reconcile net loss to net cash used in operating activities:   Depreciation and amortization	Cash flows from operating activities:			,
Depreciation and amortization   8,955   3,463   2,066   Stock-based compensation expense   8,731   8,637   1,388   Inpairment charges   2,113   — — — — — — — — — — — — — — — — — —	Net loss	\$ (82,515)	\$ (75,087)	\$ (50,777)
Stock-based compensation expense   8,731   8,637   1,388   Impairment charges   2,113   3	• • • • • • • • • • • • • • • • • • • •	•	•	
Impairment charges	Depreciation and amortization	8,955	3,463	2,066
Gain on sale of equity securities         (3,500)         —         —           Accrued interest on marketable securities         128         12         3           Changes in operating assets and liabilities:         509         (509)         —           Accounts receivables from related party         839         1,688         2,520           Inventory.         400         (400)         —           Prepaid expenses and other current assets         3,311         (753)         (2992)           Income taxes receivable         (82)         (1,347)         (576)           Other assets.         10         1,076         (26)           Accounts payable         (1,468)         1,146         1,154           Accrued expenses.         (3,596)         (982)         1,718           Payables to related party         (773)         39         —           Deferred restated party         (3,618)         15,189         (9,97)           Income taxes payable         (10)         (17)         (104         107         (104           Long-term obligations         (3,168)         15,189         (9,97)           Income taxes payable         (10)         (17)         (104         107         (104	Stock-based compensation expense	8,731	8,637	1,388
Accrued interest on marketable securities   338   (1,319)   (991)	Impairment charges	2,113	_	_
Other         128         12         3           Changes in operating assets and liabilities:         3         (509)         (509)         —           Receivables from related parry         839         1,688         2,520           Inventory.         400         (400)         —           Prepaid expenses and other current assets         3,311         (753)         (2,992)           Income taxes receivable         (82)         (1,347)         (576)           Other assets         10         1,076         (26)           Accounts payable         (1,468)         1,146         1,154           Accrued expenses         (3,596)         (982)         1,718           Payables to related parry         (773)         939         —           Deferred rent         (338)         (28)         860           Deferred revenue, related parry         (3,618)         15,189         (9,697)           Income taxes payable         (10)         (17)         (104)         (865)           Net cash used in operating activities         (70,679)         (48,833)         (56,319)           Cash flows from investing activities         (70,679)         (48,833)         (56,319)           Purchases of marketable securities <td>Gain on sale of equity securities</td> <td>(3,500)</td> <td></td> <td></td>	Gain on sale of equity securities	(3,500)		
Changes in operating assets and liabilities:         509         (509)         —           Receivables from related party         839         1,688         2,520           Inventory         400         (400)         —           Prepaid expenses and other current assets         3,311         (753)         (2,992)           Income taxes receivable         (82)         (1,347)         (576)           Other assets         10         1,076         (26)           Accounts payable         (1,468)         1,146         1,154           Accrued expenses         (3,596)         (982)         1,718           Payables to related party         (773)         939         —           Deferred rent         (338)         (28)         860           Deferred revenue, related party         (3618)         15,189         (9,697)           Income taxes payable         (10)         (17)         (104           Long-term obligations         (113)         (541)         (865)           Net cash used in operating activities         (70,679)         (48,833)         (56,319)           Cash flows from investing activities         (72,992)         (9,561)         (6,586)           Purchase of property and equipment         (7,299) <td></td> <td>338</td> <td>(1,319)</td> <td>(991)</td>		338	(1,319)	(991)
Accounts receivables.         509         (509)         —           Receivables from related party.         839         1,688         2,520           Inventory.         400         (400)         —           Prepaid expenses and other current assets.         3,311         (753)         (2,992)           Income taxes receivable         (82)         (1,347)         (576)           Other assets         10         1,076         (26)           Accounts payable         (1,468)         1,146         1,154           Accorused expenses.         (3,596)         (982)         1,718           Payables to related party         (773)         939         —           Deferred revenue, related party.         (3,618)         15,189         (9,697)           Income taxes payable         (10)         (17)         (104           Long-term obligations         (113)         (541)         (865)           Net cash used in operating activities         (70,679)         (48,833)         (56,319)           Cash flows from investing activities         (72,99)         (9,561)         (6,586)           Purchase of property and equipment         (7,299)         (9,561)         (6,586)           Purchase of marketable securities         <		128	12	3
Receivables from related party   839   1,688   2,520   Inventory   400   (400   ——————————————————————————————————	Changes in operating assets and liabilities:			
Inventory		509	, ,	_
Prepaid expenses and other current assets         3,311         (753)         (2,992)           Income taxes receivable         (82)         (1,347)         (576)           Other assets         10         1,076         (26)           Accounts payable         (1,468)         1,146         1,154           Accrued expenses         (3,596)         (982)         1,718           Payables to related party         (773)         939         —           Deferred rent         (338)         (28)         860           Deferred revenue, related party         (3,618)         15,189         (9,697)           Income taxes payable         (10)         (17)         (104)           Long-term obligations         (70,679)         (48,833)         (56,319)           Cash flows from investing activities         (70,679)         (48,833)         (56,319)           Cash flows from investing activities         (72,299)         (9,561)         (6,586)           Purchases of marketable securities         (72,299)         (9,561)         (6,586)           Purchases of marketable securities         (72,299)         (243,011)         (155,963)           Sales and maturities of marketable securities         (72,299)         (243,011)         (155,963)	Receivables from related party		•	2,520
Income taxes receivable	· · · · · · · · · · · · · · · · · · ·		, ,	
Other assets         10         1,076         (26)           Accounts payable         (1,468)         1,146         1,154           Accrued expenses         (3,596)         (982)         1,718           Payables to related party         (773)         939         —           Deferred rent         (338)         (28)         860           Deferred revenue, related party         (3,618)         15,189         (9,697)           Income taxes payable         (10)         (17)         (104)           Long-term obligations         (113)         (541)         (865)           Net cash used in operating activities         (70,679)         (48,833)         (56,319)           Cash flows from investing activities         (70,679)         (48,833)         (56,319)           Purchases of property and equipment         (7,299)         (9,561)         (6,586)           Purchases of marketable securities         (92,702)         (243,011)         (155,963)           Sales and maturities of marketable securities         159,017         272,496         113,824           Proceeds from sale of equity securities of Pharmasset, Inc         4,000         —         —           Restricted deposits         —         —         (411)	,	3,311	, ,	
Accounts payable         (1,468)         1,146         1,154           Accrued expenses         (3,596)         (982)         1,718           Payables to related party         (773)         939         —           Deferred rent         (338)         (28)         860           Deferred revenue, related party         (3,618)         15,189         (9,697)           Income taxes payable         (10)         (17)         (104           Long-term obligations         (113)         (541)         (865)           Net cash used in operating activities         (70,679)         (48,833)         (56,319)           Cash flows from investing activities:         (70,679)         (48,833)         (56,319)           Purchase of property and equipment         (70,679)         (9,561)         (6,586)           Purchase of property and equipment         (72,99)         (9,561)         (6,58	Income taxes receivable	(82)		, ,
Accrued expenses   (3,596)   (982)   1,718     Payables to related party   (773)   939   —   Deferred rent   (338)   (28)   860     Deferred revenue, related party   (3,618)   15,189   (9,697)     Income taxes payable   (10)   (17)   (104)     Long-term obligations   (113)   (541)   (865)     Net cash used in operating activities   (70,679)   (48,833)   (56,319)     Cash flows from investing activities:     Purchase of property and equipment   (7,299)   (9,561)   (6,586)     Purchases of marketable securities   (92,702)   (243,011)   (155,963)     Sales and maturities of marketable securities   (92,702)   (243,011)   (155,963)     Sales and maturities of marketable securities   (159,017)   272,496   113,824     Proceeds from sale of equity securities of Pharmasset, Inc   (4,000   — — —     Restricted deposits   — —   (411)     Net cash provided by (used in) investing activities   (3,016)   19,924   (49,136)     Cash flows from financing activities:   — —   (411)     Net cash provided by (used in) investing activities   (20,016)   (20,016)     Proceeds from sale of common stock in public offerings and private placements, net of offering costs   — — — — — — — — — — — — — — — — — —		10		` ′
Payables to related party	Accounts payable			•
Deferred rent	•		` /	1,718
Deferred revenue, related party.         (3,618)         15,189         (9,697)           Income taxes payable         (10)         (17)         (104)           Long-term obligations         (113)         (541)         (865)           Net cash used in operating activities         (70,679)         (48,833)         (56,319)           Cash flows from investing activities:         (7,299)         (9,561)         (6,586)           Purchase of property and equipment         (7,299)         (9,561)         (65,586)           Purchases of marketable securities         (92,702)         (243,011)         (155,963)           Sales and maturities of marketable securities of Pharmasset, Inc         4,000         —         —           Restricted deposits         —         —         (411)           Net cash provided by (used in) investing activities         63,016         19,924         (49,136)           Cash flows from financing activities:         —         —         —         (411)           Net proceeds from sale of common stock in public offerings and private placements, net of offering costs         —         —         —         145,433           Proceeds from exercise of common stock options         205         902         2,018           Proceeds from issuance of common stock to related party		` '		_
Income taxes payable         (10)         (17)         (104)           Long-term obligations         (113)         (541)         (865)           Net cash used in operating activities         (70,679)         (48,833)         (56,319)           Cash flows from investing activities:         (7,299)         (9,561)         (6,586)           Purchase of property and equipment         (7,299)         (9,561)         (65,586)           Purchases of marketable securities         (92,702)         (243,011)         (155,963)           Sales and maturities of marketable securities of Pharmasset, Inc         4,000         —         —         413,224           Proceeds from sale of equity securities of Pharmasset, Inc         4,000         —         —         —         (411)           Net cash provided by (used in) investing activities         63,016         19,924         (49,136)         (49,136)           Cash flows from financing activities:         —         —         —         —         (411)           Net cash provided by (used in) investing activities and private placements, net of offering costs         —         —         —         —         —         —         —         —         —         —         —         —         —         —         —         —         —				
Long-term obligations         (113)         (541)         (865)           Net cash used in operating activities         (70,679)         (48,833)         (56,319)           Cash flows from investing activities:         Purchase of property and equipment         (7.299)         (9,561)         (6,586)           Purchases of marketable securities         (92,702)         (243,011)         (155,963)           Sales and maturities of marketable securities         159,017         272,496         113,824           Proceeds from sale of equity securities of Pharmasset, Inc         4,000         —         —           Restricted deposits         4,000         —         —         (411)           Net cash provided by (used in) investing activities         63,016         19,924         (49,136)           Cash flows from financing activities         —         —         —         (411)           Net proceeds from sale of common stock in public offerings and private placements, net of offering costs         —         —         —         145,433           Proceeds from exercise of common stock options         205         902         2,018           Proceeds from issuance of common stock to related party         —         54         —           Net cash provided by financing activities         205         956	• •			
Net cash used in operating activities         (70,679)         (48,833)         (56,319)           Cash flows from investing activities:         Purchase of property and equipment         (7,299)         (9,561)         (6,586)           Purchases of marketable securities         (92,702)         (243,011)         (155,963)           Sales and maturities of marketable securities         159,017         272,496         113,824           Proceeds from sale of equity securities of Pharmasset, Inc         4,000         —         —         (411)           Net cash provided by (used in) investing activities         63,016         19,924         (49,136)           Cash flows from financing activities:         State proceeds from financing activities         —         —         —         (411)           Net proceeds from sale of common stock in public offerings and private placements, net of offering costs         —         —         —         145,433           Proceeds from exercise of common stock options         205         902         2,018           Proceeds from issuance of common stock to related party         —         54         —           Net cash provided by financing activities         205         956         147,451           Effect of changes in exchange rates on cash and cash equivalents         (174)         112         (346)	• •		` '	
Cash flows from investing activities:         Purchase of property and equipment       (7,299)       (9,561)       (6,586)         Purchases of marketable securities       (92,702)       (243,011)       (155,963)         Sales and maturities of marketable securities       159,017       272,496       113,824         Proceeds from sale of equity securities of Pharmasset, Inc       4,000       —       —         Restricted deposits       —       —       (411)         Net cash provided by (used in) investing activities       63,016       19,924       (49,136)         Cash flows from financing activities:       —       —       —       145,433         Proceeds from sale of common stock in public offerings and private placements, net of offering costs       —       —       —       145,433         Proceeds from exercise of common stock options       205       902       2,018         Proceeds from issuance of common stock to related party       —       54       —         Net cash provided by financing activities       205       956       147,451         Effect of changes in exchange rates on cash and cash equivalents       (174)       112       (346)         Net (decrease) increase in cash and cash equivalents       (7,632)       (27,841)       41,650	Long-term obligations	(113)	(541)	(865)
Purchase of property and equipment         (7,299)         (9,561)         (6,586)           Purchases of marketable securities         (92,702)         (243,011)         (155,963)           Sales and maturities of marketable securities         159,017         272,496         113,824           Proceeds from sale of equity securities of Pharmasset, Inc         4,000         —         —           Restricted deposits         —         —         (411)           Net cash provided by (used in) investing activities         63,016         19,924         (49,136)           Cash flows from financing activities:         Net proceeds from sale of common stock in public offerings and private placements, net of offering costs         —         —         —         145,433           Proceeds from exercise of common stock options         205         902         2,018           Proceeds from issuance of common stock to related party         —         54         —           Net cash provided by financing activities         205         956         147,451           Effect of changes in exchange rates on cash and cash equivalents         (174)         112         (346)           Net (decrease) increase in cash and cash equivalents         (7,632)         (27,841)         41,650           Cash and cash equivalents at end of year         \$48,260 <t< td=""><td>Net cash used in operating activities</td><td>(70,679)</td><td>(48,833)</td><td>(56,319)</td></t<>	Net cash used in operating activities	(70,679)	(48,833)	(56,319)
Purchases of marketable securities         (92,702)         (243,011)         (155,963)           Sales and maturities of marketable securities         159,017         272,496         113,824           Proceeds from sale of equity securities of Pharmasset, Inc         4,000         —         —           Restricted deposits         —         (411)           Net cash provided by (used in) investing activities         63,016         19,924         (49,136)           Cash flows from financing activities:         —         —         145,433           Proceeds from sale of common stock in public offerings and private placements, net of offering costs         —         —         145,433           Proceeds from exercise of common stock options         205         902         2,018           Proceeds from issuance of common stock to related party         —         54         —           Net cash provided by financing activities         205         956         147,451           Effect of changes in exchange rates on cash and cash equivalents         (174)         112         (346)           Net (decrease) increase in cash and cash equivalents         (7,632)         (27,841)         41,650           Cash and cash equivalents at end of year         \$48,260         \$55,892         \$83,733           Cash and cash equivalents at end of	Cash flows from investing activities:			
Purchases of marketable securities         (92,702)         (243,011)         (155,963)           Sales and maturities of marketable securities         159,017         272,496         113,824           Proceeds from sale of equity securities of Pharmasset, Inc         4,000         —         —           Restricted deposits         —         (411)           Net cash provided by (used in) investing activities         63,016         19,924         (49,136)           Cash flows from financing activities:         —         —         145,433           Proceeds from sale of common stock in public offerings and private placements, net of offering costs         —         —         145,433           Proceeds from exercise of common stock options         205         902         2,018           Proceeds from issuance of common stock to related party         —         54         —           Net cash provided by financing activities         205         956         147,451           Effect of changes in exchange rates on cash and cash equivalents         (174)         112         (346)           Net (decrease) increase in cash and cash equivalents         (7,632)         (27,841)         41,650           Cash and cash equivalents at end of year         \$48,260         \$55,892         \$83,733           Cash and cash equivalents at end of	Purchase of property and equipment	(7,299)	(9,561)	(6,586)
Proceeds from sale of equity securities of Pharmasset, Inc         4,000         —         —         —         —         —         —         —         —         —         —         —         —         —         —         —         —         (411)           Net cash provided by (used in) investing activities         63,016         19,924         (49,136)         —         —         (411)           Cash flows from financing activities:         Net proceeds from sale of common stock in public offerings and private placements, net of offering costs         —         —         —         145,433           Proceeds from exercise of common stock options         205         902         2,018           Proceeds from issuance of common stock to related party         —         54         —           Net cash provided by financing activities         205         956         147,451           Effect of changes in exchange rates on cash and cash equivalents         (174)         112         (346)           Net (decrease) increase in cash and cash equivalents         (7,632)         (27,841)         41,650           Cash and cash equivalents at beginning of year         55,892         83,733         42,083           Cash and cash equivalents at end of year         \$48,260         \$55,892         883,733		(92,702)	(243,011)	(155,963)
Restricted deposits       —       —       (411)         Net cash provided by (used in) investing activities       63.016       19,924       (49,136)         Cash flows from financing activities:         Net proceeds from sale of common stock in public offerings and private placements, net of offering costs       —       —       145,433         Proceeds from exercise of common stock options       205       902       2,018         Proceeds from issuance of common stock to related party       —       54       —         Net cash provided by financing activities       205       956       147,451         Effect of changes in exchange rates on cash and cash equivalents       (174)       112       (346)         Net (decrease) increase in cash and cash equivalents       (7,632)       (27,841)       41,650         Cash and cash equivalents at beginning of year       55,892       83,733       42,083         Cash and cash equivalents at end of year       \$ 48,260       \$ 55,892       \$ 83,733         Supplemental disclosure of cash flow information:         Taxes paid       \$ 196       \$ 144       \$ 53	Sales and maturities of marketable securities	159,017	272,496	113,824
Net cash provided by (used in) investing activities 63.016 19,924 (49,136)  Cash flows from financing activities:  Net proceeds from sale of common stock in public offerings and private placements, net of offering costs — — — — — — — — — — — — — — — — — —	Proceeds from sale of equity securities of Pharmasset, Inc	4,000	_	<del></del>
Cash flows from financing activities:  Net proceeds from sale of common stock in public offerings and private placements, net of offering costs	Restricted deposits			(411)
Net proceeds from sale of common stock in public offerings and private placements, net of offering costs	Net cash provided by (used in) investing activities	63,016	19,924	(49,136)
Net proceeds from sale of common stock in public offerings and private placements, net of offering costs	Cash flows from financing activities:			
placements, net of offering costs         —         —         —         —         145,433           Proceeds from exercise of common stock options         205         902         2,018           Proceeds from issuance of common stock to related party         —         54         —           Net cash provided by financing activities         205         956         147,451           Effect of changes in exchange rates on cash and cash equivalents         (174)         112         (346)           Net (decrease) increase in cash and cash equivalents         (7,632)         (27,841)         41,650           Cash and cash equivalents at beginning of year         55,892         83,733         42,083           Cash and cash equivalents at end of year         \$ 48,260         \$ 55,892         \$ 83,733           Supplemental disclosure of cash flow information:           Taxes paid         \$ 196         \$ 144         \$ 53				
Proceeds from exercise of common stock options         205         902         2,018           Proceeds from issuance of common stock to related party         —         54         —           Net cash provided by financing activities         205         956         147,451           Effect of changes in exchange rates on cash and cash equivalents         (174)         112         (346)           Net (decrease) increase in cash and cash equivalents         (7,632)         (27,841)         41,650           Cash and cash equivalents at beginning of year         55,892         83,733         42,083           Cash and cash equivalents at end of year         \$48,260         \$55,892         \$83,733           Supplemental disclosure of cash flow information:           Taxes paid         \$196         \$144         \$53		_		145,433
Net cash provided by financing activities         205         956         147,451           Effect of changes in exchange rates on cash and cash equivalents         (174)         112         (346)           Net (decrease) increase in cash and cash equivalents         (7,632)         (27,841)         41,650           Cash and cash equivalents at beginning of year         55,892         83,733         42,083           Cash and cash equivalents at end of year         \$ 48,260         \$ 55,892         \$ 83,733           Supplemental disclosure of cash flow information:           Taxes paid         \$ 196         \$ 144         \$ 53		205	902	2,018
Effect of changes in exchange rates on cash and cash equivalents.       (174)       112       (346)         Net (decrease) increase in cash and cash equivalents.       (7,632)       (27,841)       41,650         Cash and cash equivalents at beginning of year       55,892       83,733       42,083         Cash and cash equivalents at end of year       \$ 48,260       \$ 55,892       \$ 83,733         Supplemental disclosure of cash flow information:         Taxes paid       \$ 196       \$ 144       \$ 53	Proceeds from issuance of common stock to related party		54	
Effect of changes in exchange rates on cash and cash equivalents.       (174)       112       (346)         Net (decrease) increase in cash and cash equivalents.       (7,632)       (27,841)       41,650         Cash and cash equivalents at beginning of year       55,892       83,733       42,083         Cash and cash equivalents at end of year       \$ 48,260       \$ 55,892       \$ 83,733         Supplemental disclosure of cash flow information:         Taxes paid       \$ 196       \$ 144       \$ 53	Net cash provided by financing activities	205	956	147,451
Cash and cash equivalents at beginning of year       55,892       83,733       42,083         Cash and cash equivalents at end of year       \$ 48,260       \$ 55,892       \$ 83,733         Supplemental disclosure of cash flow information:       Taxes paid       \$ 196       \$ 144       \$ 53	Effect of changes in exchange rates on cash and cash equivalents	(174)	112	(346)
Cash and cash equivalents at beginning of year       55,892       83,733       42,083         Cash and cash equivalents at end of year       \$ 48,260       \$ 55,892       \$ 83,733         Supplemental disclosure of cash flow information:       Taxes paid       \$ 196       \$ 144       \$ 53	Net (decrease) increase in cash and cash equivalents	(7.632)	(27.841)	41.650
Cash and cash equivalents at end of year       \$ 48,260       \$ 55,892       \$ 83,733         Supplemental disclosure of cash flow information:       Taxes paid       \$ 196       \$ 144       \$ 53				
Supplemental disclosure of cash flow information:  Taxes paid				
Taxes paid	·	<u>\$ 48,200</u>	3 33,092	\$ 63,733
arbbienieniai aisenosure or noneasu investing and imaneing activities:		\$ 196	\$ 144	\$ 53
Value of charge of common etack contingently issuable or issued to related	· · · · · · · · · · · · · · · · · · ·			•
Value of shares of common stock contingently issuable or issued to related party		192	25	(0)
Accrued proposed settlement amount			<i></i>	( <i>)</i> )
	Proposed semestion untount.	12,000		_

