

ACHILLION PHARMACEUTICALS INC

Form 10-K

March 27, 2009

[Table of Contents](#)

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

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

**For the fiscal year ended December 31, 2008**

**OR**

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

**For the transition period from            to**

**Commission File Number 001-33095**

**ACHILLION PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

Edgar Filing: ACHILLION PHARMACEUTICALS INC - Form 10-K

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

**52-2113479**  
(I.R.S. Employer  
Identification No.)

**300 George Street, New Haven, CT 06511**

(Address of principal executive offices) (Zip Code)

**Registrant's telephone number, including area code: (203) 724-6000**

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

**Title of Class**  
**Common Stock, \$0.001 par value per share**

**Name of Exchange on Which Registered**  
**NASDAQ Global Market**

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

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

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

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

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

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

Large accelerated filer ☐  
Non-accelerated filer ☐  
(Do not check if smaller

Accelerated filer ☐  
Smaller reporting company ☒

reporting company)

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

The aggregate market value of the voting stock held by non-affiliates of the Registrant on June 30, 2008 was approximately \$34,920,359.1 based on the closing price of such stock as reported by the NASDAQ Global Market on June 30, 2008.

As of March 16, 2009, the registrant had 26,398,527 shares of Common Stock, \$0.001 par value per share, outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Items 10, 11, 12, 13 and 14 of Part III (except for information required with respect to our executive officers, which is set forth under Part I, Item 1 Business Executive Officers of the Registrant ) and the information required by Item 5 relating to our equity compensation plans have been omitted from this report, as we expect to file with the Securities and Exchange Commission, not later than 120 days after the close of our fiscal year ended December 31, 2008, a definitive proxy statement for our annual meeting of stockholders to be held on June 3, 2009. The information required by Items 10, 11, 12, 13 and 14 of Part III and the information required by Item 5 relating to our equity compensation plans, which will appear in our definitive proxy statement, are incorporated by reference into this report.

This document (excluding exhibits) contains 95 pages.

**Table of Contents**

**TABLE OF CONTENTS**

<b><u>PART I</u></b>	1
<u>Item 1. Business</u>	1
<u>Executive Officers of the Registrant</u>	24
<u>Item 1A. Risk Factors</u>	26
<u>Item 1B. Unresolved Staff Comments</u>	44
<u>Item 2. Properties</u>	44
<u>Item 3. Legal Proceedings</u>	44
<u>Item 4. Submission of Matters to a Vote of Security Holders</u>	44
<b><u>PART II</u></b>	45
<u>Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	45
<u>Item 6. Selected Financial Data</u>	48
<u>Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	49
<u>Item 7A. Quantitative and Qualitative Disclosures About Market Risk</u>	64
<u>Item 8. Financial Statements and Supplementary Data</u>	64
<u>Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	64
<u>Item 9A. Controls and Procedures</u>	64
<u>Item 9B. Other Information</u>	65
<b><u>PART III</u></b>	66
<u>Item 10. Directors, Executive Officers and Corporate Governance of the Registrant</u>	66
<u>Item 11. Executive Compensation</u>	66
<u>Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	66
<u>Item 13. Certain Relationships and Related Transactions, and Director Independence</u>	66
<u>Item 14. Principal Accountant Fees and Services</u>	66
<b><u>PART IV</u></b>	67
<u>Item 15. Exhibits and Financial Statement Schedules</u>	67
<u>Signatures</u>	68

## **Table of Contents**

*This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, that involve risks and uncertainties. All statements other than statements relating to historical matters (including statements to the effect that we believe, expect, anticipate, plan, target, intend and similar expressions) should be considered forward-looking statements. Our actual results could differ materially from those discussed in the forward-looking statements as a result of a number of important factors, including the factors discussed in this section and elsewhere in this Annual Report on Form 10-K, including those discussed in Item 1A of this report under the heading Risk Factors, and the risks discussed in our other filings with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis, judgment, belief or expectation only as of the date hereof. We assume no obligation to update these forward-looking statements to reflect events or circumstances that arise after the date hereof.*

## **PART I**

### **ITEM 1. BUSINESS**

#### **Overview**

We are a biopharmaceutical company focused on the discovery, development and commercialization of innovative treatments for infectious diseases. Within the anti-infective market, we are currently concentrating on the development of antivirals for the treatment of chronic hepatitis C and the development of antibacterials for the treatment of resistant bacterial infections. We are currently focusing our efforts on advancing two late-stage preclinical candidates: ACH-1095, an NS4A antagonist for the treatment of chronic hepatitis C, being developed in collaboration with Gilead Sciences, Inc. ( Gilead ), and ACH-1625, a protease inhibitor also for the treatment of chronic hepatitis C. In addition, we have a pipeline of other product candidates for which we are currently seeking appropriate collaborative partners or for which we are considering whether to seek appropriate collaborative partners but to which we are not devoting significant resources at this time. These product candidates include elvucitabine for the treatment of HIV infection and ACH-702 for the treatment of serious bacterial infections.

We believe that there are several business advantages to developing anti-infective drugs as compared to developing drugs in other therapeutic areas. The emergence of drug resistance seen with current antiviral and antibacterial therapy creates a continuing need for new drugs, which we believe provides us with a large and growing business opportunity.

We have established our current drug candidate pipeline primarily through our internal discovery capabilities except for elvucitabine, which we in-license. Through both these efforts we have identified and are developing the following drug candidates and programs:

**ACH-1095, an NS4A Antagonist for Chronic Hepatitis C Infection.** We are evaluating ACH-1095 (also known as GS-9525) for the treatment of chronic hepatitis C. In preclinical and clinical studies, NS4A antagonists studied demonstrate potent inhibition of the replication of HCV, the virus that causes hepatitis C, by targeting a non-structural, or NS, viral protein called 4A. We believe these NS4A antagonists may offer several potential advantages compared to currently available treatments, including greater potency, a novel mechanism of action, lack of cross resistance and the potential for oral administration. We believe these compounds could be used in combination with the current standard of care, or with other therapies in development, to significantly improve treatment outcomes. Since November 2004, we have collaborated with Gilead under an exclusive license agreement for the research, development and commercialization of compounds operating by this mechanism of action. Our first drug candidate under this program, ACH-806 (also known as GS-9132), demonstrated positive antiviral effect in a proof-of-concept clinical trial in HCV infected patients, but also elevated serum creatinine levels, a marker of kidney function. As a result, we discontinued further clinical

## **Table of Contents**

development of ACH-806 in favor of a next-generation back-up compound, ACH-1095, which is currently in late-stage preclinical studies. We anticipate entering clinical trials for this compound in the second half of 2009.

**ACH-1625, a Protease Inhibitor for Chronic Hepatitis C Infection.** We are evaluating ACH-1625, a protease inhibitor for the treatment of chronic hepatitis C. ACH-1625 has demonstrated strong in vitro potency and a good safety profile in preclinical studies. We have completed preclinical studies with this compound and we anticipate entering clinical trials for this compound in the first half of 2009.

**ACH-702 for Drug Resistant Bacterial Infections.** ACH-702 is a preclinical candidate with potency against a broad spectrum of bacterial pathogens including methicillin-resistant staphylococcus aureus, or MRSA. We recently completed a pre-IND consultation with the FDA on the most appropriate clinical development program for ACH-702. While the FDA provided guidance on an appropriate path toward regulatory approval for topical administration for ACH-702, the Division of Anti-Infective and Ophthalmology Products referred our request for additional guidance on systemic administration of ACH-702 to the Division of Special Pathogen and Transplant Products, or the DSPTP. We continue to assess our strategic and development options for ACH-702 for topical administration and other potential applications including use in medical biofilms and for use against tuberculosis. At this time, we do not anticipate moving into clinical development of ACH-702 until we complete this strategic assessment, and even then, we may not invest significantly in the future development of this compound without a collaboration partner.

**Elvucitabine for HIV Infection.** Elvucitabine is an antiviral we are developing for the treatment of HIV infection. We have evaluated elvucitabine in phase II clinical trials to further explore its safety and efficacy in HIV-infected patients over 48 and 96-weeks of treatment, and the open-label extension of one of those trials remains on-going through 2010. We currently retain full development and marketing rights to elvucitabine. However, we are currently seeking to enter a collaboration arrangement for elvucitabine and do not plan to advance elvucitabine into Phase III clinical trials without a collaboration partner.

We intend to focus on the discovery of new drug candidates through our extensive expertise in virology, microbiology and synthetic chemistry.

In the aggregate, members of our drug discovery, preclinical and clinical development team have contributed to the selection and development of more than 85 clinical candidates and 50 marketed products throughout their careers. Although significant additional funding and research and development will be required following the discovery of any new drug candidate, we believe our drug discovery capabilities will allow us to further expand our product candidate portfolio, providing us with strong growth potential and reducing our reliance on the success of any single drug candidate.

## **Background**

Infectious diseases are caused by pathogens present in the environment, such as viruses, bacteria and fungi, which enter the body through the skin or mucous membranes and overwhelm its natural defenses. Some infections affect the entire body, while others may be localized in one organ or system within the body. The severity of infectious diseases varies depending on the nature of the infectious agent, as well as the degree to which the body's immune system can fight the infection. According to World Health Organization reports, infectious diseases, including HIV infection, chronic hepatitis C and drug-resistant bacterial infections, represent a significant cause of morbidity and mortality worldwide.

The market for anti-infective drugs can be divided into three main categories: antivirals, antibacterials (often referred to as antibiotics) and antifungals. To date, we have focused on the research and development of products for the antiviral and antibacterial markets.

## **Table of Contents**

The widespread use of anti-infective drugs has led to a significant reduction in morbidity and mortality associated with infectious diseases. However, for many infectious diseases, current treatment options are associated with suboptimal treatment outcomes, significant drug-related adverse side effects, complex dosing schedules and inconvenient methods of administration, such as injection or infusion. These factors often lead to patients discontinuing treatment or failing to comply fully with treatment dosing schedules. As a result, physicians are often required to modify therapy regimens throughout the course of treatment.

Moreover, in recent years, the increasing prevalence of drug resistance has created ongoing treatment challenges for antiviral and antibacterial therapies. The ability of both viruses and bacteria to adapt rapidly to these treatments through genetic mutations allows new strains to develop that are resistant to currently available drugs. In addition, a patient's failure to comply fully with a treatment regimen both accelerates and exacerbates drug resistance. This is particularly well documented for HIV treatments and antibacterials.