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

### 1. Organization and Business

Idenix Pharmaceuticals, Inc. (together with its consolidated subsidiaries, the "Company") is a biopharmaceutical company engaged in the discovery and development of drugs for the treatment of human viral and other infectious diseases. The Company's current focus is on diseases caused by hepatitis C virus ("HCV") and human immunodeficiency virus ("HIV").

Effective May 8, 2003, Novartis Pharma AG ("Novartis"), a subsidiary of Novartis AG, acquired a majority interest in the Company's outstanding stock and the operations of the Company have been consolidated in the financial statements of Novartis since that date. Since May 2003, Novartis has had the ability to exercise control over the Company's strategic direction, research and development activities and other material business decisions (Note 3).

In October 2006, the Company received approval from the U.S. Food and Drug Administration ("FDA") to market its first product, Tyzeka® (telbivudine), for the treatment of patients with chronic hepatitis B in the United States. In territories outside the United States, telbivudine is marketed as Sebivo®. In April 2007, Sebivo® was approved in the European Union for the treatment of patients with chronic hepatitis B. To date, Sebivo® has been approved in more than 50 countries outside the United States, including China, Switzerland and the European Union.

In July 2007, the Company announced that the FDA had placed on clinical hold in the United States development program of valopicitabine ("NM283") for the treatment of HCV based on the overall risk/benefit profile observed in clinical testing. The Company subsequently discontinued the development of valopicitabine.

In September 2007, the Company entered into an amendment to the development, license and commercialization agreement dated as of May 8, 2003 between the Company and Novartis (the "2007 Amendment", and the 2007 Amendment and all prior amendments, the "Development Agreement"). In September 2007, the Company and Novartis also entered into a transition services agreement (the "TSA"). Pursuant to the 2007 Amendment, the Company transitioned to Novartis all of its development, commercialization and manufacturing rights and obligations to telbivudine (Tyzeka®/Sebivo®) on a worldwide basis. Effective October 1, 2007, the Company began receiving royalty payments equal to a percentage of net sales of Tyzeka®/Sebivo®, with such percentage increasing according to specified tiers of net sales. The royalty percentage will vary based upon the territory and the aggregate dollar amount of net sales.

In conjunction with the 2007 Amendment, the Company announced a restructuring of its operations in which the Company entered into a plan to enact a workforce reduction of approximately 100 positions, the majority of which had supported the development and commercialization of Tyzeka®/Sebivo® in the United States and Europe (Note 10). The restructuring was a strategic decision on behalf of the Company to focus its resources on its HCV and HIV discovery and development programs.

The Company is 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 collaborative partners, competition, technological and medical risks and management of growth.

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

### 2. Summary of Significant Accounting Policies

Significant accounting policies applied by the Company in the preparation of its consolidated financial statements are as follows:

### Principles of Consolidation

The accompanying consolidated financial statements reflect the operations of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated.

### Use of Estimates and Assumptions

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and use assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

### Cash and Cash Equivalents

The Company considers 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 operating lease commitments of the Company (Note 13), the Company 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 release date of the restrictions.

### Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk primarily consist of cash and cash equivalents, marketable securities, and receivables from related party. The Company invests its excess cash, cash equivalents and marketable securities in debt instruments and interest bearing accounts at major U.S. financial institutions. Accordingly, management believes these investments are subject to minimal credit and market risk and are of high credit quality.

At December 31, 2007 and 2006, all of the Company's receivables from related party were due from Novartis. At December 31, 2006, accounts receivable were from product sales of Tyzeka. Revenue from Novartis represented substantially all of total revenues for the years ended December 31, 2007, 2006 and 2005, respectively.

### Marketable Securities

The Company invests its excess cash balances in short-term and long-term marketable debt securities. The Company classifies all of its marketable securities as available-for-sale. The Company reports available-for-sale investments at fair value as of each balance sheet date and includes any unrealized gains and, to the extent deemed temporary, losses in stockholders' equity. If any adjustment to fair value reflects a decline in the value of the investment, the Company considers available evidence to evaluate whether the decline is "other than temporary" and, if so, marks the investment to market through a charge to the consolidated statement of operations. Realized gains and losses are determined on the specific identification method and are included in investment income. The Company classifies its marketable securities with remaining maturities of 12 months or less as current marketable securities exclusive of those categorized as cash equivalents. The Company classifies its marketable securities with remaining maturities greater than 12 months as non-current marketable securities.

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The fair value of the Company's investments is generally determined from quoted market prices received from pricing services based upon market transactions at fair value. In addition, investments in auction rate securities which consist entirely of municipal debt securities are recorded at fair value, which has historically approximated cost due to their variable interest rates, which typically reset through an auction process every seven to 35 days. This auction mechanism generally allows existing investors to roll over their holdings and continue to own their securities or liquidate their holdings by selling their securities at par value. Because of these short intervals between interest reset dates, the Company monitors the auctions to ensure they are successful. To the extent an auction were to fail and the securities were not liquid, the Company would seek other alternatives to determine the fair value of these securities which may not be based on quoted market transactions.

Investments are considered to be impaired when a decline in fair value below cost basis is determined to be other than temporary. The Company periodically evaluates whether a decline in fair value below cost basis is other than temporary using available evidence regarding the Company's investments. In the event that the cost basis of a security significantly exceeds its fair value, the Company evaluates, 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, and the Company's intent and ability to hold the investment. 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. There were no unrealized losses in investments which were deemed to be other than temporary during the years ended December 31, 2007, 2006 and 2005.

### Fair Value of Financial Instruments

Financial instruments, including cash and cash equivalents, restricted cash, marketable securities, accounts receivable, receivables from related party, accounts payable and accrued expenses, are carried in the consolidated financial statements at amounts that approximated their fair value as of December 31, 2007 and 2006 due to the short-term nature of these items.

### Inventory

Inventory is stated at the lower of cost or market with cost determined under the first-in, first-out ("FIFO") method. The Company periodically reviews its inventory for excess or obsolete inventory and writes down obsolete inventory to its estimated net realizable value. At December 31, 2007, the Company did not have any inventory as the Company, in September 2007, entered into the 2007 Amendment in which the Company transferred to Novartis development, commercialization and manufacturing rights and obligations pertaining to telbivudine (Tyzeka®/ Sebivo®) on a worldwide basis. At December 31, 2006, the Company did not have any inventory associated with products that did not receive regulatory approval.

### Investment

At December 31, 2006, the Company held a long-term investment in equity securities of Pharmasset Inc. ("Pharmasset"), a biotechnology company. The Company held an ownership interest of less than 20% and did not have the ability to exercise significant influence over Pharmasset. During the quarter ended June 30, 2007, Pharmasset completed an initial public offering allowing their stock to be publicly traded and the Company began classifying this investment as available for sale in accordance with Statement of Financial Accounting Standards No. 115, "Accounting for Certain Investments in Debt and Equity Securities" ("SFAS No. 115"). In accordance with SFAS No. 115, all available-for-sale securities are recorded at fair market value and, to the extent deemed temporary, unrealized gains and losses are included in accumulated other comprehensive income (loss) in stockholders' equity, net of related tax effects. Realized gains and losses and declines in value, if any, judged to be other than temporary on available for sale securities are reported in other income (expense). Prior to the initial public offering, the Company recorded this investment under the cost method of accounting. The Company owned

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

333,333 shares of Pharmasset with a value of \$4,053,000 at September 30, 2007 which included an unrealized gain of \$3,553,000 that was recorded in accumulated other comprehensive income at September 30, 2007. In October 2007, the Company sold all its ownership in Pharmasset and realized a gain of \$3,500,000.

### Intangible Asset

The Company's intangible asset was recorded in the fourth quarter of 2007 and relates to a settlement proposal which includes a full release of all claims by the University of Alabama at Birmingham Research Foundation ("UABRF"), an affiliate of the University of Alabama at Birmingham ("UAB") and related entities as described more fully in Note 13 below.

The Company is amortizing the \$15,000,000 accrued proposed settlement payment to UABRF and related entities over the period of the expected economic benefit of the related asset. The amount of amortization each period is determined as the greater of straight line or economic consumption. Amortization expense pertaining to the asset was \$1,452,000 for the year ended December 31, 2007, which included amounts attributable to prior period and was recorded in cost of sales. There was no expense for the years ended December 31, 2006 and 2005. As of December 31, 2007, accumulated amortization was \$1,452,000. Amortization expense for this asset is anticipated to be \$1,161,000 per year through 2012 and \$7,743,000 through the remaining term of the expected economic benefit of the asset. However, if the proposed settlement is not completed on terms acceptable to the Company, the Company will resume its defense of the claims, including through the litigation process.

### 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 accounts and any resulting gain or loss is included in the results of operations.

### Impairment of Long-Lived Assets

The Company evaluates the recoverability of its property and equipment and other long-lived assets when circumstances indicate that an event of impairment may have occurred in accordance with the provisions of Statement of Financial Accounting Standards ("SFAS") No. 144, "Accounting for the Impairment of Disposal of Long-Lived Assets" ("SFAS No. 144"). Impairment is measured based on the difference between the carrying value of the related assets or businesses and the discounted future cash flows of such assets or businesses. No impairment was recognized for any of the years ended December 31, 2006 and 2005. During the year ended December 31, 2007 as a result of the Company's restructuring announced in September 2007, the Company recorded accelerated depreciation expense of \$2,792,000 on certain enterprise software assets that would no longer be used following the transition of commercialization and development activities to Novartis. The Company also recorded an impairment charge of \$2,113,000 during the year ended December 31, 2007 for certain enterprise software assets that were recorded in construction-in-progress and which now will not be placed into service as a result of the restructuring.

### Revenue Recognition

The Company records revenue provided that there is persuasive evidence that an arrangement exists, the price is fixed or determinable and collectability is reasonably assured. The Company records revenue earned under collaborative research and development arrangements, product sales and government research grants.

Collaborative Research and Development Revenue — Revenue related to collaborative research and development arrangements includes nonrefundable license fees, milestones, royalties and collaborative research and

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

development funding from the Company's collaborative partners. Where the Company has continuing performance obligations under the terms of a collaborative arrangement, nonrefundable license fees are recognized as revenue over the specified development period as the Company completes its performance obligations. When the Company's level of effort is relatively constant over the performance period, 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 collaborative partners for research and development efforts by the Company are recognized as revenue over the contract term as the related costs are incurred, net of any amounts due to the collaborative partner for costs incurred during the period for shared development costs. Revenues from milestones related to an arrangement under which the Company has continuing performance obligations, if deemed substantive, are recognized as revenue upon achievement of the milestone. Milestones are considered substantive if all of the following conditions are met: the milestone is nonrefundable; achievement of the milestone was not reasonably assured at the inception of the arrangement; substantive effort is involved to achieve the milestone; and the amount of the milestone appears reasonablé in relation to the effort expended, the other milestones in the arrangement and the related risk associated with achievement of the milestone. If any of these conditions is not met, the milestone payment is deferred and recognized as license fee revenue as the Company completes its performance obligations.

Where the Company has no continuing involvement under a collaborative arrangement, the Company records nonrefundable license fee revenue when the Company has the contractual right to receive the payment, in accordance with the terms of the license agreement, and records milestones upon appropriate notification to the Company of achievement of the milestones by the collaborative partner.

In November 2002, the Emerging Issues Task Force ("EITF") reached a consensus on EITF Issue No. 00-21, "Accounting for Revenue Arrangements with Multiple Deliverables" ("EITF No. 00-21"). EITF No. 00-21 provides guidance on how to account for arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. The provisions of EITF No. 00-21 apply to revenue arrangements entered into on or after July 1, 2003.

The Company entered into a collaboration arrangement with Novartis in May 2003. The collaboration arrangement contemplates several joint committees in which the Company and Novartis participate. The Company participates in these committees as a means to govern or protect its interests. The committees span the period from early development through commercialization of product candidates licensed by Novartis.

As a result of applying the provisions of SAB 101, which was the applicable revenue guidance at the time the collaboration was entered into, the Company's revenue recognition policy attributes revenue to the development period of the product candidates licensed under the Development Agreement. The Company has not attributed revenue to its involvement in the committees following the commercialization of the licensed products as the Company has determined that its participation on the committees as such participation relates to the commercialization of product candidates is protective. The Company's determination is based in part on the fact that its expertise is, and has been, the discovery and development of drugs for the treatment of human viral and other infectious diseases. Novartis, on the other hand, has and continues to possess the considerable commercialization expertise and infrastructure necessary for the commercialization of such drug candidates. Accordingly, the Company believes its obligation post commercialization is inconsequential.

Product Sales — Product sales consist of sales of Tyzeka® in the United States. Revenues from product sales are recognized when the product is shipped and title and risk of ownership has been transferred to the customer, typically upon delivery. Product sales are recorded net of any applicable allowances for sales returns, trade term discounts, early pay discounts, government-related rebates, such as Medicaid, managed care discounts, vouchers, coupons, patient assistance programs and other allowances. The Company estimates its deductions from product sales at the time of sale based on a number of factors, including historical experience of Novartis and industry knowledge updated for changes in facts, where appropriate. Prior to October 1, 2007, the Company had a commercial collaboration profit-sharing arrangement with Novartis on Tyzeka® sales in the United States. In this

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

arrangement, the Company co-promoted Tyzeka® with Novartis in the United States, but the Company had primary responsibility for U.S. commercialization. As a result, the Company recorded net product sales and related production costs for the Company's U.S. commercial collaboration in the statement of operations on a gross basis since the Company had the inventory and credit risk, and met the criteria as a principal in the transaction. The Company recorded the U.S. commercial collaboration profit-sharing expense with Novartis as a reduction of collaboration revenue-related party.

In September 2007, the Company amended its Development Agreement with Novartis (Note 3) in which Novartis assumed sole responsibility for product sales of Tyzeka\*/Sebivo\* on a worldwide basis beginning on October 1, 2007. As a result, beginning in the fourth quarter of 2007, the Company no longer recorded product sales of Tyzeka\*.

Government Research Grant Revenue — Government research grants that provide for payments to the Company for work performed are recognized as revenue when the related expense is incurred and the Company has obtained governmental approval to use the grant funds for these expenses.

### Research and Development Expenses

All costs associated with internal research and development and external research and development services, including pre-clinical and clinical trial studies are expensed as incurred. Research and development expenses include costs for salaries, employee benefits, subcontractors, facility related expenses, depreciation, license fees and stock-based compensation related to employees involved in the Company's research and development.

### Patents

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

### Share-Based Compensation

In December 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 123 (revised 2004) "Share-Based Payment" ("SFAS No. 123(R)"). This Statement replaces SFAS No. 123, "Accounting for Stock-Based Compensation," and supersedes Accounting Principles Board Opinion No. 25, or APB No. 25, "Accounting for Stock Issued to Employees." SFAS No. 123(R) requires share-based transactions for employees and directors to be accounted for using a fair value based method that results in expense being recognized in the Company's financial statements.

The Company adopted SFAS No. 123(R) on January 1, 2006. The Company applied the modified prospective method at adoption in which stock compensation expense was determined based on fair value using the Black-Scholes method at grant dates for stock options. Accordingly, financial statement amounts for the periods prior to the adoption of SFAS No. 123(R), including the year ended December 31, 2005, have not been restated to reflect the fair value method of expensing. Prior to January 1, 2006, the Company accounted for its stock-based awards to employees and directors using the intrinsic method prescribed in APB No. 25 and related interpretations.

In November 2005, the FASB issued FASB Staff Position FAS 123(R)-3, "Transition Election Related to Accounting for Tax Effects of Share-based Payment Awards," or FSP FAS 123(R)-3. In accordance with FSP FAS 123(R)-3, entities can choose to follow either the transitional guidance of SFAS 123(R) or the alternative transition method described in FSP FAS 123(R)-3. Effective in the fourth quarter of 2006, the Company elected to adopt the alternative transition method for calculating the tax effects of stock-based compensation pursuant to SFAS 123(R). The alternative transition method includes simplified methods to establish the beginning balance of the additional paid-in capital pool, or APIC pool or windfall, related to the tax effects of employee stock-based compensation, and to determine the subsequent impact on the APIC pool and consolidated statements of cash flows of the tax effects of employee-stock based compensation awards that are outstanding upon adoption of

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

SFAS 123(R). The adoption of the alternative transition method resulted in no impact on the Company's financial statements.

The Company recognizes compensation expense for stock options granted to non-employees in accordance with the requirements of SFAS No. 123(R) and EITF Issue No. 96-18, "Accounting for Equity Instruments that Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services" ("EITF 96-18"). EITF 96-18 requires such equity instruments to be recorded at their fair value at the measurement date, which is generally the vesting date of the instruments. Therefore, the measurement of stock-based compensation is subject to periodic adjustments as the underlying equity instruments vest.

### Foreign Currency

The functional currencies of the Company's 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. 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. Revenue and expense amounts are remeasured using the average exchange rate for the period. Gains and losses resulting from foreign currency remeasurements are included in the consolidated statement of operations. Net realized gains and losses from foreign currency transactions are included in the consolidated statement of operations.

### Income Taxes

Deferred tax assets and liabilities are recognized based on the expected future tax consequences, using current tax rates, of temporary differences between the financial statement carrying amounts and the income tax basis of assets and liabilities. A valuation allowance is applied against any net deferred tax asset if, based on the weighted available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized (Note 14). The Company records liabilities for tax contingencies if it is probable that the Company has incurred a tax liability and the liability or the range of loss can be reasonably estimated.

In June 2006, the FASB published FASB Interpretation ("FIN") No. 48, "Accounting for Uncertain Tax Positions," ("FIN No. 48"). FIN No. 48 requires that a tax position meet "a more likely than not" threshold for the benefit of the uncertain tax position to be recognized in the financial statements. This threshold is to be met assuming that the tax authorities will examine the uncertain tax position. FIN No. 48 contains guidance with respect to the measurement of the benefit that is recognized for an uncertain tax position, when that benefit should be derecognized, and other matters. The Company adopted the provisions of FIN No. 48 effective January 1, 2007.

### Comprehensive Income (Loss)

Comprehensive income (loss) is comprised of net loss and certain changes in stockholders' equity that are excluded from net loss. The Company includes foreign currency translation adjustments for subsidiaries in which the functional currency is not the U.S. dollar and unrealized gains and losses on marketable securities in other comprehensive income (loss). The consolidated statements of stockholders' equity and comprehensive loss reflect total comprehensive loss for the years ended December 31, 2007, 2006 and 2005.

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

### Net Income (Loss) per Common Share

The Company accounts for and discloses net income (loss) per common share in accordance with SFAS No. 128, "Earnings Per Share" ("SFAS No. 128"). Under the provisions of SFAS No. 128, basic net income (loss) per common share is computed by dividing net income (loss) available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted net income (loss) per common share is computed by dividing net income (loss) available to common stockholders by the weighted average number of common shares and dilutive 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 subscription rights (Note 3) and restricted stock awards.

### Segment Reporting

SFAS No. 131, "Disclosures About Segments of an Enterprise and Related Information" ("SFAS No. 131"), requires companies to report information about the annual financial statements of operating segments. It also establishes standards for related disclosures about products and services, geographical areas and major customers. Management of the Company, which uses consolidated financial information in determining how to allocate resources and assess performance, has determined that it operates in only one reportable segment.

### 3. Novartis Relationship

### Overview

In May 2003, the Company entered into a collaboration with Novartis relating to the worldwide development and commercialization of the Company's product candidates. The collaboration includes the Development Agreement.