As a result of these treatment challenges, the industry is focused on developing anti-infective drugs that delay the emergence of drug resistance, improve patient compliance and improve treatment responses in infections associated with drug-resistant pathogens.

We believe there are significant business advantages to focusing on the development of drugs to treat infectious diseases, including the following:

the emergence of drug resistance creates a continuing need for new drugs to combat infectious diseases, thus creating a large and growing business opportunity;

infectious disease research and development programs generally have shorter development cycle times when compared to various therapeutic areas such as oncology, cardiovascular and central nervous system disorders; and

evidence suggests systemic anti-infectives have a higher clinical success rate compared to various therapeutic areas such as oncology, cardiovascular and central nervous system disorders.

### ***Viruses***

Viruses are submicroscopic infectious agents consisting of an outer layer of protein surrounding a core of genetic material comprised of DNA or RNA. Viruses require living host cells to grow and multiply. In many cases, the body's immune system can effectively combat the viral infection. However, in certain viral infections, the body's immune system is unable to destroy the virus, and the infection becomes chronic. In chronic infections, persistent viral replication and subsequent infection of healthy cells may, over time, lead to the deterioration or destruction of the infected cells, resulting in disease. Antiviral drugs are utilized to assist the body's immune system in combating or eliminating the infection.

The development of resistance to antiviral drugs is a major challenge for the treatment of life-threatening viral infections such as HIV and chronic hepatitis C. The ability of viruses to mutate spontaneously during replication allows drug-resistant viral strains to emerge when patients are on treatment regimens that do not completely inhibit viral replication. Resistance occurs because viruses continually make billions of copies of themselves, some of which will contain mutations in their genetic material. Mutations that confer a replication advantage in the presence of a suppressive antiviral drug will give rise to viral strains that are resistant or partially resistant to that antiviral drug. These mutated viruses, while initially found in low numbers, will eventually become the predominant strain in an infected patient. Once this occurs, the treatment benefit of the antiviral drug diminishes or disappears, which may result in treatment failure and create a need for an alternate therapy with new drugs.

Antiviral drug resistance is clinically managed by the administration of one or more potent direct-acting antiviral drugs and/or by enhancing the body's immune system through treatment with an immune response modifier to apply the highest possible level of suppression against viral replication. These direct acting antiviral

## **Table of Contents**

drugs prevent viral replication by disrupting processes that are essential for completion of a viral infection cycle. The most effective disruption generally results from the use of multiple drugs that have different mechanisms of action.

### ***Bacteria***

Bacteria are unicellular, self-propagating microorganisms that multiply through growth in bacterial cell size and the subsequent division of the cell. Bacteria can be broadly classified into two categories based upon the composition of their cell walls: Gram-positive or Gram-negative. Many antibacterial drugs that are effective against Gram-positive bacteria are less effective or ineffective against Gram-negative bacteria, and vice versa. Antibacterial drugs that are active against a large number of both classes of bacteria are often referred to as broad-spectrum antibacterials.

Bacteria adapt remarkably well to their surroundings due to the high level of variation found within bacterial DNA and the ability of bacteria to reproduce rapidly. Replication of bacterial DNA is often error prone and can result in a high frequency of mutations. Because the bacterial reproductive cycle is very short, ranging from minutes to several days, a mutation that helps a bacterium survive exposure to an antibiotic drug may quickly become dominant throughout the population. Additionally, bacteria can acquire segments of DNA from other bacteria and organisms, which can also convey drug resistance.

Currently marketed antibacterials have historically proved highly successful in controlling the morbidity and mortality that accompany bacterial infections. The first antibacterials, introduced over 60 years ago, were highly effective in limiting or completely inhibiting bacterial reproduction, and thus were considered miracle drugs. A majority of the antibiotics currently in use were developed and introduced into the market before 1980. However, due to the widespread use of antibacterials over time and the ability of bacteria to develop drug resistance, many of these antibiotics now have diminished or limited antibacterial activity. This problem is particularly acute in the hospital setting, where approximately 70% of certain types of serious infections are associated with multi-drug-resistant bacteria. The inability to effectively treat serious infections caused by drug-resistant bacteria has led to increased mortality rates, prolonged hospitalizations and increased health care costs. The rate at which bacteria are now developing resistance to multiple antibacterials, and the pace at which those multi-drug-resistant bacteria are spreading, represent significant medical challenges.

### ***Our Strategy***

Our objective is to become a leading infectious disease-focused biopharmaceutical company. In order to achieve our objective, we intend to:

*Advance the Development of Our Current HCV Drug Candidates.* We are developing two compounds for the treatment of chronic hepatitis C: ACH-1095, our NS4A antagonist, developed under a collaboration and exclusive license arrangement with Gilead, and ACH-1625, our protease inhibitor. In particular, in the next twelve months, we expect to:

complete late-stage preclinical studies and initiate phase Ia and phase Ib clinical testing of ACH-1095, in collaboration with Gilead;

initiate and complete phase Ia and phase Ib clinical testing of ACH-1625; and

continue to develop back-up HCV candidates to both ACH-1095 and ACH-1625.

*Accelerate Growth Through Selective Collaborations.* We intend to establish strategic collaborations where we believe we can accelerate the development or maximize the value of our drug candidates by utilizing the financial, clinical development, manufacturing and/or commercialization strengths of a leading biotechnology or pharmaceutical company as well as regional institutions or companies. For example, we entered into a collaboration with Gilead in 2004 for the development and commercialization of certain of our HCV compounds demonstrating a mechanism of action we call





**Table of Contents**

NS4A antagonism, pursuant to which we received a significant up-front payment. We are currently utilizing Gilead's broad capabilities to accelerate the progress of our NS4A antagonists. In addition, we currently maintain all rights to two drug candidates for which we have made a strategic decision to advance under collaboration with a partner—elvucitabine for treatment of HIV and ACH-702 for treatment of resistant bacterial infections. In addition to seeking collaboration support for these programs, we may seek to accelerate program development through affiliations with governmental, educational or other not-for-profit funding sources. Also, if any of our drug candidates are approved for sale, we may agree to collaborate with other companies to co-promote our drug candidates in North America, and/or utilize strategic alliances with third parties outside North America. For example, we have granted Gilead worldwide commercialization rights for our NS4A antagonists for treatment of HCV infection, and we have the option to participate on a limited basis in marketing efforts in the United States.

*Expand our Infectious Disease Portfolio.* We intend to leverage our expertise in synthetic chemistry, virology and microbiology to quickly and efficiently discover and develop additional anti-infective compounds. As recent examples of our capabilities, our research team designated clinical lead candidates in our HCV NS4A program (both ACH-806, a discontinued drug candidate, and ACH-1095, its successor compound with a similar mechanism of action), our HCV protease program (ACH-1625), and antibacterial program (ACH-702) in fewer than 24 months from program inception.

We have spent substantial research and development funds to develop our product pipeline and expect to continue to do so in the future. We incurred approximately \$21.2 million, \$28.1 million and \$22.7 million in research and development costs for the years ended December 31, 2008, 2007 and 2006, respectively.

**Our Drug Candidates**

The following table summarizes key information regarding our drug candidates:

<b>Drug</b>				
<b>Candidate/</b>				<b>Current Marketing Rights</b>
<b>Indication</b>	<b>Target</b>	<b>Stage of Development</b>	<b>Current Status</b>	
<b>ACH-1095</b>	HCV protein NS4A	Preclinical	Late-stage preclinical studies	Gilead Sciences*
<i>Chronic Hepatitis C Infection</i>				
<b>ACH-1625</b>	HCV protein NS3 protease	Preclinical	Preparation for phase I initiation	Achillion
<i>Chronic Hepatitis C Infection</i>				
<b>ACH-702</b>	Triple target of gyrase, topoisomerase IV, and DNA primase	Preclinical	Assessing potential strategic and development options	Achillion
<i>Resistant Bacterial Infections</i>				
<b>Elvucitabine</b>	HIV reverse transcriptase	Phase II extension	Multiple Phase II studies completed, including comparative safety, antiviral efficacy and pharmacokinetics trials in HIV treatment-naïve and treatment-experienced patients—open label extension on-going	Achillion
<i>HIV Infection</i>				

\* Achillion has a one-time option to participate on a limited basis in marketing in the United States.

## **Table of Contents**

### **ACH-1095, an NS4A Antagonist for HCV Infection**

Through our internal drug discovery efforts, we identified a series of novel inhibitors which share a unique mechanism of action from other HCV inhibitors currently in development. The current lead compound from this series is ACH-1095. All compounds in this series function by targeting the NS4A protein of the hepatitis C virus and preventing formation of replicase complex, a necessary step in viral replication. In November 2004, we entered into a strategic alliance with Gilead for the discovery, development and commercialization of these compounds to treat chronic hepatitis C.

A discontinued predecessor compound, ACH-806, our first clinical stage compound from this series, demonstrated positive antiviral activity in human patients infected with HCV, but also demonstrated early signs of elevated serum creatinine, a marker of kidney function.

### ***Overview of HCV Market***

HCV is a virus which is a common cause of viral hepatitis, an inflammation of the liver. HCV infection is contracted by contact with the blood or other body fluids of an infected person. Hepatitis due to HCV can result in an acute process where a person is affected for only several months and then the virus is cleared from the body. However, the American Association of Liver Disease estimates that up to 85% of individuals become chronically infected following exposure. HCV disease progression then occurs over a period of 20 to 30 years during which patients are generally asymptomatic, meaning they exhibit no symptoms of the disease. Chronic hepatitis can lead to permanent liver damage, which can result in the development of liver cancer, liver failure or death.

The current standard of care for patients with chronic HCV infection is treatment with a combination of long-acting, pegylated forms of interferon alpha administered through weekly injections coupled with daily, oral doses of ribavirin. The duration of treatment for patients infected with non-genotype 1 virus is six months and results in undetectable viral load and normalization of liver function markers in up to 80% of patients receiving a full course of treatment. However, in individuals infected with the genotype 1 virus, the standard of care calls for 12 months of treatment and is successful in only approximately 50% of patients receiving a full course of treatment.

Treatment with pegylated interferon and ribavirin is further complicated by significant adverse side effects, including flu-like symptoms, anemia, depression, fatigue, suicidal tendencies and abnormal fetal development. Since chronic hepatitis C infection, with the exception of late-stage disease, is generally asymptomatic, the nature and extent of the treatment-related adverse side effects make patients feel sicker than they were prior to treatment. As a result of these treatment-related adverse side effects, nearly 40% of treated patients require dosage adjustments, and many of these patients may discontinue therapy altogether. In addition, current treatments are administered by injection, which is inconvenient and problematic for patients who are afraid of needles. Therefore, important goals for new HCV therapies are to:

improve efficacy against the genotype 1 virus;

offer a treatment response in patients who have failed an interferon and ribavirin based treatment;

reduce the magnitude of treatment-related adverse side effects; and

offer a more convenient, orally available, treatment option.

We believe the lessons learned from the treatment of HIV infection, specifically the improved antiviral response achieved through the use of combination therapies, are relevant for the treatment of HCV due to its rapid replication and high frequency of mutations. One common approach to the discovery of new therapies to treat chronic hepatitis C focuses on the inhibition of viral proteins essential to the completion of the HCV replication cycle. The two most common of these HCV drug targets are NS5B polymerase and NS3 protease. NS5B polymerase is essential for viral replication, as it is directly involved in creating new copies of the viral

## **Table of Contents**

RNA genome. NS3 protease is essential for viral protein processing and completion of the viral lifecycle. All of the NS3 inhibitors of which we are aware work by binding to the protein's active site, thus preventing protein processing. Both NS5B and NS3 inhibitors have demonstrated in clinical trials significant viral load reduction in infected patients. Many experts believe that these drugs, if approved, will need to be used in combination with other drugs in order to improve upon the efficacy obtained with the current standard of care.

### ***Achillion Approach: NS4A Antagonist ACH-1095***

Our next-generation NS4A antagonists, including ACH-1095, are novel small molecule potent inhibitors of HCV replication which we identified through our internal research program. We believe these compounds have the following benefits:

*Novel Mechanism of Action.* Based upon extensive virology and biochemistry studies, we believe that the mechanism of action of our compounds is novel and involves targeting the NS4A protein of HCV, preventing the formation of a functional replicase complex, a necessary step in viral replication that occurs before copying the viral RNA genome, the step that polymerase inhibitors affect, but after viral protein processing, the step that protease inhibitors affect. Accordingly, we believe this unique mechanism leads to the lack of cross resistance *in vitro* between our compounds and other HCV inhibitors.

*Potency.* Data obtained in the standard laboratory assays used to determine anti-HCV activity against the genotype 1 virus demonstrate that our compounds have potency *in vitro* in a range similar to the published data on Boehringer Ingelheim's protease inhibitor under clinical development, and 14 to 21 times more potency *in vitro* than either the Schering-Plough or Vertex HCV protease inhibitors under clinical development.

*Lack of Cross Resistance.* In laboratory studies, our compounds have not demonstrated cross resistance to any of the polymerase inhibitors or protease inhibitors of which we are aware and have tested.

*Ease of Administration.* Based on current animal studies, we believe the compounds in this series could be administered orally.

*Potential for Combination Treatment.* Because of the lack of cross resistance in *in vitro* tests with all other known classes of HCV inhibitors, we believe that NS4A antagonists are well positioned for evaluation as a treatment for chronic hepatitis C in combination with the current standard of care and/or in combination with other direct acting antivirals.

### ***Clinical Development History***

In 2005, we initiated a single dose-escalating phase I clinical trial of ACH-806 in 20 subjects using a liquid formulation. There were no clinically significant findings in this trial, and we determined that this formulation is not suitable for further clinical trials or commercialization. We then evaluated the pharmacokinetics and safety of a tablet formulation of ACH-806 in a single dose-escalating phase I clinical trial in 20 subjects. We completed this trial in May 2006, and results revealed the drug was safe and well tolerated in healthy volunteers.

In 2006, we initiated a multiple dose proof-of-concept clinical trial of ACH-806 in HCV-infected patients. A proof-of-concept trial is generally a late-stage phase I or early-stage phase II clinical trial, the objective of which is to demonstrate that the tested drug shows a beneficial effect (e.g., a reduction in viral RNA levels) in human subjects. From this trial we observed that ACH-806 demonstrated positive antiviral effect, but we also observed elevations in serum creatinine, a marker of kidney function, which we concluded limited further dose escalation. As a result, in February 2007, we discontinued further development of ACH-806.

Based on our experience in the HCV area, and as part of our collaboration with Gilead, we maintained an active back-up program. As a result of this backup program, we developed a series of HCV inhibitors, including ACH-1095, with the following characteristics:

*Chemical Structure.* The chemical structure of these compounds is distinct from ACH-806.



**Table of Contents**

*Mechanism of Action.* These compounds inhibit HCV replication through the same mechanism of action as ACH-806.

*Potency.* These compounds display *in vitro* potency equal to or better than ACH-806.

*Ease of Administration.* Based on preclinical studies, we believe these compounds could be administered orally. We expect to initiate human clinical trials in the second half of 2009. As appropriate, based upon the clinical experience gained with ACH-806 and the outcome of phase I clinical trials with ACH-1095, our collaborative partner, Gilead, may conduct phase II and/or phase III clinical trials and would assume financial and operational responsibility for this phase II and phase III development if it chooses to conduct such trials.

**Preclinical Development History**

In our preclinical studies, we demonstrated that our NS4A antagonists inhibit HCV replication in cell-based replicon assays that have developed resistance to other HCV protease and polymerase inhibitors.

In 2005 and 2006, we compared the potency of our NS4A antagonists, including ACH-806 and ACH-1095, as well as other compounds, with two other NS3 protease inhibitors currently in clinical development, VX-950, being developed by Vertex, and SCH-503034, being developed by Schering-Plough. Potencies of ACH-1095, VX-950 and SCH-503034 for inhibition of HCV replication are represented by the amount of inhibitor required (as measured in nanomoles, or nM) to inhibit 50% of HCV replication in *in vitro* laboratory tests. A lower nM number represents greater inhibition and potency. Our results demonstrated that, in laboratory testing, ACH-1095 is approximately 10-fold more potent than SCH-503034, and approximately 14-fold more potent than VX-950. The following table describes these results:

HCV Inhibitor	Potency (nM)
ACH-1095	21
VX-950	300
SCH-503034	200

In addition, this compound has demonstrated good oral bioavailability and a satisfactory safety profile in animals.

**Collaboration Operations**

Under the terms of the collaboration with Gilead, research activities are overseen by a joint research committee comprised of equal numbers of our representatives and representatives from Gilead. Under the terms of a jointly-agreed upon research plan for ACH-1095, we will perform certain early-stage preclinical activities and Gilead is responsible for performing later preclinical and clinical studies. We continue to be responsible for back-up activities until such time as proof-of-concept is achieved and Gilead will continue to be responsible for manufacturing, formulation and commercialization activities.

In connection with commercialization of any products under the collaboration, we have a one-time option to participate on a limited basis in the marketing effort in the United States.

**ACH-1625, a Protease Inhibitor for Chronic Hepatitis C Infection**

Our HCV protease inhibitor, ACH-1625, was discovered by our internal research team. The compound has demonstrated strong *in vitro* potency and a good safety profile in animals. We have completed preclinical studies with this compound and we anticipate initiating human clinical trials for this compound in the first half of 2009.

**Table of Contents*****Achillion Approach: HCV Protease Inhibitor ACH-1625***

We believe combination therapy for the treatment of chronic HCV infection will benefit from drugs that inhibit HCV replication through complementary mechanisms of action. For this reason, we have leveraged our experience in HCV drug discovery to identify protease inhibitors that are distinct from our NS4A antagonists in their mechanism of action. Furthermore, these protease inhibitors are not subject to our collaboration and exclusive license agreement with Gilead.

We believe ACH-1625 and its back-up compounds have the following benefits:

*Potency and Specificity.* Data obtained in the standard laboratory assays used to determine anti-HCV activity against the genotype 1 virus demonstrate that ACH-1625 has potency *in vitro* in a range similar to the published data on Boehringer Ingelheim's protease inhibitor (BI-2064), and several times greater potency *in vitro* than either the Schering-Plough (SCH-503034) or Vertex (VX-950) HCV protease inhibitors under clinical development. In addition, ACH-1625 demonstrates no cross resistance with these other inhibitors in development.

*Safety.* In laboratory and animal studies, ACH-1625 has demonstrated high safety margins, meaning the amount of drug exposure in animals is many times higher than the concentrations required to inhibit the HCV virus, and has minimal dose-related side effects.

*Pharmacokinetics.* In laboratory and animal studies, ACH-1625 is rapidly and extensively partitioned to the liver, the organ of infection in HCV. Based upon these data, we believe ACH-1625 could be dosed orally once daily.

*Potential for Combination Treatment.* As a member of a known and extensively studied drug class, we believe our protease inhibitor, ACH-1625, is well positioned for evaluation as a treatment for chronic hepatitis C in combination with the current standard of care and/or in combination with other direct acting antivirals.

***Preclinical Development History***

In preclinical studies, we have demonstrated that ACH-1625 is efficacious *in vitro* against genotype 1 virus. A lower nM potency number represents greater inhibition and potency, indicating that a lower concentration of drug is needed for viral inhibition. The following table describes these results.

<b>HCV Inhibitor</b>	<b>Potency (nM)</b>
ACH-1625	1
VX-950	300
SCH-503034	200

Preclinical data indicate that ACH-1625 has high safety margins in animals in both single ascending dose and multiple dose preclinical trials. ACH-1625 is metabolically stable and is rapidly and extensively partitioned in the liver, the organ of infection in HCV patients. Therefore, we believe ACH-1625 has potential for once-daily dosing.

***ACH-702 for Drug Resistant Bacterial Infections***

ACH-702 is a preclinical candidate with potency against a broad spectrum of bacterial pathogens including MRSA, which we are developing for the treatment of serious hospital-based and other bacterial infections. We recently completed a pre-IND consultation with the FDA on the most appropriate clinical development program for ACH-702. While the FDA provided guidance on an appropriate path toward regulatory approval for topical administration for ACH-702, the Division of Anti-Infective and Ophthalmology Products referred our request for additional guidance on systemic administration of ACH-702 to the DSPTP. We continue to assess our strategic





## Table of Contents

and development options for ACH-702 for topical administration and other potential applications including use in medical biofilms, and for use against tuberculosis. At this time, we do not anticipate moving into clinical development of ACH-702 until we complete this strategic assessment, and even then, we may not invest significantly in the future development of this compound without a collaboration partner.

### *Achillion Approach: ACH-702*

We believe ACH-702 has the following benefits:

*Broad-Spectrum Potency.* ACH-702 has a novel target profile against bacterial DNA replication enzymes and potent broad-spectrum activity. We have established potent activity of ACH-702 against multi-drug-resistant bacteria in a laboratory evaluation of recent clinical isolates obtained from infected patients, as well as in preclinical models of infection. The spectrum of activity includes inhibition of the DNA replication enzymes: gyrase, topoisomerase IV and primase.