In September 2007, the Company entered into the 2007 Amendment and the TSA. The 2007 Amendment and TSA are effective as of October 1, 2007. Pursuant to the 2007 Amendment, the Company transferred to Novartis all of its development, commercialization and manufacturing rights and obligations related to telbivudine, the Company's drug product for the treatment of hepatitis B virus ("HBV"), on a worldwide basis. Telbivudine is marketed as Tyzeka® in the United States and as Sebivo® in the rest of the world. The Company will receive royalty payments equal to a percentage of net sales of Tyzeka®/Sebivo®, with such percentage increasing according to specified tiers of net sales. The royalty percentage shall vary based upon the territory and the aggregate dollar amount of net sales. Novartis is responsible for development and commercialization expenses relating to telbivudine beginning on October 1, 2007. Novartis shall also be responsible for certain costs associated with the transition of third party contracts and arrangements relating to telbivudine and any intellectual property prosecution and enforcement activities. Pursuant to the TSA, the Company will provide Novartis with certain services relating to telbivudine through June 2008 (or later if agreed to by the parties). The Company will be reimbursed by Novartis for these services.

As part of the Development Agreement, Novartis paid the Company a license fee of \$75,000,000 for its HBV product and product candidate, Tyzeka\*/Sebivo\* and valtorcitabine, respectively, provided development funding for Tyzeka\*/Sebivo\* and valtorcitabine and was obligated to make milestone payments which could have totaled up to \$35,000,000 upon the achievement of certain regulatory approvals, as well as additional commercial milestone payments. Of these \$35,000,000 in milestone payments, the Company received payment on two of these regulatory milestones in 2007 totaling \$20,000,000. One of these regulatory milestones for \$10,000,000 was achieved in the quarter ended March 31, 2007 with the regulatory approval of Sebivo\* in China. The Company recognized this regulatory milestone as collaboration revenue from related party during the quarter ended March 31, 2007 as the milestone was deemed to be substantive. The second regulatory milestone for \$10,000,000 was achieved in April 2007 with the regulatory approval of Sebivo\* in the European Union. This milestone was deemed

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

not to be substantive and the Company has included this milestone as part of the license fee and is being recorded as collaboration revenue from related party over the remaining development period of the Company's licensed product candidates.

As part of the Development Agreement, Novartis also acquired an option to license the Company's HCV and other product candidates. In March 2006, Novartis exercised its option to license valopicitabine, the Company's lead HCV product candidate at that time. As a result, Novartis paid the Company a license fee of \$25,000,000 in March 2006 and provided development funding for valopicitabine. Under the development agreement, Novartis agreed to pay the Company up to \$500,000,000 in additional license fees and regulatory milestone payments for an HCV product candidate. In July 2007, the Company announced that the FDA had placed on clinical hold in the United States the Company's development program of valopicitabine for the treatment of HCV based on the overall risk/benefit profile observed in clinical testing. The Company subsequently discontinued the development of valopicitabine. As a result, the Company is not expected to receive any additional license fees or milestone payments for valopicitabine from Novartis.

Under the Development Agreement, the Company has granted Novartis an exclusive worldwide license to market and sell Tyzeka®/Sebivo®, valtorcitabine and valopicitabine, subject to the Company's commercialization rights. The Company will grant Novartis similar licenses at a future amount to be determined with respect to any other product candidates for which Novartis exercises its option to license. The Company initially retained the right to co-promote or co-market licensed products in the United States, United Kingdom, France, Germany, Italy and Spain. Under the 2007 Amendment, the Company transferred to Novartis all of its development, commercialization and manufacturing rights and obligations related to telbivudine (Tyzeka®/Sebivo®) on a worldwide basis in exchange for royalty payments equal to a percentage of net sales of Tyzeka®/Sebivo®, with such percentage increasing according to specified tiers of net sales. The royalty percentage will vary based upon the territory and the aggregate dollar amount of net sales.

The Company is reimbursed by Novartis on a quarterly basis for expenses it incurs in connection with the development and registration of its licensed products and product candidates. Effective October 1, 2007, Novartis is solely responsible for clinical trial costs and related expenditures associated with telbivudine. The Company will be reimbursed by Novartis for approved costs associated with telbivudine for certain agreements that will be transitioned to Novartis under the TSA.

Simultaneously with the initial collaboration described above, Novartis purchased approximately 54% of the Company's outstanding capital stock from the Company's then existing stockholders for \$255,000,000 in cash, with an additional aggregate amount of up to \$357,000,000 contingently payable to these stockholders if the Company achieves predetermined development milestones relating to an HCV product candidate. As of December 31, 2007, Novartis owned approximately 56% of the Company's outstanding stock.

To date, the Company has received from Novartis a \$25,000,000 license fee for valopicitabine, a \$75,000,000 license fee for Tyzeka®/Sebivo® and valtorcitabine, offset by \$75,000 in interest costs, and a \$5,000,000 reimbursement for reacquiring product rights from Sumitomo to develop and commercialize Sebivo® in certain markets in Asia. The Company included this reimbursement as part of the license fee for accounting purposes because Novartis required the repurchase of these rights as a condition to entering into the Development Agreement. The Company also incurred approximately \$2,250,000 in costs associated with the development of valopicitabine prior to Novartis licensing valopicitabine in March 2006 for which Novartis reimbursed the Company. The Company has included the \$10,000,000 milestone payment for the regulatory approval of Sebivo® in the European Union as part of the license fee for accounting purposes as the milestone was deemed not to be substantive. The sum of these non-refundable payments received from Novartis, totaling \$117,175,000, has been recorded as license fees and is being recognized over the development period of the licensed product candidates.

The Company reviews its assessment and judgment on a quarterly basis with respect to the expected duration of the development period of its licensed product candidates. During the quarter ended December 31, 2007, the

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS -- (Continued)

Company has estimated that the performance period during which the development of its licensed product and product candidates will be completed is a period of approximately ten and a half years following the effective date of the Development Agreement that the Company entered into with Novartis, or December 2013. The Company is recognizing revenue on the license fee payments over this period. If the estimated performance period changes, the Company will adjust the periodic revenue that is being recognized and will record the remaining unrecognized license fee payments over the remaining development period during which the Company's performance obligations will be completed. Significant judgments and estimates are involved in determining the estimated development period and different assumptions could yield materially different results.

### Stockholders' Agreement

In connection with Novartis' purchase of stock from the Company's stockholders, the Company, Novartis and substantially all of the Company's stockholders entered into a stockholders' agreement which was amended and restated in 2004 in connection with the Company's initial public offering of its common stock ("Stockholders' Agreement"). The Stockholders' Agreement provides, among other things, that the Company will use its reasonable best efforts to nominate for election as a director at least two designees of Novartis for so long as Novartis and its affiliates own at least 35% of the Company's voting stock and at least one designee of Novartis for so long as Novartis and its affiliates own at least 19.4% of the Company's voting stock. As long as Novartis and its affiliates continue to own at least 19.4% of the Company's voting stock, Novartis will have approval rights over a number of corporate actions that the Company may take, including the authorization or issuance of additional shares of capital stock and significant acquisitions and dispositions.

Subject to certain exceptions, Novartis and its affiliates have contractually agreed not to acquire prior to May 8, 2008, additional shares of the Company's voting stock unless a majority of the independent board members waive such contractual provision. Acquisitions of the Company's voting stock by exercise of Novartis' stock purchase rights under the Stockholders' Agreement or acquisitions of voting stock to maintain a 51% ownership interest in the Company's fully diluted common stock, exclusive of any shares formerly held by Novartis BioVentures, Ltd., are specifically excepted from this restriction.

### Novartis' Stock Purchase Rights

Novartis has the right to purchase, at par value of \$0.001 per share, such number of shares as is required to maintain its percentage ownership of the Company's voting stock if the Company issues shares of capital stock in connection with the acquisition or in-licensing of technology through the issuance of up to 5% of the Company's stock in any 24-month period. These purchase rights of Novartis remain in effect until the earlier of: a) the date that Novartis and its affiliates own less than 19.4% of the Company's voting stock; or b) the date that Novartis becomes obligated to make the additional contingent payments of \$357,000,000 to holders of the Company's stock who sold shares to Novartis on May 8, 2003.

If the Company issues any shares of its capital stock, other than in certain situations, Novartis has the right to purchase such number of shares required to maintain its percentage ownership of the Company's voting stock for the same consideration per share paid by others acquiring the Company's stock. Upon the grant of options and stock awards under stock incentive plans, with the exception of the 1998 Equity Incentive Plan, the fair value of the Company's common stock that would be issuable to Novartis, less the exercise price, if any payable by the option or award holder, is recorded as a reduction of the license fees associated with the Novartis collaboration. The amount is attributed proportionately between cumulative revenue recognized through that date and the remaining amount of deferred revenue. These amounts will be adjusted through the date that Novartis elects to purchase the shares to maintain its percentage ownership based upon changes in the value of the Company's common stock and in Novartis' percentage ownership. These adjustments will also be attributed proportionately between cumulative revenue recognized through the final measurement date and the remaining deferred revenue.

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

In connection with the closing of the Company's initial public offering in July 2004, Novartis terminated a common stock subscription right with respect to 1,399,106 shares of common stock issuable by the Company as a result of the exercise of stock options granted after May 8, 2003 pursuant to the 1998 Equity Incentive Plan. In exchange for Novartis' termination of such right, the Company issued 1,100,000 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 \$15,400,000 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 Equity Incentive Plan are terminated, and no additional adjustments to revenue and deferred revenue will be required. Prior to the termination of the stock subscription rights under the 1998 Equity Incentive Plan, as the Company granted options that were subject to this stock subscription right, the fair value of the Company's common stock that would be issuable to Novartis, less par value, was recorded as an adjustment of the license fee and payments received from Novartis. The Company remains subject to potential revenue adjustments with respect to grants of options and stock awards under its stock incentive plans other than the 1998 Equity Incentive Plan.

As of December 31, 2007, Novartis stock subscription rights have reduced the license fees by an aggregate of \$15,643,000 which has been recorded to additional paid-in capital. Of this amount, \$6,314,000 has been recorded as deferred revenue as of December 31, 2007 with the remaining amount of \$9,329,000 recorded as a reduction of revenue.

### Manufacturing and Packaging Agreements

In June 2006, after completing a competitive bid process where Novartis had the right to match the best third-party offer, the Company entered into a commercial manufacturing agreement ("Manufacturing Agreement") with Novartis and a packaging agreement ("Packaging Agreement") with Novartis Pharmaceuticals Corporation, an affiliate of Novartis. Under the Manufacturing Agreement, Novartis would manufacture the commercial supply of Tyzeka® that was intended for sale in the United States. The Packaging Agreement provided that the supply of Tyzeka® intended for commercial sale in the United States will be packaged by Novartis Pharmaceuticals Corporation.

As a result of the 2007 Amendment, the Manufacturing Agreement was terminated as it relates to telbivudine and the Company will work with Novartis to terminate the Company's rights and obligations to the Packaging Agreement. Effective October 1, 2007, Novartis is solely responsible for the manufacture and supply of Tyzeka®/Sebivo® on a worldwide basis. No penalties were incurred by the Company as a result of the termination.

### **Product Sales Arrangements**

In connection with the Novartis license of product candidates under the Development Agreement, the Company has retained the right to co-promote or co-market all licensed products in the United States, United Kingdom, France, Germany, Italy and Spain. In the United States, the Company will act as the lead party and record revenue from product sales and share equally the net benefit from co-promotion from the date of product launch. In the United Kingdom, France, Germany, Italy and Spain, Novartis would act as the lead party, record revenue from product sales and will share with the Company the net benefit from co-promotion and co-marketing. The net benefit was defined as net product sales minus related cost of sales. The amount of the net benefit that would be shared with the Company would start at 15% for the first 12-month period following the date of launch, increasing to 30% for the second 12-month period following the date of launch and 50% thereafter. In other countries, the Company would effectively sell products to Novartis for their further sale to third parties. Novartis would pay the Company for such products at a price that is determined under the terms the Company's supply agreement with Novartis.

In October 2006, the Company received approval from the FDA to market its first product, Tyzeka®, in the United States. The Company recognized \$3,187,000 and \$424,000 in net sales from Tyzeka® during the years ended December 31, 2007 and 2006, respectively, after receiving FDA approval. Sebivo® also has been approved in a

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

number of jurisdictions, including Switzerland, China, South Korea and Canada. There were no sales of Sebivo® in territories outside of the United States during the year ended December 31, 2006.

In September 2007, the Company amended its Development Agreement with Novartis in which Novartis assumed sole responsibility for product sales of Tyzeka®/Sebivo® on a worldwide basis beginning on October 1, 2007. As a result, beginning in the fourth quarter of 2007, the Company no longer recorded product sales of Tyzeka®.

The Company recognized \$617,000 in royalty income from Novartis' sales of Tyzeka®/Sebivo® during the year ended December 31, 2007.

### 4. Public Offerings of Common Stock

### Public Offering of Common Stock

In October 2005, the Company completed a public offering in which:

- the Company issued and sold 7,278,020 shares of its common stock; and
- certain stockholders sold 942,507 shares of the Company's common stock.

The net proceeds to the Company were approximately \$145,400,000, after deducting underwriting discounts and commissions and offering expenses. Of the shares offered and sold by the Company, 3,939,131 shares were sold to Novartis. In November 2005, the underwriters exercised the over allotment option associated with this offering resulting in the sale by the selling stockholders of 1,130,387 additional shares of the Company's common stock. The Company did not receive any proceeds from the sale of shares by the selling stockholders.