*Bactericidal Mechanism of Action.* ACH-702 has demonstrated bactericidal activity against multi-drug-resistant MRSA. A number of the other drugs currently used to treat MRSA infections are bacteriostatic, meaning they are able to prevent the growth of new bacteria, but have a limited effect on the bacteria existing at the time of treatment.

*Dosing.* We believe the properties of ACH-702 support the potential for administration through a variety of formulations.

### *Preclinical Development History*

In preclinical studies, ACH-702 has demonstrated potent antibacterial activity against a number of medically relevant bacteria, including drug-resistant strains such as MRSA and vancomycin-resistant enterococcus. The following table illustrates ACH-702 activity versus MRSA clinical strains, compared to other marketed antibacterial products. The standard measurement of antibacterial activity is minimum inhibitory concentration, or MIC, meaning the minimum amount of drug required to inhibit complete growth of bacteria (as measured in micrograms per ml, or µg/ml). The lower the MIC, the greater the potency of the compound. In this study, for example, ACH-702 demonstrated potent activity *in vitro* against three MRSA strains that are resistant to Vancomycin and Zyvox (linezolid), which are the current standards of care.

Compound	MIC (µg/ml)		
	MRSA (F-2121)	MRSA (F-2128)	MRSA (F-2137)
ACH-702	0.12	0.25	0.25
Vancomycin	8.00	>32.00	2.00
Linezolid	2.00	2.00	>16.00

Potent antibacterial activity has been demonstrated against both sensitive and drug-resistant strains in well-established preclinical infection models. In addition, IND-enabling preclinical pharmacokinetic and safety studies have been completed.

After our preclinical studies, we completed a pre-IND consultation with the FDA on the most appropriate clinical development program for ACH-702. While the FDA provided guidance on an appropriate path toward regulatory approval for topical administration for ACH-702, the Division of Anti-Infective and Ophthalmology Products referred our request for additional guidance on systemic administration of ACH-702 to the DSPTP. We continue to assess our strategic and development options for ACH-702 for topical administration and other potential applications including use in medical biofilms and for use against tuberculosis. We may undertake incremental preclinical studies as the result of this strategic assessment.

## **Table of Contents**

### **Elvucitabine for HIV**

We are currently testing Elvucitabine in phase II trials. Elvucitabine is a member of the nucleoside reverse transcriptase inhibitor, or NRTI, class of compounds, the predominant class of drugs used in the current standard of care for HIV therapy. Elvucitabine has demonstrated potent antiviral activity against HIV, including activity against HIV that contains mutations associated with resistance to other reverse transcriptase inhibitors such as Viread (tenofovir), Zerit (d4T) and Retrovir (AZT). Furthermore, elvucitabine has been demonstrated to have a significantly longer half-life than the other marketed drugs in its class. We believe that these attributes should allow elvucitabine to deliver consistent, potent antiviral activity to patients infected with HIV, particularly those patients with less than perfect compliance with their existing treatment regimens. We believe a treatment regimen containing elvucitabine may also delay the emergence of resistance and prolong the effectiveness of therapy. To date, results from phase II trials indicate that elvucitabine is safe, well-tolerated and similarly efficacious to Epivir (lamivudine).

We currently anticipate entering into an alliance for the phase III development and commercialization of elvucitabine, and have made a strategic decision not to independently pursue further development or commercialization of elvucitabine prior to entering such an alliance. Further, we currently do not plan to initiate any additional efforts in HIV research or development. Given the limited number of global pharmaceutical companies which currently develop and market drugs for the treatment of HIV, and the strategic need for elvucitabine to be suitable for co-formulation with drugs already marketed or under development by a potential partner, the number of potential partners is relatively small. To date, we have been unsuccessful in partnering with the major pharmaceutical companies with whom we have had on-going discussions. We are continuing partnering efforts with regional companies and institutions, including those in Asia, South America and elsewhere. If we are not successful in forming an alliance before the completion of the currently ongoing trial extensions, we do not plan to advance the elvucitabine HIV program.

### ***Overview of HIV Market***

HIV is a viral infection that, if left untreated, results in the development of the Acquired Immune Deficiency Syndrome, or AIDS. The goal of antiviral treatment is to provide long-term suppression of HIV replication, which decreases the likelihood of AIDS and/or death. Without treatment, HIV infection progresses to AIDS in 20-25% of infected individuals within six years and in 50% within ten years.

Currently, there is no cure for HIV infection. In addition, there are no preventative or therapeutic vaccines, but there are more than two dozen antiretroviral drugs on the market that target various steps in the HIV replication cycle. These can be divided into six drug classes that have been approved for the treatment of HIV infection:

NRTIs;

non-nucleoside reverse transcriptase inhibitors, or NNRTIs;

protease inhibitors;

fusion inhibitors;

entry inhibitors; and

integrase inhibitors.

### ***Achillion Approach: Elvucitabine***

Elvucitabine is an L-cytosine NRTI, which represents the most frequently prescribed class of NRTIs based upon sales. We believe L-cytosine NRTIs are frequently prescribed given their established potency, favorable short and long-term safety profile and fewer and less adverse side effects.



## **Table of Contents**

We believe elvucitabine addresses the limitations of currently available NRTIs in the following ways:

*Long Half-Life.* Elvucitabine's plasma and intracellular half-life has been demonstrated in clinical trials to be 5-20 times greater than that of leading NRTIs Epivir (lamivudine) and Emtriva (FTC). We believe this long half-life may mitigate the negative effects of less than perfect patient compliance, providing a more durable NRTI for use in highly active antiretroviral therapy, or HAART, regimens.

*Potency Against Common Resistance Mutations.* The laboratory antiviral profile of elvucitabine demonstrates superior potency against many of the most common resistance mutations associated with NRTIs. In addition, elvucitabine retains greater antiviral activity in laboratory tests against HIV with resistance to Epivir (lamivudine) and Emtriva (FTC). We believe this enhanced antiviral activity could provide an increased barrier to the emergence of drug resistance in patients and improve antiviral suppression.

*Low Once-Daily Dosing.* In phase 2 clinical studies, elvucitabine was demonstrated to be safe, well-tolerated and efficacious at doses of 10 mg once daily. Other leading cytosine NRTIs, Epivir (lamivudine) and Emtriva (FTC), are dosed at 300 mg and 200 mg daily, respectively. We believe elvucitabine's low daily dose is an advantage in developing fixed-dose co-formulations in partnership with potential collaborators.

*Patient Compliance.* We believe that a well-tolerated L-cytosine NRTI with convenient, flexible oral dosing will enhance patient compliance and will make elvucitabine attractive as a component of a fixed-dose or other combination HAART regimen.

### ***Recently Completed and Ongoing Clinical Development***

Our Phase II clinical development plan for elvucitabine included multiple trials to explore the safety and efficacy profile of elvucitabine in both naïve and treatment-experienced HIV-infected patients. One of these phase II trials remains on-going. To date in this on-going trial, we have completed three treatment segments of 12-, 24- and 48-weeks of a randomized, double-blind phase II trial of a 10 mg daily dose of elvucitabine in combination with two additional antiretrovirals, Sustiva (efavirenz) and Viread (tenofovir), as compared to 300 mg daily dose of Epivir (lamivudine) in combination with the same two additional antiretrovirals, in 78 treatment-naïve HIV patients. We evaluated the safety, antiviral efficacy and pharmacokinetics of 12-, 24- and 48- weeks of therapy with these two treatment regimens, and will evaluate the same parameters after all eligible patients complete 96 weeks of treatment, anticipated to occur in the first half of 2009.

In June 2008, we announced that results at 48 weeks of treatment demonstrated that elvucitabine had a potent anti-viral effect similar to lamivudine, with a mean decrease in viral load in the elvucitabine treatment group of more than 99%, or  $3.0 \log_{10}$ , similar to a decrease of more than 99%, or  $3.2 \log_{10}$ , in the lamivudine treatment group. In the elvucitabine-treated group, 96% of patients reached undetectable viral load at 48 weeks, defined as achieving fewer than 50 copies/ml after 48 weeks of therapy, compared to 97% in lamivudine group. In this trial, elvucitabine was demonstrated to be safe and well-tolerated, as indicated by the absence of any serious drug-related clinical adverse events. These results are based on a small number of patients in an early-stage clinical trial and are not necessarily predictive of results in later-stage clinical trials with larger and more diverse patient populations.

In a separate phase II trial in HIV-experienced patients, we completed a randomized, double-blind phase II trial in which we evaluated the viral kinetics, safety and pharmacokinetics of elvucitabine in 18 HIV-infected patients who had failed a HAART regimen which included Epivir (lamivudine). Treatment failure is defined as the presence of the M184V mutation, which signifies Epivir (lamivudine) drug resistance. Patients received either 10 mg of elvucitabine once daily in place of Epivir (lamivudine) or continued receiving 300 mg of Epivir (lamivudine) once daily for 14 days. The patients' other two HAART regimen drugs remain unchanged. During the first 14 days of treatment, announced in January 2008, patients receiving elvucitabine had similar viral load reduction as those patients receiving Epivir (lamivudine). In addition, the trial results demonstrate significant

## **Table of Contents**

improvement in response when measured during the extension phase in which 8 of 14 patients who received elvucitabine, or 57%, had achieved 0.5 log<sub>10</sub> reduction or more in viral load, likely related to the fact that elvucitabine is believed to reach steady-state levels in patients after approximately 21 days of treatment. We observed no serious or clinically significant adverse events during this trial. These results are based on a small number of patients in an early-stage clinical trial and are not necessarily predictive of results in later-stage clinical trials with larger and more diverse patient populations. In November 2008, the last eligible patient completed the 48 week treatment extension of this trial. We are currently analyzing the data from this trial and expect to publish the final results at an upcoming medical meeting.

### **Drug Discovery Programs and Capabilities**

We have successfully advanced two drug candidates into human clinical trials, with two additional drug candidates in late-stage preclinical studies. We discovered three of these drug candidates in house by applying our deep understanding of virology, microbiology and synthetic chemistry. We intend to continue to capitalize on our internal drug discovery and development capabilities to expand our product candidate portfolio.

From early lead identification through clinical candidate selection, we have coupled our knowledge base in genomic replication targets with an integrated drug discovery infrastructure to aid in the rapid advancement of our discovery programs.

### ***Target Selection and Assay Development***

We are focused on addressing unmet medical needs in infectious diseases, with an emphasis on inhibiting viral and bacterial proteins essential for genomic replication. We select targets for our drug discovery programs based upon the relevance of the target to key steps within the viral or bacterial replication cycle, our ability to develop appropriate assays for early assessment of potency, selectivity and safety and confidence in our ability to identify small molecules that can be optimized within a reasonable time period to become drug candidates. We have developed proprietary assays for identification and optimization of small molecule inhibitors of viral and bacterial genomic replication.

### ***Compound Synthesis, Hit Identification and Lead Optimization***

Our focused compound library contains a diverse set of molecules that have been synthesized for the principal purpose of inhibiting genomic replication in viruses and bacteria. We have developed the following discovery tools that enable us to manage our compounds efficiently and advance our discovery programs:

AACP (Achillion Automated Chemistry Platform) is a proprietary software program that facilitates medium and high throughput synthesis of compounds. AACP allows us to synthesize thousands of small molecules in support of our drug discovery programs.

CART (Compound Acquisition and Repository Tracking) is a software tool that streamlines our scientists' ability to select and acquire compounds for lead identification. CART is integrated with computational chemistry tools and a virtual database of greater than two million small molecules.

CHEM-ACH is data mining software that allows compounds synthesized at Achillion to be cross-referenced against biological activities associated with them. Structure-activity relationships are elaborated with CHEM-ACH, greatly facilitating design and synthesis of compounds for lead optimization.

D2P2 (Drug Design Through Pharmacophore Perception) is a software application which allows our scientists to study interactions between a drug target and its inhibitors in three dimensions. D2P2 has facilitated lead optimization in our HCV program.

## **Table of Contents**

### ***Preclinical Candidate Selection***

A cornerstone of our approach to drug discovery and development is the early assessment of the drug-like properties associated with optimized lead compounds. Potency and activity against a given target are necessary but not sufficient predictors of eventual successful clinical development of a new drug. In order to perform an early assessment of the potential for successful development, prior to progression of a compound into late-stage preclinical studies in support of clinical trials, we aggressively evaluate compounds in numerous tests relating to safety, metabolism, pharmacokinetic properties and physical properties associated with the feasibility for an oral formulation.

### **Competition**

Our industry is highly competitive and subject to rapid and significant technological change. All of the drugs we are developing, if approved, would compete against existing therapies. In addition, we believe a significant number of drug candidates are currently under development and may become available for the treatment of HIV infection, chronic hepatitis C and bacterial infections. The key competitive factors affecting the commercial success of these drugs are likely to be efficacy, safety profile and reliability, convenience of dosing, price and reimbursement.

Many of our potential competitors, including many of the organizations named below, either alone or with their collaborative partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of drug candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Accordingly, our competitors may be more successful than we may be in obtaining FDA approval for drugs and achieving widespread market acceptance. Our competitors' drugs may be more effective, have fewer negative side effects or be more effectively marketed and sold, than any drug we may commercialize and may render our drug candidates obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our drug candidates. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. These organizations may also establish collaborative or licensing relationships with our competitors. Finally, the development of a cure or new treatment methods for the diseases we are targeting could render our drugs non-competitive or obsolete.

### ***ACH-1095 and ACH-1625 for HCV***

*ACH-1095 and ACH-1625*, if approved, our NS4A antagonist, ACH-1095, and our protease inhibitor, ACH-1625, would compete with drugs currently approved for the treatment of hepatitis C, the interferon-alpha based products from Roche (Pegasys and Roferon-A) or Schering-Plough (Intron-A or Peg-Intron) and the ribavirin based products from Schering-Plough (Rebetrol), Roche (Copegus) or generic versions sold by various companies. In addition, our HCV compounds may compete with the interferon and ribavirin based drugs currently in development such as Valeant's ribavirin analog (Viramidine) and Human Genome Sciences' Albuferon. Other direct-acting antiviral products are also under development for the treatment of hepatitis C by companies such as Abbott, Anadys, Boehringer Ingelheim, Bristol-Myers Squibb, Gilead Sciences, GlaxoSmithKline, Human Genome Sciences, Intermune, Johnson & Johnson, Medivir, Merck, Novartis, Pfizer, Pharmasset, Roche, Schering-Plough and Vertex.

### ***ACH-702 for Drug Resistant Bacterial Infections***

ACH-702, if approved, would compete with drugs currently marketed for the treatment of serious gram-positive nosocomial infections including: vancomycin (multiple generic forms), Cubicin (daptomycin) by Cubist Pharmaceuticals, Zyvox (linezolid) by Pfizer and Synercid (dalbavancin + quinupristin) by King Pharmaceuticals. In addition, ACH-702 may compete with other drugs currently under development for the treatment of nosocomial gram-positive infections including: dalbavancin in development by Pfizer, telavancin from Theravance, oritavancin by Intermune, doripenem by Johnson & Johnson, ceftobiprole by Basilea and Johnson &

## **Table of Contents**

Johnson, iclaprim by Arpida and garenoxacin by Schering-Plough. In addition, ACH-702 may compete with other drugs currently marketed or under development for the treatment of topical skin infections including Altabax by GlaxoSmithKline and XOMA-629 by Xoma Therapeutics Ltd. We may also compete with the following companies that have a strategic interest in the discovery, development and marketing of drugs for the treatment of bacterial infections: Abbott, Aventis, Bristol-Myers Squibb, Cubist, GlaxoSmithKline, Merck, Novartis, Roche and Wyeth.

### ***Elvucitabine for HIV***

Elvucitabine, if approved, would compete with the NRTIs currently marketed for treatment of HIV infection, including: Epivir (lamivudine), Retrovir (AZT), Ziagen (abacavir), Combivir (lamivudine + AZT), Trizivir (lamivudine + AZT + abacavir) and Epzicom (lamivudine + abacavir) from GlaxoSmithKline, Hivid (ddC) from Hoffman-La Roche, Emtriva (FTC), Viread (tenofovir) and Truvada (FTC + tenofovir) from Gilead Sciences and Videx EC, Videx (ddI) and Zerit (d4T) from Bristol-Myers Squibb. In addition, elvucitabine may compete with other NRTIs currently under development for HIV by companies such as Avexa, Medivir, Pharmasset and Koronis. Other drugs in other classes recently approved for treatment of HIV infection include Selzentry (maraviroc, an entry inhibitor) from Pfizer and Isentress (raltegravir, an integrase inhibitor) from Merck. In addition, there are other classes of drugs under development for the treatment of HIV infection by companies such as Abbott, Boehringer Ingelheim, Johnson & Johnson, Myriad, Roche and Schering-Plough.

### **Intellectual Property**

Our strategy is to pursue patents, developed internally and licensed from third parties, and other means to otherwise protect our technology, inventions and improvements that are commercially important to the development of our business. We also rely on trade secrets that may be important to the development of our business.

Our success will depend significantly on our ability to:

obtain and maintain patent and other proprietary protection for the technology, inventions and improvements we consider important to our business;

defend our patents;

preserve the confidentiality of our trade secrets; and

operate without infringing the patents and proprietary rights of third parties.

Our hepatitis C patent portfolio currently includes five issued U.S. patent, four U.S. provisional patent applications, twelve pending U.S. non-provisional applications, two associated issued non-U.S. patents, seventy-five associated pending non-U.S. patent applications, and five pending PCT applications. These patent applications, if issued, will expire between 2023 and 2029. The patent applications contain claims directed to compounds, method of use, process for synthesis, mechanism of action, and research assays.

In connection with our November 2004 collaboration with Gilead, we granted a worldwide exclusive license to Gilead for past, present and future patents, patent applications and patent filings with claims directed to our first NS4A antagonists and chemically related compounds, any additional compounds which inhibit HCV via a mechanism similar to that of NS4A antagonism and intellectual property relating to the mechanism of action. Gilead has a right to present and discuss with us its capabilities to participate in the development and commercialization of new HCV compounds.

In addition, we have obtained non-exclusive licenses to HCV drug discovery patents and patent applications owned by Chiron, a Novartis business unit, Apath, L.L.C., and ReBlikon, GmbH.

## **Table of Contents**

Our antibacterial patent portfolio currently includes one issued US patent, seven pending U.S. patent applications, fifty-five associated pending non-U.S. applications and two pending PCT applications. These patent applications, if issued, will expire between 2024 and 2028. The patent applications contain claims directed to compounds, method of use, process for synthesis and mechanism of action.

Our elvucitabine patent portfolio currently includes seven issued U.S. patents, thirty-two associated issued non-U.S. patents, fifteen associated pending non-U.S. patent applications, three pending US patent applications and one pending PCT application. We either own or hold exclusive worldwide sublicenses from Vion Pharmaceuticals of patents owned by Yale University or exclusive worldwide licenses from Emory University to these patents and patent applications. The issued patents and patent applications, if issued, will expire between 2013 and 2027. The issued U.S. patents contain claims directed to elvucitabine chemical compound, method of use, synthesis, and formulation, which claims expire in 2013, 2013 to 2016 and 2023, respectively. The issued foreign patents contain claims directed to the elvucitabine compound and elvucitabine use and expire in 2014 and 2016.

## **Collaborations and Licenses**

### ***Gilead***

In November 2004, we entered into a research collaboration and license agreement with Gilead, Inc. pursuant to which we agreed to collaborate exclusively with Gilead throughout the world to develop and commercialize compounds for the treatment of chronic hepatitis which inhibit HCV replication through a novel mechanism of action targeting the NS4A protein involving HCV, including ACH-806, our previous lead candidate (also known as GS-9132), and successor compounds, including ACH-1095 (also known as GS-9525). Research and development activities prior to proof-of-concept are overseen by a research committee comprised of equal numbers of our representatives and representatives from Gilead. The joint research committee assigns research and development tasks, agrees upon a budget for the research program, and shares equally in the related costs. In addition, the parties may agree at any time to increase or decrease the research budget. Prior to proof-of-concept, any disputes within the joint research committee that cannot be resolved between designated executives of each party will be resolved by Gilead.

According to a jointly-agreed upon research plan for ACH-1095, the joint research committee determined that we would perform certain early-stage preclinical activities while Gilead would perform later preclinical and clinical studies. We would continue to be responsible for back-up activities until such time as proof-of-concept is achieved, and Gilead would continue to be responsible for manufacturing, formulation and commercialization activities. In the most recently updated project plan, approved by the joint research committee in March 2009, our remaining obligations under the collaboration continue through the second half of 2010.