### 5. Net Loss Per Common Share

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

	Years	Ended Decemb	er 31,
	2007	2006	2005
	(In thousan	ds, except per	share data)
Basic and diluted net loss per common share:			
Net loss	\$(82,515)	\$(75,087)	\$(50,777)
Basic and diluted weighted average number of common shares			
outstanding	56,169	56,005	49,395
Basic and diluted net loss per common share	\$ (1.47)	\$ (1.34)	\$ (1.03)

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

	Years E	nded Decei	mber 31,				
	2007	2007 2006 2009					
	(I	(In thousands)					
Options	5,712	4,387	3,584				
Contingently issuable shares to related party	790	77	26				
Restricted stock	_	_	11				

### 6. Marketable Securities

The Company invests its excess cash with large U.S. based financial institutions and considers its investment portfolio and marketable securities available-for-sale as defined in SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities." Accordingly, these marketable securities are recorded at fair value,

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

which is based on quoted market prices. The fair values of available-for-sale investments by type of security, contractual maturity and classification in the consolidated balance sheets as of December 31, 2007 and 2006 are as follows:

		December :	31, 2007	
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Market Value
		(In thous	ands)	
Type of security:				
Money market funds	\$21,702	\$ —	\$ <del></del>	\$21,702
Commercial paper	1,993	_	_	1,993
Corporate debt securities	56,361	15	(109)	56,267
Municipal bonds	1,990		_	1,990
Auction rate securities	11,050	_	_	11,050
Accrued interest	<u>763</u>			<u>763</u>
	<u>\$93,859</u>	<u>\$ 15</u>	<u>\$(109)</u>	<u>\$93,765</u>
		December .		
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Market Value
		(In thous	ands)	
Type of security:				
Money market funds	\$ 13,940	\$ <del></del>	\$ —	\$ 13,940
Commercial paper	5,988	_		5,988
Corporate debt securities	111,486	17	(53)	111,450
U.S. Treasury securities and obligations of U.S.				
government agencies	9,176	2	(11)	9,167
Taxable auction rate	0.511	1.4	(2)	0.500
securities	8,511	14	(2)	8,523
Accrued interest	1,371		_	<u>1,371</u>
	<u>\$150,472</u>	<u>\$ 33</u>	<u>\$(66)</u>	<u>\$150,439</u>
			December 31, 2007	December 31, 2006
			(In tho	usands)
Contractual maturity:				
Maturing in one year or less			\$69,883	\$ 91,231
Maturing after one year through				16,310
Maturing after two years through	n ten years		7,274	24,922
Maturing after ten years			12,118	17,976
			\$93,765	\$150,439
			435,105	<u> </u>

Included in the table above are taxable auction rate securities, At December 31, 2007 and 2006, approximately \$11,050,000 and \$8,511,000, respectively, of the Company's investments in marketable securities were auction rate securities. These auction rate securities consisted entirely of municipal debt securities, and were classified as long term based on contractual maturity. These investments were recorded at fair value, which approximates cost due to their variable interest rates, which typically reset through an auction process every seven to 35 days. As of

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

December 31, 2007, \$8,700,000 of these municipal auction rate securities were rated AAA/Aaa with the remaining \$2,350,000 being rated Aa3/AA or better, by investments rating agencies. Despite the long-term nature of their stated contractual maturities, the Company expects to have the ability to quickly liquidate these securities. In the event that a future auction is not able to be completed due to sell orders exceeding buy orders, the Company may not have the ability to quickly liquidate these investments. In the event that access to investments in these securities is necessary, the Company will not be able to do so until a future auction is successful, the issuer redeems the outstanding securities, a buyer is found outside the auction process, or the securities mature. For all of the Company's auction rate securities the underlying maturity date is in excess of one year and can be as far as 38 years in the future.

In mid-February 2008, certain of the Company's municipal auction rate securities experienced a failed auction. The Company's investment portfolio included municipal auction rate securities of \$11,050,000 as of December 31, 2007. As of March 11, 2008, the Company had liquidated all but \$4,000,000 of the Company's auction rate securities, of which \$3,100,000 was held at December 31, 2007. The liquidation of these auction rate securities did not result in any losses.

As of March 13, 2008, the fair value of cash and other investments held at Bear, Stearns Securities Corp., or BSSC was \$39,882,000. BSSC is a separately capitalized broker/dealer subsidiary of Bear, Stearns and Co. Inc., or Bear Stearns. On March 14, 2008, Bear Stearns announced that it had received funding from outside parties, including the Federal Reserve Bank of New York, for a limited period of time in order to manage an ongoing deterioration of its liquidity position. The Company does not believe Bear Stearns' liquidity position will affect its access to or the fair value of its cash and other investments held at BSSC.

	December 31, 2007	December 31, 2006
	(In tho	usands)
Classification in balance sheets:	,	_
Cash equivalents	\$30,021	\$ 19,980
Marketable securities	39,862	71,251
Marketable securities, non-current	23,882	59,208
	\$93,765	\$150,439

The cash equivalent amounts of \$30,021,000 and \$19,980,000 at December 31, 2007 and 2006, respectively, are included as part of cash and cash equivalents on the Company's consolidated balance sheets. The Company has the ability to hold its marketable securities to their effective maturities.

### 7. Receivables from Related Party

Receivables from related party consist of the following:

	Decem	ber 31,
	2007	2006
	(In tho	usands)
Unbilled receivables from related party	\$11,196	\$12,035

Unbilled receivables from related party represent amounts under collaborative arrangements in the normal course of business for reimbursement of development, regulatory and marketing expenditures that have not been billed at December 31, 2007 and 2006. The reimbursement of development and regulatory expenditures is billed quarterly. All related party receivables are due from Novartis.

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

### 8. Property and Equipment, Net

Property and equipment consists of the following:

	Estimated Useful Life	ĵ	Decemb	er 31,	,
	(Years)	2007			006
			(In thousands)		
Office equipment	5	\$	67	\$	71
Scientific equipment	7	6.	,958	5	,738
Computer equipment and software	2	3.	,787	4	,005
Enterprise software	5	2.	,599	2	,307
Office furniture	7	1,	,575	1	,645
Trade show booths	2		_		382
Leasehold improvements	*	11,	,043	7	,540
Construction-in-progress			60	3	,944
		26	,089	25	,632
Less — accumulated depreciation		(10.	,629)	(8	,184)
	-	\$ 15	,460	\$17	,448

<sup>\*</sup> Shorter of asset life or lease term.

Depreciation and amortization expense related to property and equipment for the years ended December 31, 2007, 2006 and 2005 was \$7,503,000, \$3,463,000, and \$2,066,000 respectively. Construction-in-progress consists primarily of build-out costs of office and laboratory space and computer software projects.

During the year ended December 31, 2007, as a result of the Company's restructuring announced in September 2007, the Company accelerated depreciation expense of \$2,792,000 on certain enterprise software assets that would no longer be used following the transfer of commercialization and development activities to Novartis. The Company also recorded an impairment charge of \$2,113,000 during the year ended December 31, 2007 for certain enterprise software assets that were recorded in construction-in-progress and which now will not be placed into service as a result of the restructuring.

### 9. Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2007	2006
	(In tho	usands)
Research and development contract costs	\$ 2,050	\$ 5,502
Payroll and benefits	4,231	5,676
License fees	1,000	1,000
Professional fees	1,309	753
Restructuring	1,838	_
Accrued proposed settlement amount	4,000	_
Other	2,009	2,748
	<u>\$16,437</u>	\$15,679

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Accrued license fees represent amounts owing to Microbiologica for the right to use certain manufacturing technology and patents (Note 19).

The accrued restructuring liability represents costs associated with the Company's announcement in September 2007 that it would restructure its operations with the transfer of development, commercialization and manufacturing rights of telbivudine and obligations related to Novartis (Note 10).

### 10. Restructuring and Impairment Charges

On September 28, 2007, the Company announced a restructuring of its operations as a result of an agreement with Novartis in which the Company would transfer to Novartis all development, commercialization and manufacturing rights and obligations related to telbivudine (Tyzeka®/Sebivo®) on a worldwide basis effective October 1, 2007. As a result, the Company entered into a plan to enact a workforce reduction of approximately 100 positions, the majority of which had supported the development and commercialization of Tyzeka®/Sebivo® in the United States and Europe. The restructuring was a strategic decision on behalf of the Company to focus its resources on its HCV and HIV discovery and development programs.

	Year En	ded December 31, 2007	Current Liability at December 31,
	Charge Payments/Settlements		2007
		(In thousands)	
Employee severance, benefits and related costs	\$6,492	\$(4,654)	\$1,838
Contract termination and other costs	139	<u>(139</u> )	
Total	\$6,631	<u>\$(4,793)</u>	<u>\$1,838</u>

In connection with the restructuring, the Company recorded impairment charges of \$2,113,000 in 2007 related to enterprise software that was no longer needed with the transfer of telbivudine related commercialization and development activities to Novartis.

### 11. Common Stock

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, if any, as may be declared by the Board of Directors.

In December 2005, the stockholders approved an amendment to the Company's restated certificate of incorporation increasing the authorized number of shares of the Company's capital stock from 60,000,000 shares of common stock to 75,000,000 shares of common stock. The amendment to the Company's restated certificate of incorporation became effective in January 2006.

In May 2007, the stockholders approved an amendment to the Company's restated certificate of incorporation increasing the authorized number of shares of the Company's capital stock from 75,000,000 shares of common stock to 125,000,000 shares of common stock. The amendment to the Company's restated certificate of incorporation became effective in June 2007.

Novartis and certain holders of the Company's common stock are party to the Stockholders' Agreement. The terms of the stockholders' agreement generally provide for registration rights in favor of Novartis and such other stockholders and certain approval rights in favor of Novartis with respect to corporate actions that might be taken by the Company.

### 12. Equity Incentive Plans and Share-Based Compensation

In May 1998, the Company adopted the 1998 Equity Incentive Plan, as amended ("1998 Plan"), which provides for the grant of incentive stock options, nonqualified stock options, stock awards and stock appreciation rights. The Company initially reserved 1,468,966 shares of common stock for issuance pursuant to the 1998 Plan.

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The Company subsequently amended the 1998 Plan and reserved an additional 3,600,000 shares of common stock for issuance under the 1998 Plan.

In July 2004, the Company adopted the 2004 Stock Incentive Plan ("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 800,000 shares of common stock.

In June 2005, the Company's stockholders approved the 2005 Stock Incentive Plan ("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 ("Awards"). The 2005 Plan, as approved by the Company's stockholders, provided for the authorization of Awards covering an aggregate of 2,200,000 shares of common stock plus 800,000 shares previously authorized for issuance under the 2004 Plan. In connection with the Company's public offering in October 2005, the Company's Board of Directors reduced the number of shares of common stock reserved for issuance under the 2005 Plan to 1,400,000 shares. In March 2006, the Company's Board of Directors authorized the restoration of the reserve of 1,600,000 shares for issuance under the 2005 Plan. In May 2007, the Company's stockholders approved an amendment to the 2005 Plan increasing the number of shares of common stock thereunder from 3,000,000 to 6,000,000 shares.

The equity incentive plans are administered by the Compensation Committee of the Board of Directors. The Compensation Committee determines the type and term of each award, the award exercise or purchase price, if applicable, the number of shares underlying each award granted and the rate at which each award becomes vested or exercisable. Incentive stock options may be granted only to employees of the Company 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 the Company's 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 the Company's 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 stock-based awards on such terms and conditions as it may determine.

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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

· · · · · · · · · · · · · · · · · · ·	Number of Options Available for Future Grant	Number of Options Outstanding	Weighted Average Exercise Price
Outstanding, December 31, 2004	749,258	3,161,790	\$ 7.50
Granted		1,167,750	\$20.27
Exercised		(590,618)	\$ 3.42
Cancelled		(154,600)	\$10.67
Outstanding, December 31, 2005	338,608	3,584,322	\$12.20
Granted		1,373,187	\$14.50
Exercised		(263,804)	\$ 3.42
Cancelled		(306,944)	\$17.84
Outstanding, December 31, 2006	869,869	4,386,761	\$13.05
Granted		2,568,956	\$ 5.19
Exercised		(97,835)	\$ 2.09
Cancelled		(1,145,593)	\$12.36
Outstanding, December 31, 2007	2,446,506	5,712,289	\$ 9.83
Exercisable, December 31, 2006		2,483,361	\$11.16
Exercisable, December 31, 2007		3,298,337	\$11.78

The weighted average fair value of options granted during the years ended December 31, 2007, 2006 and 2005 was \$2.83, \$8.38 and \$13.96, respectively. The total intrinsic value of options exercised during the years ended December 31, 2007, 2006 and 2005 was \$710,000, \$2,816,000 and \$10,404,000, respectively. The intrinsic value was calculated as the difference between the market value and the exercise price of the shares at the date of exercise. The aggregate intrinsic value of stock options outstanding at December 31, 2007 and 2006 was \$686,000 and \$4,288,000, respectively. The aggregate intrinsic value of stock options exercisable at December 31, 2007 and 2006 was \$397,000 and \$4,263,000, respectively.

At December 31, 2007 the options vested and unvested expected to vest aggregated 4,959,854. At December 31, 2007, the weighted average exercise price was \$10.39, the weighted average remaining contractual term was 7.5 years and the aggregate intrinsic value was \$583,000 for these options.

As a result of adopting SFAS No. 123(R) on January 1, 2006, the Company's net loss for the year ended December 31, 2006 is \$8,393,000 or \$0.15 per share on a basic and diluted basis higher than if the Company had continued to account for employee stock-based compensation expense under APB No. 25.

The following table shows stock-based compensation expense as reflected in the Company's consolidated statements of operations:

	Years Ended December 31,			
	2007	2006	2	005
•		(In thousands	;)	
Research and development	\$3,005	\$2,892	\$	722
Selling, general and administrative	4,758	5,745		666
Restructuring and impairment	968		_	
Total stock-based compensation expense	\$8,731	<u>\$8,637</u>	<u>\$1</u>	,388

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The Company has an aggregate of \$10,129,000 of stock compensation as of December 31, 2007 remaining to be amortized over a weighted average expected term of 3.3 years. The weighted average remaining contractual term of the options outstanding at December 31, 2007 is 7.76 years.

The assumptions used are as follows:

·	2007	2006	2005	
Expected dividend yield	_	_	-	
Risk-free interest rate	4.35%	4.78%	3.94%	
Expected option term (in years)	5.1	5.0	5.0	•
Expected volatility	59.5%	63.0%	83.0%	

No dividend yield was assumed as the Company does not pay dividends on its common stock. The risk-free interest rate is based on the yield of U.S. Treasury securities consistent with the expected life of the option. The expected option life and expected volatility were determined by examining the expected option life and expected volatilities of similarly sized biotechnology companies as well as expected life and expected volatility of the Company's stock.

Share-based compensation expense recognized in the consolidated statements of operations for the years ended December 31, 2007 and 2006 is based on awards ultimately expected to vest and is reduced for estimated forfeitures. SFAS No. 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods as options vest, if actual forfeitures differ from those estimates. During the years ended December 31, 2007 and 2006, because substantially all of the Company's stock option grants vest monthly, stock-based employee compensation expense includes the actual impact of forfeitures. In the Company's pro forma information required under SFAS No. 123 for the periods prior to fiscal 2006, the Company accounted for forfeitures as they occurred.

The following table illustrates the effect on net loss and net loss per share as if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock options for employees for the year ended December 31, 2005:

Voor Ended

	Year Ended December 31, 2005
	(In thousands, except per share data)
Net loss — as reported	\$(50,777)
Add stock-based employee compensation expense included in reported net loss	1,388
Deduct stock-based compensation expense determined under fair value based method	(7,216)
Net loss — pro forma	<u>\$(56,605)</u>
Net loss per common share (basic and diluted)	
As reported	\$ (1.03)
Pro forma	(1.15)

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

### 13. Commitments and Contingencies

### Lease Arrangements

The Company leases its facilities and certain equipment under operating leases. The Company's lease arrangements have terms through the year 2017. Total rent expense under operating leases was approximately \$3,550,000, \$2,688,000 and, \$1,905,000 for the years ended December 31, 2007, 2006 and 2005, respectively. Future minimum payments under lease arrangements at December 31, 2007 are as follows:

Year Ending December 31,	Operating Leases
	(In thousands)
2008	\$ 3,228
2009	3,332
2010	2,322
2011	2,092
2012	2,049
2013 and thereafter	4,332
Total	<u>\$17,355</u>

In October 2003, the Company entered into an operating lease commitment for office and laboratory space in Cambridge, Massachusetts. The term of the lease is for ten years, expiring in December 2013. The lease agreement provided for a landlord allowance of \$1,561,000 to be paid to the Company to finance a portion of capital improvements to the facility. This landlord allowance was recorded as deferred rent which is being amortized as a reduction of rent over the ten-year lease term. In connection with this operating lease commitment, a commercial bank issued a letter of credit in October 2003 for \$750,000 collateralized by cash held with that bank. The letter of credit expires in December 2013.

In April 2005, the Company 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 after six years. The lease agreement also includes an option entitling the Company to purchase the building at any time after April 16, 2011. The purchase option extends until the expiration of the lease term.

In June 2005, the Company entered into a lease agreement for additional office space in Cambridge, Massachusetts. The Company entered into amendments to this lease agreement in July 2006 and September 2006 to lease additional office space in the same building. The term of the lease for all office space being rented under this lease agreement and its amendments expires in March 2010. The lease agreement also includes an option, exercisable by the Company not later than nine months prior to the expiration of the initial term, to extend the term of the lease for one additional 48-month period and with rights of first offer with respect to certain expansion space on two of the floors that the Company occupies. The Company also has been provided allowances totaling \$1,211,000 to finance a portion of capital improvements to the facility. These allowances have been recorded as deferred rent which is being amortized as a reduction of rent over the lease term. In connection with this operating lease commitment, a commercial bank issued a letter of credit in May 2005 for \$411,000 collateralized by cash we have on deposit with that bank. The letter of credit expires in May 2008.

### Legal Contingencies

### Hepatitis C Product Candidates

In May 2004, the Company and, in an individual capacity, its Chief Executive Officer ("CEO"), entered into a settlement agreement with UAB and its affiliate, UABRF, to resolve a dispute among these parties. In March 2004, the Company and, in an individual capacity, its CEO, filed a lawsuit against UABRF in the United States District

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Court, District of Massachusetts, seeking declaratory judgment regarding the Company's ownership of inventions and discoveries made during the period from November 1999 to November 2002 ("Leave Period") by the CEO and the Company's ownership of patents and patent applications related to such inventions and discoveries. During the Leave Period, while acting in the capacity of the Company's Chief Scientific Officer, the CEO was on sabbatical from November 1999 to November 2000 ("Sabbatical Period") and then unpaid leave prior to resigning in November 2002 from his position as a professor at UAB.

As a part of the settlement agreement, UAB and UABRF agreed that neither UAB nor UABRF has any right, title or ownership interest in the inventions and discoveries made or reduced to practice during the Leave Period or the related patents and patent applications. In exchange, the Company made a \$2,000,000 payment to UABRF in May 2004. The Company also dismissed the pending litigation and agreed to make certain future payments to UABRF. These future payments consist of: (i) a \$1,000,000 payment upon the receipt of regulatory approval to market and sell in the United States a product which relates to inventions and discoveries made by the CEO during the Sabbatical Period; and (ii) payments in an amount equal to 0.5% of worldwide net sales of such products with a minimum sales based payment to equal \$12,000,000. The sales based payments (including the minimum amount) are contingent upon the commercial launch of products that relate to inventions and discoveries made by the CEO during the Sabbatical Period. The minimum amount is due within seven years after the later of the commercial launch in the United States or any of the United Kingdom, France, Germany, Italy or Spain, of a product that: (i) has within its approved product label a use for the treatment of HCV; and (ii) relates to inventions and discoveries made by the CEO during the Sabbatical Period, if sales based payments for such product have not then exceeded \$12,000,000. At that time, the Company will be obligated to pay to UABRF the difference between the sales based payments then paid to date for such product and \$12,000,000. The Company has no amounts accrued or payable under this settlement agreement at December 31, 2007 as the Company has had no sales of products relating to these inventions and discoveries by the CEO.

### Hepatitis B Product

In addition to the Leave Period matter noted above, the Company was notified in January 2004, February 2005 and June 2005, that UABRF believes that patent applications which the Company has licensed from UABRF can be amended to obtain broad patent claims that would generally cover the method of using telbivudine to treat HBV. In July 2005, UABRF filed this continuation patent application.

In February 2006, UABRF notified the Company that it and Emory University were asserting a claim, that as a result of filing a continuation patent application in July 2005 by UABRF, the UAB license agreement covers the Company's telbivudine technology and that the Company is obligated to pay to UABRF, Emory University and Le Centre Nationale de la Recherché Scientifique ("CNRS") (collectively, the "1998 licensors") an aggregate of \$15,300,000, comprised of 20% of the \$75,000,000 license fee that the Company received from Novartis in May 2003 in connection with the license of its HBV product candidates and a \$300,000 payment in connection with the submission to the United States Food and Drug Administration ("FDA") of the investigational new drug application ("IND") pursuant to which the Company conducted its clinical trials of telbivudine. The Company disagrees with the assertion made by UABRF and Emory University and is actively defending against these assertions. Under the terms of the license agreement, the dispute will be resolved by arbitration under the rule of the American Arbitration Association before a panel of three arbitrators if the parties are unable to reach agreement after a period of negotiation and mediation. Pursuant to the terms of the dispute resolutions procedure in the UAB license agreement, in September 2007 the CEOs of UABRF and the Company met and agreed to begin a mediation process. Pursuant to the terms of the dispute resolution procedure in the UAB license agreement, in September 2007 the Company's CEO and the CEO of UABRF met and agreed to begin a mediation process. While the parties participated in a joint mediation session in January 2008, no resolution of these matters has yet been reached. However, a non-binding settlement proposal has been discussed by the parties. Such settlement proposal remains subject to several terms and conditions, including a full release of all claims by UABRF and related entities. The Company does not believe that the matters disputed by UABRF and Emory University regarding the UAB license

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS -- (Continued)

agreement will have any effect on either the cooperative agreement with CNRS and the University of Montpellier or the technology licenses, including the license for telbivudine, which have been granted to the Company pursuant to the cooperative agreement.

However, if we do not settle these disputes and it is determined that the license agreement does cover the Company's telbivudine technology, the Company will become obligated to make payments to the 1998 licensors in the amounts and manner specified in the license agreement. While the Company disputes the demands made by UABRF, even if liability were found to exist, UABRF's claims, in addition to those described above would likely include payments in the aggregate amount of \$1,000,000 due upon achievement of certain regulatory milestones, a 6% royalty on annual sales up to \$50,000,000 and a 3% royalty on annual sales greater than \$50,000,000 made by the Company or any affiliate of the Company. Additionally, if the Company sublicenses its rights to any entity other than one which holds or controls at least 50% of its capital stock, or if Novartis' ownership interest in the Company declines below 50% of the Company's outstanding shares of capital stock, UABRF would likely contend that the Company is obligated to pay to the 1998 licensors 30% of all royalties received on sales by the sublicensee of telbivudine and 20% of all fees, milestone payments and other cash consideration received from the sublicensee with respect to telbivudine.

In January 2007, the Board of Trustees of the University of Alabama and related entities filed a complaint in the United States District Court for the Northern District of Alabama, Southern Division against the Company, CNRS and the University of Montpellier. The complaint alleges that a former employee of UAB is a co-inventor of certain patents in the United States and corresponding foreign patent applications related to the use of \( \beta \- \text{L-2}' deoxy-nucleosides for the treatment of HBV assigned to one or more of the Company, CNRS and the University of Montpellier and which cover the use of Tyzeka®/Sebivo® for the treatment of HBV. The University of Alabama has included a demand for damages under various theories in its complaint, but did not specify the amount of damages that it alleges to have incurred. In response to the complaint in March 2007, the Company filed a motion to dismiss pased upon lack of personal jurisdiction. In September 2007, the parties agreed to stay the action and pursue nediation relating to the disputes associated with the license agreement and this litigation. As a result of a joint mediation session held in January 2008, a non-binding settlement has been proposed by the parties which could potentially require the Company to make payments to UABRF and related entities. The Company has assessed this settlement proposal under the provisions of FAS 5, and recorded a related liability for the quarter ended December 31, 2007. If the proposed settlement is not completed on terms acceptable to the Company, the Company will resume its defense of these claims, including through the litigation process. Accruals related to the ettlement proposal may be adjusted in future periods if a settlement agreement is not reached. The Company cannot ascertain with certainty the likelihood this or any settlement proposal will be accepted by or entered into by he parties. If the Company is not able to reach a settlement agreement with the parties, it will continue to vigorously defend against claims made by UABRF and related entities.

### ndemnification

The Company has agreed to indemnify Novartis and its affiliates against losses suffered as a result of any preach of representations and warranties in the Development Agreement. Under the Development Agreement and he stock purchase agreement (the "Stock Purchase Agreement"), the Company made numerous representations and warranties to Novartis regarding its HBV and HCV product candidates, including representations regarding the Company's ownership of the inventions and discoveries described above. If one or more of the representations or varranties were not true at the time they were made to Novartis, the Company would be in breach of one or both of hese agreements. In the event of a breach by the Company, Novartis has the right to seek indemnification from the Company and, under certain circumstances, the Company and its stockholders who sold shares to Novartis, which include many of its directors and officers, for damages suffered by Novartis as a result of such breach. While it is possible that the Company may be required to make payments pursuant to the indemnification obligations it has under the Development Agreement, the Company cannot reasonably estimate the amount of such payments or the itselfihood that such payments would be required.

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS -- (Continued)

### 14. Income Taxes

The components of loss before income taxes and of income tax expense (benefit) for the years ended December 31, 2007, 2006 and 2005 are as follows:

<b>United 5.1, 2007, 2000 and 2000</b>	2	007		006 ousands)	2	005
Loss before income taxes						
U.S	\$(8	2,210)	\$(6	1,877)	\$(2	6,400)
Foreign		193	(1	<u>4,355</u> )	(2	5,091)
	<u>\$(8</u>	<u>2,017</u> )	<u>\$(7</u>	6,232)	\$(5	<u>1,491</u> )
Income tax expense (benefit)					`	
Current						
Federal — U.S	\$	(257)	\$	(48)	\$	
State — U.S		176		135		51
Foreign		<u> 579</u>	(	1,232)	_	(765)
-		498	(	1,145)		(714)
Deferred						
Federal — U.S	\$	_	\$	_	\$	
State — U.S		_		_		_
Foreign						
Total income tax expense (benefit)	\$	498	\$ (	<u>(1,145</u> )	\$	(714)

The Company's recognized income tax expense (benefit) consists of amounts incurred by the Company and its U.S. and various foreign subsidiaries. The foreign income tax expense in 2007 was due to \$1,400,000 of expense recorded as a result of re-assessing an uncertain tax position related to the Company's international operations offset by French research and development credits. The foreign income tax benefits in 2006 and 2005 were due to amounts that the Company's French subsidiary has received or is expected to receive for certain research and development credits. Foreign subsidiaries performed services for the Company and are reimbursed for these costs, plus a profit margin.

Under current laws of the Cayman Islands, there are no income or other Cayman Island taxes payable by the Company, its Cayman Island subsidiary or the Company's stockholders and therefore there are no Cayman Island loss carryforwards available to offset future taxes. Since the domestication of the Company to the United States in May 2002, losses incurred by the Company have been shared between the Company and its Cayman subsidiary with losses incurred in the United States available to offset future taxes. As a result of an election to treat the Cayman subsidiary as part of the U.S. tax group, all losses incurred by the Cayman subsidiary after July 31, 2006 will be attributed to the United States.