Gilead is otherwise responsible for all development and commercialization of compounds, including all regulatory filings and clinical trials after proof-of-concept. Gilead is responsible for the manufacturing of compounds throughout all stages of development and commercialization. Gilead has agreed under the agreement to use reasonably diligent efforts to develop and commercialize at least one compound in each of the United States, Japan, Germany, France, Italy, Spain and the United Kingdom. In connection with Gilead's exclusive right to market and commercialize products, we have a one-time option to participate on a limited basis in the marketing effort in the United States. Pursuant to the terms of the collaboration agreement, Gilead must provide us with notice following commencement of a phase III clinical trial and prior to filing of an NDA. We must then notify Gilead whether we intend to designate field-based personnel to support their commercial activities within the United States. Following Gilead's receipt of our notice, the parties must negotiate in good faith to determine the number of Achillion field-based personnel and the manner of their participation. These field-based personnel will operate under the supervision of Gilead and receive training at a similar level to equivalent Gilead field-based personnel. We will bear the costs associated with the commercial participation of our field-based personnel; provided, however, that Gilead shall bear the expense of training. Our participation does not change the amount of any royalty payments Gilead is obligated to pay us on net sales of any drugs pursuant to our



## **Table of Contents**

collaboration agreement. Under the agreement, Gilead is required to make royalty payments, if any, to us until the end of the royalty term, which is the earlier of (i) ten years following the date of the first commercial sale of a compound or (ii) the expiration of the last Achillion patent or patent owned jointly with Gilead.

We received \$10.0 million from Gilead upon the execution of the agreement, consisting of license fees and an equity investment, and could receive up to \$157.5 million in development, regulatory and sales milestone payments, assuming the successful simultaneous development of a lead and back-up compound, and annual sales in excess of \$600 million. We may also receive royalties on net sales of products if commercialization is achieved.

Under the Gilead Arrangement through March 31, 2007, agreed upon research or development expenses, including internal full-time equivalent, or FTE, costs and external costs, incurred by both companies during the period up to proof-of-concept were borne equally by both parties. Effective April 1, 2007, internal full-time equivalent costs are no longer subject to this cost-sharing arrangement. Instead, each party bears its own internal costs, including FTE costs. External costs continue to be shared equally by both parties. We also revised our joint research program to focus on next-generation NS4A antagonists, after discontinuing clinical trials for ACH-806, an NS4A antagonist we previously evaluated.

The agreement will expire on the last to expire royalty term. In addition, Gilead may terminate the agreement for any reason by providing us with 120 days notice. Either party has the right to terminate for material breach, though we may terminate for Gilead's breach only on a market-by-market basis and, if applicable, a product-by-product basis.

### ***FOB Synthesis, Inc.***

In April 2008, we entered into a license and research agreement with FOB Synthesis, Inc., or FOB, granting us an exclusive worldwide license for the research, development and commercialization of certain FOB compounds for the treatment of serious bacterial infections.

Under the terms of the agreement, we paid to FOB a \$500,000 upfront license payment. We provided FOB with funding at specified levels to collaborate with us on the further characterization and development of the compounds through April 4, 2009. We had the option to extend the research term for an additional one year period with 30 days written notice to FOB prior to the end of the first year of the research term. In accordance with the agreement, in February 2009, we terminated this agreement effective April 4, 2009.

### ***Vion Pharmaceuticals/Yale University***

In February 2000, we entered into a license agreement with Vion Pharmaceuticals, pursuant to which we obtained a worldwide exclusive sublicense from Vion on the composition of matter and use of elvucitabine. Vion's license rights were granted to it by Yale, and Yale is a party with respect to certain provisions of this agreement. This license covers the use of elvucitabine alone, as a pharmaceutical composition containing elvucitabine alone, or its use as monotherapy to treat HIV. Yale has retained rights to utilize the intellectual property licensed by this agreement for its own noncommercial purposes. Pursuant to the agreement, we issued 6,250 shares of our common stock to each of Vion and Yale. In addition, pursuant to an amendment to the agreement entered into in January 2002, we granted options to purchase 7,500 shares of our common stock to each of Vion and Yale. Through December 31, 2008, we have made aggregate payments of \$35,000 to Yale under this agreement, including a \$10,000 initial license fee and a \$25,000 development milestone payment. Under the terms of the agreement, we may also be required to make additional milestone payments to Yale of up to an aggregate of \$850,000 for each licensed product based on the achievement of specified development and regulatory approval milestones. We are also required to pay Yale specified royalties on net product sales and a specified share of sublicensing fees that we receive under any sublicenses that we grant.

## **Table of Contents**

This agreement will remain in effect until the later of 15 years after the date of the agreement or the expiration of the last-to-expire licensed patent, which is currently scheduled to expire June 14, 2016, unless earlier terminated. We may terminate this agreement for convenience upon 30 days notice. The agreement may also be terminated by Vion upon 30 days notice of our uncured material breach of the agreement, including, among other things, nonpayment of any amounts owed under the agreement, our failure to provide reasonable assistance in connection with the enforcement of patents by Vion and Yale, upon 60 days notice of our uncured failure to meet specified development and marketing diligence requirements and upon notice of specified bankruptcy and insolvency events involving us. The agreement also provides that if the underlying license agreement between Vion and Yale terminates, our agreement with Vion will also terminate, provided that, if Yale terminates the underlying license agreement between Yale and Vion for cause, Yale has agreed to enter into a direct license with us on terms substantially similar to our agreement with Vion.

### ***Emory University***

In July 2002, we entered into a license agreement with Emory University, pursuant to which we obtained a worldwide exclusive license under specified licensed patents to use elvucitabine in combination with other antivirals. Under the license, Emory retains a right to use the intellectual property for educational and research purposes only and also retains the right to approve sublicenses under specified circumstances. Through December 31, 2008, we have made aggregate payments of \$150,000 to Emory under this agreement, including an initial license fee of \$100,000 and a development milestone payment of \$50,000. We may also be required to make additional payments of up to an aggregate of \$400,000 based on the achievement of specified development and regulatory approval milestones. Under this agreement, we are also required to pay Emory specified royalties on net product sales and a specified share of sublicensing fees that we receive under any sublicenses that we grant.

This agreement will remain in effect until the expiration of the last-to-expire licensed patent, which is currently scheduled to expire on January 27, 2015, unless earlier terminated. Each party has the right to terminate this agreement upon 60 days notice for an uncured material breach. Emory may terminate this agreement upon 60 days notice of specified bankruptcy and insolvency events involving us. We may terminate this agreement for convenience upon 60 days notice. Even after termination, we may continue selling licensed products for three months so long as royalties and all other monies owed are paid to Emory.

### **Manufacturing and Supply**

We currently rely on contract manufacturers to produce drug substances and drug products required for our clinical trials under current good manufacturing practices, with oversight by our internal managers. We plan to continue to rely upon contract manufacturers and collaboration partners to manufacture commercial quantities of our drug candidates if and when approved for marketing by the FDA. We currently rely on a single manufacturer for the preclinical or clinical supplies of each of our drug candidates and do not currently have relationships for redundant supply or a second source for any of our drug candidates. We believe that there are alternate sources of supply that can satisfy our clinical trial requirements without significant delay or material additional costs.

### **Sales and Marketing**

We intend to establish our own sales and marketing capabilities if and when we obtain regulatory approval of our drug candidates. In North America and Western Europe, patients in the markets for our drug candidates are largely managed by medical specialists in the areas of infectious diseases, hepatology and gastroenterology. Historically, companies have experienced substantial commercial success through the deployment of these specialized sales forces which can address a majority of key prescribers, particularly within the infectious disease marketplace. Therefore, we expect to utilize a specialized sales force in North America for the sales and marketing of drug candidates that we may successfully develop. We currently have no marketing, sales or distribution capabilities. In order to participate in the commercialization of any of our drugs, we must develop

## **Table of Contents**

these capabilities on our own or in collaboration with third parties. We may also choose to hire a third party to provide sales personnel instead of developing our own staff. Pursuant to our collaboration agreement with Gilead, we have granted Gilead worldwide commercialization rights for our HCV compounds that operate by the mechanism of NS4A antagonism. However, we have the option to participate on a limited basis in marketing efforts in the United States.

Outside of North America, and in situations or markets where a more favorable return may be realized through licensing commercial rights to a third party, we may license a portion or all of our commercial rights in a territory to a third party in exchange for one or more of the following: up-front payments, research funding, development funding, milestone payments and royalties on drug sales.

## **Regulatory Matters**

### ***Government Regulation and Product Approval***

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, record keeping, packaging, promotion, storage, advertising, distribution, marketing and export and import of products such as those we are developing. Our drugs must be approved by the FDA through the new drug application, or NDA, process before they may be legally marketed in the United States.

In the United States, drugs are subject to rigorous regulation by the FDA under the Federal Food, Drug and Cosmetic Act, or FDCA, and implementing regulations, as well as other federal and state statutes. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

completion of preclinical laboratory tests, animal studies and formulation studies according to FDA's Good Laboratory Practice regulations;

submission of an investigational new drug application, or IND, which must become effective before human clinical trials may begin and which must include approval by an institutional review board, or IRB, at each clinical site before the trials are initiated;

performance of adequate and well-controlled human clinical trials according to FDA's Good Clinical Practice regulations to establish the safety and efficacy of the proposed drug for its intended use;

submission to, and acceptance by, the FDA of an NDA;

satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practice, or cGMP, regulations to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and

FDA review and approval of the NDA.

### ***United States Drug Development Process***

## Edgar Filing: ACHILLION PHARMACEUTICALS INC - Form 10-K

Once a pharmaceutical candidate is identified for development it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. Prior to beginning human clinical trials, an IND sponsor must submit an IND to the FDA. The IND

## **Table of Contents**

sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. Some preclinical or nonclinical testing may continue even after the IND is submitted. In addition to including the results of the preclinical studies, the IND will also include a protocol detailing, among other things, the objectives of the first phase of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated, if the first phase lends itself to an efficacy evaluation. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the trial. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. 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.

Clinical trials involve the administration of the investigation new drug to healthy volunteers or patients under the supervision of one or more qualified investigators in accordance with Good Clinical Practice regulations. Clinical trials must be conducted under protocols detailing the objectives of the trial and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. Further, an institutional review board, or IRB, at each institution participating in the clinical trial must review and approve each protocol before any clinical trial commences at that institution. All research subjects must provide informed consent, and informed consent information must be submitted to the IRB for approval prior to initiation of the trial. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if adverse events or other certain types of other changes occur.

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

*Phase I:* The drug is initially introduced into healthy human subjects or patients with the disease and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

*Phase II:* Involves studies in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

*Phase III:* Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population, typically at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product and provide, if appropriate, an adequate basis for product labeling.

Phase I, phase II and phase III testing may not be completed successfully within any specified period, if at all. The FDA or an IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk.

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

### ***United States Review and Approval Processes***

FDA approval of an NDA is required before marketing of the product may begin in the United States. The NDA must include the results of product development, preclinical studies and clinical studies, together with other

## **Table of Contents**

detailed information, including information on the chemistry, manufacture and composition of the product. The FDA has 60 days from its receipt of the NDA to review the application to ensure that it is sufficiently complete for substantive review before accepting it for filing. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The submission of an NDA is also subject to the payment of user fees; a waiver of such fees may be obtained under certain limited circumstances. Further, the sponsor of an approved NDA is subject to annual product and establishment user fees. The approval process is lengthy and difficult and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. The FDA may also refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians 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. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured to determine whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality, purity and stability. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured.

NDAs receive either standard or priority review. A drug representing a potential significant improvement in treatment, prevention or diagnosis of disease may receive priority review. In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. Priority review and accelerated approval do not change the standards for approval, but may expedite the approval process.

If the FDA evaluation of the NDA and inspection of manufacturing facilities are favorable, the FDA may issue an approval letter or an approvable letter. An approvable letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for a specific indication. As a condition of NDA approval, the FDA may require post approval testing, including phase IV trials, and surveillance to monitor the drug's safety or efficacy and may impose other conditions, including labeling or distribution restrictions which can materially impact the potential market and profitability of the drug. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

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 in order for the FDA to reconsider the application. Even after submitting this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. With limited exceptions, the FDA may withhold approval of a NDA regardless of prior advice it may have provided or commitments it may have made to the sponsor.

### ***Post-Approval Requirements and Considerations***

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. After approval, some types of changes

## **Table of Contents**

to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products that have been commercialized, and in some circumstances the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

Any drug products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the drug, providing the FDA with updated safety and efficacy information, drug sampling and distribution requirements, notifying the FDA and gaining its approval of certain manufacturing or labeling changes, and complying with certain electronic records and signature requirements. Certain changes to the product, its labeling or its manufacturing require prior FDA approval and may require the conduct of further clinical investigations to support the change. Such approvals may be expensive and time-consuming and, if not approved, the product will not be allowed to be marketed as modified. FDA also regulates the promotional claims that are made about prescription drug products. In particular, a drug or biologic may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. In addition, the FDA requires clinical substantiation of any claims of superiority of one product over another, including that such claims be proven by adequate and well-controlled head-to-head clinical trials. For anti-infective drugs, *in vitro* superiority taken alone is generally not sufficient to permit promotional claims of product superiority. To the extent that market acceptance of our products 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 or our costs. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP regulations and other laws.

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

Once a new drug application is approved, the product covered thereby becomes a listed drug that can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application, or ANDA. An approved ANDA provides for marketing of a drug product that has the same active ingredients in the same strength, dosage form, and route of administration as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. There is generally no requirement, other than the requirement for bioequivalence testing, for an ANDA applicant to conduct or submit results of non-clinical or clinical tests to prove the safety or effectiveness of its drug product. Drugs approved in this way are commonly referred to as generic equivalents to the listed drug, are listed as such by the FDA, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

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

### ***Foreign Regulation***

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign

## **Table of Contents**

countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

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

## ***Reimbursement***

Sales of pharmaceutical products depend in significant part on the availability of third-party reimbursement. It is time consuming and expensive to seek reimbursement from third-party payors. Reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

The passage of the Medicare Prescription Drug and Modernization Act of 2003, or the MMA, imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries, which may affect the marketing of our products. The MMA also introduced a new reimbursement methodology, part of which went into effect in 2004, and a new prescription drug plan, which went into effect on January 1, 2006. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

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

There have been and we expect that there will continue to be frequent federal and state proposals to impose governmental pricing controls or cost containment measures for prescription drugs. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability.

## **Segment Reporting**

We are engaged solely in the discovery and development of innovative anti-infective drug therapies. Accordingly, we have determined that we operate in one operating segment.



**Table of Contents****Employees**

As of March 1, 2009, we had 54 employees, 24 of whom hold doctoral degrees. Approximately 45 of our employees are engaged in research and development, with the remainder engaged in administration, finance and business development functions. We believe our relations with our employees are good.

Our internet address is [www.achillion.com](http://www.achillion.com). We are not including the information contained in our website as part of, or incorporating it by reference into, this annual report on Form 10-K. We make available free of charge through our web site our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, as soon as reasonably practicable after we electronically file such materials with the Securities and Exchange Commission.

**Executive Officers of the Registrant**

<b>Name</b>	<b>Age</b>	<b>Position</b>
Michael D. Kishbauch	59	President and Chief Executive Officer
Milind S. Deshpande, Ph.D.	52	Executive Vice President and Chief Scientific Officer
Gautam Shah, Ph.D.	52	Senior Vice President and Chief Compliance Officer
Mary Kay Fenton	45	Vice President and Chief Financial Officer
Elizabeth A. Olek, D.O.	44	Vice President and Chief Medical Officer
Joseph Truitt	44	Vice President and Chief Commercial Officer

*Michael D. Kishbauch, President and Chief Executive Officer.* Prior to joining Achillion in July 2004 as our President and Chief Executive Officer, Mr. Kishbauch founded and served as President and Chief Executive Officer from September 1996 to July 2004 of OraPharma, Inc., a publicly traded, commercial-stage pharmaceutical company focused on oral health care, which was acquired by Johnson & Johnson in 2003. Prior to OraPharma, Inc., Mr. Kishbauch held senior management positions with MedImmune, Inc. Mr. Kishbauch holds an M.B.A. from the Wharton School of the University of Pennsylvania and a B.A. in biology from Wesleyan University.

*Milind S. Deshpande, Ph.D., Executive Vice President and Chief Scientific Officer.* Dr. Deshpande joined Achillion in September 2001 as Vice President of Chemistry, was named head of drug discovery in April 2002, Senior Vice President of Drug Discovery in December 2002, Senior Vice President and Chief Scientific Officer in December 2004 and Executive Vice President and Chief Scientific Officer in June 2007. Prior to joining Achillion, Dr. Deshpande was Associate Director of Lead Discovery and Early Discovery Chemistry at the Pharmaceutical Research Institute at Bristol-Myers Squibb from 1991 to 2001, where he managed the identification of new clinical candidates to treat infectious and neurological diseases. From 1988 to 1991, he held a faculty position at Boston University Medical School. Dr. Deshpande received his Ph.D. in Organic Chemistry from Ohio University, following his undergraduate education in India.

*Gautam Shah, Ph.D., Senior Vice President and Chief Compliance Officer.* Dr. Shah joined Achillion in May 2004 as Vice President of Regulatory Affairs and was named Senior Vice President and Chief Compliance Officer in September 2006. Prior to joining Achillion, he was Senior Director of Regulatory Affairs with Sepracor from February 2003 to May 2004. Prior to Sepracor, Dr. Shah was in the Regulatory Affairs Group of Bayer Health Care. Before Bayer, he held positions of increasing responsibilities at Pfizer Inc. in the area of Product and Process Development. Dr. Shah received his Ph.D. in Pharmaceutics from the University of Illinois, as well as a M.S. in Medicinal Chemistry from Wayne State University and a B.A. in Pharmacy from MSU University in India.

*Mary Kay Fenton, Vice President and Chief Financial Officer.* Ms. Fenton, a certified public accountant, has led Achillion's financial function since October 2000. From 1991 to 2000, Ms. Fenton held various positions within the Technology Industry Group at PricewaterhouseCoopers LLP, most recently as Senior Manager

## **Table of Contents**

responsible for the life sciences practice in Connecticut. Prior to 1991, Ms. Fenton was an economic development associate in the nonprofit sector. Ms. Fenton holds an M.B.A. in Finance from the Graduate School of Business at the University of Connecticut and an A.B. in Economics from the College of the Holy Cross.

*Elizabeth A. Olek, D.O., Vice President and Chief Medical Officer.* Prior to joining Achillion in December 2007, Dr. Olek served as Global Brand Medical Director and Clinical Research Physician in the Infectious Disease, Transplant and Immunology Group at Novartis Pharmaceuticals Corporation from January 2005 through November 2007. Between August and December 2004, Dr. Olek was employed as a clinical research consultant at the Avidia Research Institute. Between January 2003 and July 2004, Dr. Olek served as a Director of Clinical Research at InterMune Inc. From September 1998 through December 2002, Dr. Olek was a Director of Clinical Research at Genetics Institute/Wyeth Research. Dr. Olek holds an M.P.H. in epidemiology and biostatistics from the Boston University School of Public Health. She also holds a D.O. from Philadelphia College of Osteopathic Medicine and a B.S. in Pharmacy from the Philadelphia College of Pharmacy and Science University of Sciences Philadelphia.

*Joseph Truitt, Vice President and Chief Commercial Officer.* Prior to joining Achillion in January 2009, Mr. Truitt was Vice President of Business Development and Product Strategy for Lev Pharmaceuticals, Inc. from October 2007 to December 2008. From July 2006 through September 2007, he served as Lev's Vice President of Sales and Marketing and led the build out of the commercial team and infrastructure in preparation for product launch. From February 2002 to July 2006, Mr. Truitt was Vice President of Sales and Operations at Johnson & Johnson where he directed commercial operations at the company's OraPharma subsidiary. From 2000 to 2002, Mr. Truitt was Vice President of Sales and Operations of OraPharma, Inc. prior to its acquisition by Johnson & Johnson. Mr. Truitt holds an M.B.A. from St. Joseph's University, Philadelphia and a B.S. in Marketing from LaSalle University, Philadelphia.

## **Table of Contents**

### **ITEM 1A. RISK FACTORS**

*You should carefully consider the risks described below in addition to the other information contained in this report, before making an investment decision. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not currently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.*

#### **Risks 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 August 1998. As of December 31, 2008, our accumulated deficit was approximately \$180 million. We have not generated any revenue from the sale of drug candidates to date. We expect that our annual operating losses will increase substantially over the next several years as we expand our research, development and commercialization efforts, including as we:

complete late-stage preclinical studies and initiate clinical testing of ACH-1095;

initiate clinical testing of ACH-1625;

complete the open-label extension phases of our phase II clinical trials for elvucitabine; and

progress additional drug candidates.