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The components of the Company's net deferred taxes were as follows at December 31:

	2007	2006
	(In tho	usands)
Depreciation	\$ 132	\$ (337)
Development contracts	1,909	2,740
Nonqualified stock options	3,350	1,788
Deferred licensing income	16,320	10,644
Accrued expenses and other	3,586	1,244
Capitalized research costs	28,842	32,986
Research and development credits	5,555	5,555
Foreign tax credit carryforward	1,326	877
Net operating carryforwards	64,204	41,045
Valuation allowance	(125,224)	(96,542)
Deferred tax asset	<u>\$</u>	<u>\$ —</u>

The Company's effective income tax rate differs from the statutory federal income tax rate as follows:

	2007	2006	2005
Federal statutory rate benefit	(34)%	(34)%	(34)%
Foreign tax expense (benefit)	_	(1)	(2)
State tax benefit, net of federal benefit	(4)	(10)	(6)
Permanent items	ì	(35)	(13)
Foreign rate differentials	_	7	17
Valuation allowance	38	<u>72</u>	37
Effective income tax rate	_1%	<u>(1</u> )%	<u>(1</u> )%

As of December 31, 2007, the Company had U.S. federal and state net operating loss carryforwards of approximately \$156,000,000 and \$187,000,000 respectively, which may be available to offset future federal and state income tax liabilities. The federal net operating loss carryforwards begin to expire in 2022 and the state net operating loss carryforwards begin to expire in 2008. The Company has foreign net operating loss carryforwards of approximately \$4,300,000, which have no expiration date. Approximately \$7,400,000 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. The Company has federal and state tax credits of approximately \$4,622,000 and \$2,759,000, respectively. The federal research and development credits begin to expire in 2022, and the state credits begin to expire in 2016. The Company also has foreign tax credit carryforwards of \$1,326,000, which begin to expire in 2016.

During the year ended December 31, 2005, the Company filed elections with the Internal Revenue Service to capitalize various research and development expenses incurred by the Company prior to its domestication in the United States for tax years ending December 31, 1998 through May 30, 2002. The effect of these elections is that the Company inherited tax basis as a result of its domestication transaction in May 2002 and is required to amortize these costs over a ten year period. Included in the company's net deferred tax assets is \$4,370,000 relating to these costs.

During the year ended December 31, 2006, the Company filed an election with the Internal Revenue Service to treat the Cayman Island subsidiary as a disregarded entity for tax purposes. The result of this election produced a taxable dividend in the amount of \$31,963,000. Due to the size of the taxable loss in the current year, this dividend did not create a tax liability for tax purposes. As a result of the election, approximately, \$80,000,000 of tax basis

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

relating to previously capitalized research costs carried over into the U.S. tax group. This increase is reflected in the capitalized research costs line of the net deferred taxes schedule.

As required by SFAS No. 109 "Accounting for Income Taxes" ("SFAS No. 109") management of the Company has evaluated the positive and negative evidence bearing upon the realization of its 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 the Company will not realize the benefits of federal, state and foreign deferred tax assets and, as a result, a valuation allowance of \$125,224,000 has been established at December 31, 2007.

Due to the extent of international transactions in which the Company is engaged, there is a risk that tax authorities in the US or other jurisdictions in which the Company conducts business could challenge the nature of these transactions. The Company periodically assesses its exposures related to the provision for income taxes and appropriately accrues taxes for contingencies that may result in potential tax obligations. The Company believes the accruals are necessary to appropriately reflect tax obligations that may arise out of current and future audits. The ultimate resolution of tax matters is unpredictable and could result in tax liabilities that differ significantly from the amounts which have been provided by the Company.

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.

In June 2006, the FASB published FIN No. 48. This Interpretation seeks to reduce the significant diversity in practice associated with recognition and measurement in the accounting for income taxes. It applies to all tax positions reported in accordance with SFAS 109. FIN No. 48 requires that a tax position meet "a more likely than not" threshold for the benefit of the uncertain tax position to be recognized in the financial statements. This threshold is to be met assuming that the tax authorities will examine the uncertain tax position. FIN No. 48 contains guidance with respect to the measurement of the benefit that is recognized for an uncertain tax position, when that benefit should be derecognized, and other matters. The Company has adopted the provisions of FIN No. 48 effective January 1, 2007.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

Balance at January 1, 2007	\$ 7,934
Additions based on tax positions related to the current period	459
Additions for tax positions of prior periods	1,324
Reductions for tax positions for closing of statute of limitations	(6,877)
Settlements	
Balance at December 31, 2007	\$ 2,840

The total amount of unrecognized tax benefits was \$7,934,000 and \$2,840,000 at January 1, 2007 and December 31, 2007, respectively. Of this amount, \$1,416,000 will impact the effective tax rate if ultimately realized and \$1,424,000 would be offset be an increase in the valuation allowance on deferred tax assets. Upon adoption of FIN No. 48, the Company has recorded an adjustment of \$300,000 to decrease its opening retained earnings and \$7,400,000 as a reduction of gross deferred tax assets since the Company's gross deferred tax assets have been offset by a valuation allowance, this amount has not been reflected in the Company's financial statements.

During the fourth quarter of 2007, the Company re-assessed an uncertain tax position related to its international operations. As a result, the Company recorded \$1,800,000 of expense associated with this uncertain tax position including \$1,280,000 associated with prior years which consisted of expense, interest and penalties. Of the total charge recorded, \$415,000 was classified in investment and other income, net consistent with the Company's policy for classification of interest and penalties. The Company determined that the amount related to prior years

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

was not material to its 2007 results. If estimates related to this matter change, this amount may be adjusted accordingly in future periods.

The open tax years by major jurisdiction are: (1) the years ended December 31, 2004 through 2006 for the United States and (2) the years ended December 31, 2005 and 2006 for France.

During the year ended December 31, 2007, an uncertain tax position relating to the tax year ended December 31, 2003 has been reversed due to the closing of the statute of limitations. The effect of this adjustment was to increase the federal income tax benefit by \$273,000 and increase the gross deferred tax assets by \$6,600,000.

As of January 1, 2007, the Company had accrued \$343,000 of interest and penalties relating to uncertain tax positions. During the fourth quarter of 2007, the Company accrued \$415,000 of interest and penalties related to an uncertain tax position. The Company accounts for interest and penalties related to its uncertain tax positions as part of investment and other income, net.

#### 15. Employee Benefit Plans

The Company maintains a retirement savings plan under Section 401(k) of the Internal Revenue Code ("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 U.S. employees of the Company who meet minimum age and service requirements.

Contributions to the 401(k) Plan may be made by the Company at the discretion of the Board of Directors. In December 2006, the Board of Directors authorized a resolution requiring the Company to match 25% of employee contributions up to 6% of participants' annual compensation beginning in 2007. The Company made contributions totaling \$213,000 to the 401(k) Plan in December 31, 2007.

The Company is required by statute to maintain a defined benefit plan for its employees in France. The Company has recorded \$205,000 in long-term obligations for the liability associated with this benefit plan.

#### 16. Related Party Transactions

In connection with the Development Agreement entered into between the Company and Novartis, the Company has generated revenues from Novartis from license payments and reimbursements of certain research and development expenses in the amount of \$64,751,000, \$66,724,000 and \$64,418,000 for the years ended December 31, 2007, 2006 and 2005, respectively. All amounts included in receivables from related party at December 31, 2007 and 2006 are due from Novartis. The amount included in payables to related party of \$939,000 to Novartis at December 31, 2006 represents amounts owing to Novartis for marketing costs and profit-sharing arrangements in connection with the Company's collaboration with Novartis. The Company also included \$50,233,000, \$53,961,000 and \$38,784,000 in deferred revenue as of December 31, 2007, 2006 and 2005, respectively, relating to license fees received from Novartis.

In connection with the 2007 Amendment, the Company transferred its inventory of Tyzeka® (approximately \$836,000) and outstanding accounts receivable (approximately \$744,000) to Novartis in October 2007. In December 2007, Novartis paid the Company approximately \$1,580,000 for the full value of the assets transferred. Novartis has the right to recover any payment made to the Company for inventory that is not sold by Novartis before its expiration date. At December 31, 2007, the Company believes that the inventory purchased by Novartis will be sold prior to its expiration date.

Effective May 31, 2004 to June 7, 2005, the Company had on its board of directors a partner in the law firm of Wilmer Cutler Pickering Hale and Dorr LLP. The Company retains Wilmer Cutler Pickering Hale and Dorr LLP as its corporate counsel. The Company incurred legal expenses of \$120,000 during the year ended December 31, 2005 for services rendered by Wilmer Cutler Pickering Hale and Dorr LLP during the period in which such law firm partner was on the Company's Board of Directors. The partner is no longer on the Company's Board of Directors.

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## 17. Segment Reporting

The Company operates in a single segment and has no organizational structure dictated by product lines, geography or customer type. The following table presents total long-lived assets by geographic area as of December 31, 2007 and 2006:

	2007	2006
	(In tho	usands)
United States	\$11,530	\$14,198
Europe	3,930	3,250
	\$15,460	\$17,448

## 18. Licensing Agreements

#### **UAB Research Foundation**

In June 1998, the Company entered into an exclusive license agreement with UABRF pursuant to which the Company acquired the rights to use and commercialize, including by means of sublicense, certain technology and to make, use or sell licensed products. The agreement was subsequently amended in June 1998 and July 1999. The Company made a nonrefundable \$100,000 license fee payment to UABRF in 1998 which was recorded as research and development expense.

The agreement requires the Company to make, for each significant disease indication for which licensed technology is used, payments aggregating \$1,300,000 if certain regulatory milestones are met. Of such amount, two-thirds is payable in cash and one-third is payable in shares of the Company's common stock. Additionally, if commercialization is achieved for a licensed product, the Company will be required to pay a royalty with respect to annual net sales of licensed products by the Company or an affiliate of the Company at the rate of 6% for net sales up to \$50,000,000 and at the rate of 3% for net sales in excess of \$50,000,000. If the Company enters into a sublicense arrangement with an entity other than one which controls at least 50% of the Company's capital stock, the Company would be required to remit to UABRF 30% of all royalties received by the Company on sales of the licensed product by the sublicensee. The Company is also required to pay to UABRF 20% of all license fees, milestone payments and other cash consideration the Company receives from the sublicensee with respect to the licensed products. The Company is required to reimburse UABRF for costs UABRF incurs in connection with the prosecution, maintenance and protection of patent applications and patents associated with the licensed technology.

## 19. Collaborative Agreements and Contracts

## Le Centre National de la Recherche Scientifique and L'Universite Montpellier II

Effective January 1, 1999, the Company entered into a Cooperative Agreement with Le Centre National de la Recherche Scientifique ("CNRS") and L'Universite Montpellier II ("University of Montpellier") pursuant to which the Company acquired a license to certain antiviral technology. The Company is required to make royalty payments to the University of Montpellier upon commercialization of any products resulting from the licensed technology, which technology covers telbivudine among other things. The Company was also required to provide personnel and is required to make payments to the University of Montpellier for supplies and improvement and use of the facilities. The Company incurred expenses of approximately \$215,000 and \$221,000 for the years ended December 31, 2006 and 2005, respectively, in connection with this agreement. This agreement expired in December 2006 but the Company retains rights to exploit the patents derived from the collaboration.

#### Universita di Cagliari

In January 1999, the Company entered into a Cooperative Antiviral Research Activity Agreement, as amended with the Dipartimento di Biologia Sperimentale "Bernardo Loddo" dell'Universita di Cagliari ("University of

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

Cagliari") pursuant to which the Company acquired an exclusive license to certain antiviral technology. The Company is required to make royalty payments to the University of Cagliari upon commercialization of any products resulting from the licensed technology. The Company is also required to provide personnel and to make payments to the University of Cagliari for services rendered by the University of Cagliari and for use of its facility. The term of this agreement extends through January 2011. The Company incurred expenses of approximately \$230,000, \$267,000 and \$122,000 for the years ended December 31, 2007, 2006 and 2005, respectively, in connection with this agreement.

In December 2000, the Company and University of Cagliari also entered into a license agreement pursuant to which the Company was granted an exclusive license under certain patent rights resulting from specified research activities. In May 2003, the Company, 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 the Company's rights under the agreement if the agreement terminates due to an uncured breach of the agreement by the Company. In October 2005, the Company and the University of Cagliari amended such agreements in a manner that will require certain payments to the University of Cagliari if the Company receives license fees or milestone payments in connection with a sublicense by the Company of technology covered by the agreements between the University of Cagliari and the Company. As a result of the license by Novartis of valopicitabine and the payment of a \$25,000,000 license fee to the Company (Note 3), the Company made a payment to the University of Cagliari in the amount of \$250,000 in the quarter ended June 30, 2006. The payment has been recorded as deferred license fees and is being amortized to expense on a straight-line basis over the related development period.

### Sumitomo Pharmaceuticals Co., Ltd.

The Company entered into collaborative agreements with Sumitomo Pharmaceuticals Co., Ltd. ("Sumitomo") in 2001, in connection with the development and commercialization in the territories of Japan, the People's Republic of China ("China"), the Republic of China ("Taiwan") and the Republic of Korea ("South Korea") of telbivudine, a product candidate for the treatment of HBV infection at that time. In connection with this arrangement, the Company and Sumitomo agreed to share certain direct third-party expenses of development of telbivudine.

In March 2003, the Company 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 the Company. This agreement with Sumitomo became effective upon consummation of the Company's collaboration with Novartis in May 2003. The Company repurchased these product rights for \$5,000,000 and as a result of this payment the Company reversed approximately \$4,571,000 of revenue previously recognized in original arrangements with Sumitomo with the remaining amount recorded as a reduction of deferred revenue.

The Company also has recorded \$4,272,000 included in deferred revenue on its consolidated balance sheet at each of December 31, 2007 and 2006 representing amounts received from Sumitomo that have not been included in revenue to date. The Company must pay an additional \$5,000,000 to Sumitomo upon the first commercial sale of telbivudine in Japan. This payment will be recorded first as a reduction of the remaining \$4,272,000 of deferred revenue, with the excess recorded as an expense. If regulatory approval is not received for telbivudine in Japan, the Company would have no further obligations under the settlement agreement with Sumitomo and, therefore, the \$4,272,000 of remaining deferred revenue would be recognized as revenue at that time.

### Microbiologica Quimica E Farmaceutica Ltda

In May 2003, the Company finalized an agreement with Microbiologica Quimica E Farmaceutica Ltda. ("Microbiologica") in which Microbiologica granted to the Company a license to use certain of Microbiologica's manufacturing technology and patents for the treatment of hepatitis B infection. The Company is obligated to pay

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Microbiologica \$7,000,000 in total for this license. The Company is required to pay the license fee over a five-year period commencing in January 2004 with a payment of \$2,000,000 and continuing each year thereafter through January 2009 with annual payments each in the amount of \$1,000,000. Since there was no alternative use for this technology, the net present value of these payments using an implied interest rate of 3.63% was approximately \$6,300,000 and was recorded as research and development expense during the year ended December 31, 2003. The Company has a liability of \$1,964,000 and \$2,895,000 under this agreement as of December 31, 2007 and 2006, respectively.

## Metabasis Therapeutics, Inc.

In October 2006, the Company entered into a two-year research collaboration agreement with Metabasis Therapeutics, Inc. ("Metabasis"). Under the terms of the agreement, Metabasis' proprietary liver-targeted technology was to be applied to certain of the Company's compounds to develop second-generation nucleoside analog product candidates for the treatment of HCV. As part of the agreement, the Company provided a \$2,000,000 upfront payment to Metabasis in November 2006 and would provide certain amounts of development funding. Including the upfront payment, the Company has incurred \$1,299,000 and \$2,110,000 in research and development expenses related to this collaboration during the years ended December 31, 2007 and 2006. If a lead candidate was identified, the Company would have assumed development responsibility and Metabasis would have been eligible to receive payments upon achievement of predetermined clinical development and regulatory milestones. For any resulting marketed products, the Company would have retained full commercial rights and pay Metabasis a royalty based on net sales of the product.

In July 2007, the Company notified Metabasis that it would exercise its option to terminate the research collaboration on the first anniversary of the agreement in October 2007. Prior to the termination of the agreement, Metabasis asserted that a certain scientific milestone was met and thus a \$1,000,000 payment under the collaboration agreement came due. The Company does not agree with Metabasis' assessment that the scientific milestone has been met and therefore does not believe that it has any liability for this payment and has so notified Metabasis.

### 20. Quarterly Financial Data (Unaudited)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total Year
		(In thousands	, except per sh	are amounts)	
2007					
Total revenues	\$ 24,806	\$ 19,732	\$ 10,888	\$ 12,602	\$ 68,028
Total operating expenses	38,464	44,574	43,530	33,364	159,932
Net loss	(11,569)	(22,902)	(30,549)	(17,495)	(82,515)
Basic and diluted net loss per common share	(0.21)	(0.41)	(0.54)	(0.31)	(1.47)
2006					
Total revenues	\$ 13,111	\$ 19,313	\$ 19,645	\$ 15,308	\$ 67,377
Total operating expenses	32,708	37,025	42,007	41,356	153,096
Net loss	(17,182)	(14,609)	(19,715)	(23,581)	(75,087)
Basic and diluted net loss per common share	(0.31)	(0.26)	(0.35)	(0.42)	(1.34)

#### 21. Recent Accounting Pronouncements

In September 2006, FASB Statement No. 157, "Fair Value Measurements," ("SFAS No. 157") was issued. This statement defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles in the United States ("GAAP") and expands disclosures about fair value measurements. This statement applies under other accounting pronouncements that require or permit fair value measurements, the

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

FASB having previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Accordingly, this statement does not require any new fair value measurements. However, for some entities, the application of this Statement will change current practice. The statement is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually) which SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2008 and interim periods within those fiscal years. The Company is currently evaluating the impact, if any, that this standard will have on its financial statements.

In February 2008, the FASB issued FASB Staff Position No. FAS 157-2, "Effective Date of FASB Statement No. 157" or FSP FAS 157-2. FSP FAS 157-2 defers the effective date provision of SFAS 157 for certain non-financial assets and liabilities until fiscal years beginning after November 15, 2008. The Company is currently evaluating the impact of adopting SFAS 157 on its financial statements.

In February 2007, FASB Statement No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities" ("SFAS No. 159") was issued. SFAS No. 159 includes an amendment of FASB Statement No. 115, "Accounting for Certain Investments in Debt and Equity Securities" and permits entities to choose, at specified election dates, to measure eligible items at fair value and requires unrealized gains and losses on items for which the fair value option has been elected to be reported in earnings. This Statement is effective for fiscal years beginning after November 15, 2007. The Company is currently evaluating the impact, if any, that this standard will have on its financial statements.

In June 2007, EITF Issue No. 07-03, "Accounting for Nonrefundable Advance Payment for Goods and Services Received for Use in Future Research and Development Activities" ("EITF 07-03") was issued. EITF 07-03 provides guidance on whether nonrefundable advance payments for goods and services that will be used in research and development activities should be expensed when the advance payment is made or when the research and development activity has been performed. EITF 07-03 is effective for fiscal years beginning after December 15, 2007. The Company is currently evaluating the impact, if any, that this standard will have on its financial statements.

On December 12, 2007, EITF Issue No. 07-01, "Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property", or EITF 07-01, was issued. EITF- 07-01 prescribes the accounting for collaborations. It requires certain transactions between collaborators to be recorded in the income statement on either a gross or net basis within expenses when certain characteristics exist in the collaboration relationship. EITF 07-01 is effective for all of the Company's collaborations existing after January 1, 2009. The Company is evaluating the impact this standard will have on its financial statements.

### **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.

/s/ JEAN-PIERRE SOMMADOSSI

Jean-Pierre Sommadossi
Chairman and Chief Executive Officer

Date: March 14, 2008

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>	Date
/s/ Jean-Pierre Sommadossi  Jean-Pierre Sommadossi	Chairman, Chief Executive Officer and Director (Principal Executive Officer)	March 14, 2008
/s/ RONALD C. RENAUD, Jr. Ronald C. Renaud, Jr.	Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 14, 2008
/s/ CHARLES CRAMB Charles Cramb	Director	March 14, 2008
/s/ Wayne Hockmeyer Wayne Hockmeyer	Director	March 14, 2008
/s/ Thomas Hodgson Thomas Hodgson	Director	March 14, 2008
/s/ Norman Payson Norman Payson	Director	March 14, 2008
/s/ ROBERT PELZER Robert Pelzer	Director	March 14, 2008
/s/ Denise Pollard-Knight  Denise Pollard-Knight	Director	March 14, 2008
/s/ EMMANUEL PUGINIER Emmanuel Puginier	Director	March 14, 2008
/s/ Pamela Thomas-Graham Pamela Thomas-Graham	Director	March 14, 2008
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# **EXHIBIT INDEX**

Incorporated by Reference to

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

Incorporat	ed by I	Reference	e to
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Exhibit Number	<b>Description</b>	Form	Exhibit No.	Filing Date	SEC File Number
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
	Material contracts Novartis				
10.10	Letter Agreement, dated as of March 21, 2003, by and between the Registrant and Novartis Pharma AG	S-1 Amendment 3	10.28	7/6/2004	333-111157
10.11+	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
10.12+	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-I	10.18	12/15/2003	333-111157
10.13+	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	10.24	12/15/2003	333-111157
10.14+	Master Manufacturing and Supply Agreement, dated as of May 8, 2003, by and between Idenix (Cayman) Limited and Novartis Pharma AG	S-1	10.25	12/15/2003	333-111157
10.15+	Second Amendment, dated as of December 21, 2004, to the Development, License and Commercialization Agreement, by and among the Registrant, Idenix (Cayman) Limited and Novartis Pharma AG, as amended on April 30, 2004	10-K for 12/31/2004	10.16	3/17/2005	000-49839
10.16+	Amendment No. 3 to the Development, License and Commercialization Agreement, effective as of February 27, 2006, by and among the Registrant, Idenix (Cayman) Limited and Novartis Pharma AG	10-K for 12/31/2005	10 .14	3/16/2006	000-49839
10.17+	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+	Transition Services Agreement, dated as of September 28, 2007, by and among the Registrant, Idenix (Cayman) Limited and Novartis Pharma AG	10-Q for 9/30/2007	10 .2	11/8/2007	000-49839

I	ncor	porated	by	Ref	erence	to

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Exhibit Number	Description	Form	Exhibit No.	Filing Date	SEC File Number
10.19	Amended and Restated Stockholders' Agreement, dated July 27, 2004, by and among the Registrant, Novartis and the stockholders identified on the signature pages thereto	10-K for 12/31/2004	10.20	3/17/2005	000-49839
10.20	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
10.21+	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
10.22	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
10.23+	Commercial Manufacturing Agreement dated as of June 22, 2006 by and between the Registrant and Novartis Pharma AG	10-Q for 6/30/2006	10.1	8/8/2006	000-49839
10.24+	Packaging Agreement dated as of June 22, 2006 by and between the Registrant and Novartis Pharma AG	10-Q for 6/30/2006	10.2	8/8/2006	000-49839
	University of Cagliari				
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 Agreement, dated March 22, 2004, by and between the Registrant and the University of Cagliari, as amended June 30, 2004 (English translation)	S-1 Amendment 3	10.18.2	7/6/2004	333-111157
10.30+	Agreement, dated October 24, 2005, by and among the Registrant, Idenix SARL and the Universita deqli Studi Cagliari,	10-Q for 9/30/2005	10.1	11/08/2005	000-49839

Incorporated	by	Reference to
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		Incorporated by Reference to			
Exhibit Number	<u>Description</u>	Form	Exhibit No.	Filing Date	SEC File Number
	Miscellaneous				
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	1/27/2004	333-111157
10.32	Master Services Agreement, dated February 25, 2003, by and between the Registrant and Quintiles, Inc.	S-1	10.20	12/15/2003	333-111157
10.33+	Master Services Agreement, dated May 27, 1999, between Idenix (Massachusetts), Inc. and Quintiles Scotland Ltd	S-1	10.21	12/15/2003	333-111157
10.34+	License Agreement, dated as of June 20, 1998, by and among the Registrant, TherapX Pharmaceuticals, L.L.C. and Raymond Schinazi	S-1	10.15	12/15/2003	333-111157
10.35	Multiproject Development and Supply Agreement, dated as of December 20, 2001, by and among the Registrant, Idenix SARL and Clariant Life Science Molecules (Missouri) Inc.	S-1	10.22	12/15/2003	333-111157
10.36+	Agreement, dated as of May 1, 2003, between Idenix (Cayman Limited and Microbiologica Quimica E Farmaceutica Ltda.	S-1 Amendment 3	10.23	7/6/2004	333-111157
10.37	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
10.38	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	5/28/2004	333-111157
	Material contracts — management contracts and compensatory plans				
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
10.41#	Form of Non-Statutory Stock Option Agreement for awards granted pursuant to the 2005 Stock Incentive Plan, as amended	8-K	10.3	6/13/2005	000-49839
10.41#	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

		Incorporated by Reference to				
Exhibit Number	Description	Form '	Exhibit No.	Filing Date	SEC File Number	
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#	2005 Stock Incentive Plan	8-K	10.4	6/13/2005	000-49839	
10.44#	2004 Stock Incentive Plan	S-1 Amendment 2	10.32	5/28/2004	333-111157	
10.45#	Amended and Restated 1998 Equity Incentive Plan	S-1 Amendment 2	10.1	5/28/2004	333-111157	
10.46#	Employment Agreement, dated as of May 6, 2003, by and between the Registrant and Jean-Pierre Sommadossi	S-1	10.5	12/15/2003	333-111157	
10.47#	Employment Agreement, dated July 28, 2003, by and between the Registrant and Guy Macdonald	S-1	10.10	12/15/2003	333-111157	
10.48#	Letter Agreement, dated September 1, 2006, by and between the Registrant and Guy Macdonald	8-K	10.3	9/8/2006	000-49839	
10.49#	Letter Agreement, dated October 19, 2007, by and between the Registrant and Guy Macdonald	8-K	10 .1	10/22/2007	000-49839	
10.50#	Summary of Relocation Adjustment, effective as of December 8, 2005, between the Registrant and Guy Macdonald	10-K for 12/31/2005	10.48	3/16/2006	000-49839	
10.51#	Employment Letter, dated August 18, 2006, by and between the Registrant and John Weidenbruch	8-K	10.1	9/8/2006	000-49839	
10.52#	Employment Letter, dated January 7, 2007, by and between the Registrant and Douglas L. Mayers, M.D.	8-K	10.1	5/8/2007	000-49839	
10.53#	Employment Letter, dated June 13, 2007, by and between the Registrant and Ronald C. Renaud, Jr.	8-K	10.1	6/19/2007	000-49839	
	Additional Exhibits					
21.1	Subsidiaries of the Company	*				
23.1	Consent of PricewaterhouseCoopers LLP, an independent registered public accounting firm	*		·		
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended	*				
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended	*				

Incorporated by Reference to

		Incorporated by Reference to				
Exhibit Number	<u>Description</u>		Form	Exhibit No.	Filing Date	SEC File Number
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	*				

<sup>\*</sup> File herewith

<sup>#</sup> 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

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

















# FORWARD-LOOKING STATEMENTS

This annual report contains "forward-looking statements" within the meaning of The Private Securities Litigation Reform Act of 1995. Such forward-looking statements can be identified by the use of forward-looking terminology such as "expect," "may," "plans," "anticipates," "preliminary," "will," or similar expressions, or by express or implied statements with respect to the company's clinical development programs or commercialization activities in HIV or hepatitis C, or any potential pipeline candidates and expectations with respect to additional milestone payments, potential payments related to a settlement proposal, assessment of uncertain tax positions and cash balances at the end of 2008. 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. There can be no guarantees that historical sales of Tyzeka/Sebivo will in any way suggest future royalty payments or royalty rates owed to the company, or 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. In particular, management's expectations could be affected by unexpected regulatory actions of 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 dependence on its collaboration with Novartis Pharma AG; 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. These and other risks which may impact management's expectations are described in greater detail under the caption "Risk Factors" in the company's annual report on Form 10-K for the year ended December 31, 2007 as filed with the Securities and Exchange Commission (SEC) and other fillings that the company makes with the SEC.





















**END**