To become profitable, we must successfully develop and obtain regulatory approval for our drug candidates and effectively manufacture, market and sell any drug candidates we develop. Accordingly, we may never generate significant revenues and, even if we do generate significant revenues, we may never achieve profitability.

**We will need substantial additional capital to fund our operations, including drug candidate development, manufacturing and commercialization. If we do not have or cannot raise additional capital when needed, we will be unable to develop and commercialize our drug candidates successfully, and our ability to operate as a going concern may be adversely affected.**

We believe that our existing cash and cash equivalents will be sufficient to support our current operating plan through at least the next twelve months. Our operating plan may change as a result of many factors, including:

the outcome of future clinical trials of ACH-1095, which will determine our ability to earn future milestone payments from our partner Gilead;

the costs involved in the clinical development, manufacturing and formulation of ACH-1625;

the outcome of our strategic and development assessment of ACH-702;

the costs involved in the preclinical and clinical development of ACH-1095 and other NS4A antagonists, certain portions of which we share with Gilead;

## Edgar Filing: ACHILLION PHARMACEUTICALS INC - Form 10-K

our ability to enter into corporate collaborations and the terms and success of these collaborations;

the costs involved in obtaining regulatory approvals for our drug candidates;

the scope, prioritization and number of programs we pursue;

the costs involved in preparing, filing, prosecuting, maintaining, enforcing and defending patent and other intellectual property claims;

our ability to raise incremental debt or equity capital, including any changes in the credit market that may impact our ability to obtain capital in the future;

## **Table of Contents**

our acquisition and development of new technologies and drug candidates; and

competing technological and market developments currently unknown to us.

If our operating plan changes, we may need additional funds sooner than planned. Such additional financing may not be available when we need it or may not be available on terms that are favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. If adequate funds are not available to us on a timely basis, or at all, we may be required to:

terminate or delay preclinical studies, clinical trials or other development activities for one or more of our drug candidates; or

delay our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our drug candidates, if approved for sale.

We may seek additional financing through a combination of private and public equity offerings, debt financings and collaboration, strategic alliance and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include adverse liquidation or other preferences that adversely affect your rights as a stockholder. For example, in August 2008, we issued in a private placement 10,714,655 shares of our common stock, plus common stock warrants to purchase a total of 2,678,644 additional shares of stock, resulting in gross proceeds to us of \$31.1 million but which substantially diluted our existing stockholders. We also issued warrants in the private placement, which if exercised in full would generate approximately \$10.4 million in additional proceeds. However, there can be no assurance that the investors will exercise their warrants. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration, strategic alliance and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or drug candidates, or grant licenses on terms that are not favorable to us.

### **We depend on the success of our HCV drug candidates, ACH-1095 and ACH-1625, which are still under development.**

We have invested a significant portion of our efforts and financial resources in the development of our HCV candidates, ACH-1095 and ACH-1625, for the treatment of chronic hepatitis C. Our ability to generate revenues will depend heavily on the successful development and commercialization of these drug candidates. The development and commercial success of these drug candidates will depend on several factors, including the following:

our ability to provide acceptable evidence of the safety and efficacy of these drug candidates in current and future clinical trials;

receipt of marketing approvals from the FDA and similar foreign regulatory authorities;

establishing commercial manufacturing arrangements with third-party manufacturers;

launching commercial sales of the drugs, whether alone or in collaboration with others; and

acceptance of the drug in the medical community and with third-party payors.

We plan to enter human clinical trials for our HCV candidates, ACH-1095 and ACH-1625 in 2009. Positive results in preclinical studies of a drug candidate may not be predictive of similar results in human clinical trials, and promising results from early clinical trials of a drug candidate may not be replicated in later clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in early-stage development. Accordingly, the results from

## Edgar Filing: ACHILLION PHARMACEUTICALS INC - Form 10-K

the completed preclinical studies for ACH-1095 and ACH-1625 may not be predictive of the results we may obtain in later stage trials. We do not expect any of our drug candidates to be commercially available for at least several years, if at all.

## **Table of Contents**

**If we are not successful in forming an alliance for the commercialization of elvucitabine, or are significantly delayed in doing so, our business may be harmed.**

We currently plan to enter into an alliance for the phase III development and commercialization of elvucitabine. Given the limited number of global pharmaceutical companies which currently develop and market drugs for the treatment of HIV, and the strategic need for elvucitabine to be suitable for co-formulation with drugs already marketed or under development by a potential partner, the number of potential partners is relatively small. To date, we have been unsuccessful in partnering with the major pharmaceutical companies with whom we have had on-going discussions. We are continuing partnering efforts with regional companies and institutions, including those in Asia, South America and elsewhere. If we are not successful in forming an alliance before the completion of the currently ongoing trial extensions, we do not plan to enter phase III clinical trials and would not independently pursue further development or commercialization of elvucitabine.

**If we are not able to determine the most appropriate therapeutic use for ACH-702, or determine and execute a successful business strategy pursuant to that use, our business may be harmed.**

Following preclinical studies, we completed a pre-IND consultation with the FDA on the most appropriate clinical development program for ACH-702. While the FDA provided guidance on an appropriate path toward regulatory approval for topical administration for ACH-702, the Division of Anti-Infective and Ophthalmology Products referred our request for additional guidance on systemic administration of ACH-702 to the DSTPP. We continue to assess our strategic and development options for ACH-702 for topical administration and other potential applications including use in biofilms and for use against tuberculosis. At this time, we do not anticipate moving into clinical development of ACH-702 until we complete our strategic assessment, and even then, we may not invest significantly in the future development of this compound without a collaboration partner. Even if we elect to seek a collaboration partner, we may be unable to find an appropriate collaboration partner to advance the program.

**Our market is subject to intense competition. If we are unable to compete effectively, our drug candidates may be rendered noncompetitive or obsolete.**

We are engaged in segments of the pharmaceutical industry that are highly competitive and rapidly changing. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations are pursuing the development of novel drugs that target infectious diseases. We face, and expect to continue to face, intense and increasing competition as new products enter the market and advanced technologies become available. In addition to currently approved drugs, there are a significant number of drugs that are currently under development and may become available in the future for the treatment of chronic hepatitis C, serious hospital-based bacterial infections and HIV infection. We would expect ACH-1095, ACH-1625, ACH-702 and elvucitabine to compete with the following approved drugs and drug candidates currently under development:

*ACH-1095 and ACH-1625.* If approved, our NS4A antagonist, ACH-1095, and our protease inhibitor, ACH-1625, would compete with drugs currently approved for the treatment of hepatitis C, the interferon-alpha based products from Roche (Pegasys and Roferon-A) or Schering-Plough (Intron-A or Peg-Intron) and the ribavirin based products from Schering-Plough (Rebetrol), Roche (Copegus) or generic versions sold by various companies. In addition, our HCV compounds may compete with the interferon and ribavirin based drugs currently in development such as Valeant's ribavirin analog (Viramidine) and Human Genome Sciences Albuferon. Other products are also under development for the treatment of hepatitis C by companies such as Abbott, Anadys, Boehringer Ingelheim, Bristol-Myers Squibb, Gilead, GlaxoSmithKline, Human Genome Sciences, Intermune, Johnson & Johnson, Medivir, Merck, Novartis, Pfizer, Pharmasset, Roche, Schering-Plough, Valeant and Vertex.

*ACH-702.* ACH-702, if approved, would compete with drugs currently marketed for the treatment of serious gram-positive nosocomial infections including: vancomycin (multiple generic forms), Cubicin (daptomycin) by Cubist Pharmaceuticals, Zyvox (linezolid) by Pfizer and Synercid (dalbapristin + quinupristin) by King Pharmaceuticals. In addition, ACH-702 may compete with other drugs currently under development for the

## Table of Contents

treatment of nosocomial gram-positive infections including: dalbavancin in development by Pfizer, telavancin from Theravance, oritavancin by Intermune, doripenem by Johnson & Johnson, ceftobiprole by Basilea and Johnson & Johnson, iclaprim by Arpida and garenoxacin by Schering-Plough. In addition, ACH-702 may compete with other drugs currently marketed or under development for the treatment of topical skin infections including Altabax by GlaxoSmithKline and XOMA-629 by Xoma Therapeutics Ltd. We may also compete with the following companies that have a strategic interest in the discovery, development and marketing of drugs for the treatment of bacterial infections: Abbott, Aventis, Bristol-Myers Squibb, Cubist, GlaxoSmithKline, Merck, Novartis, Roche and Wyeth.

*Elvucitabine.* If approved, elvucitabine would compete with the NRTIs currently marketed for treatment of HIV infection, including: Epivir (lamivudine), Retrovir (AZT), Ziagen (abacavir), Combivir (lamivudine + AZT), Trizivir (lamivudine + AZT + abacavir) and Epzicom (lamivudine + abacavir) from GlaxoSmithKline, Hivid (ddC) from Hoffman-La Roche, Emtriva (FTC), Viread (tenofovir) and Truvada (FTC + tenofovir) from Gilead and Videx EC, Videx (ddI) and Zerit (d4T) from Bristol-Myers Squibb. In addition, elvucitabine may compete with other NRTIs currently under development for HIV by companies such as Avexa, Medivir, Pharmasset and Koronis. Other drugs in other classes recently approved for treatment of HIV infection include Selzentry (maraviroc, an entry inhibitor) from Pfizer and Isentress (raltegravir, an integrase inhibitor) from Merck. In addition, there are other classes of drugs under development for the treatment of HIV infection by companies such as Abbott, Boehringer Ingelheim, Johnson & Johnson, Myriad, Roche, Schering-Plough and.

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 drug candidates;

more extensive experience in preclinical testing and clinical trials, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products;

drug candidates that have been approved or are in late-stage clinical development; and/or

collaborative arrangements in our target markets with leading companies and research institutions.

Competitive products may render our products obsolete or noncompetitive before we can recover the expenses of developing and commercializing our drug candidates. Furthermore, the development of new treatment methods and/or the widespread adoption or increased utilization of any vaccine for the diseases we are targeting could render our drug candidates noncompetitive, obsolete or uneconomical. If we successfully develop and obtain approval for our drug candidates, we will face competition based on the safety and effectiveness of our drug candidates, the timing of their entry into the market in relation to competitive products in development, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, price, patent position and other factors. If we successfully develop drug candidates but those drug candidates do not achieve and maintain market acceptance, our business will not be successful.

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

We depend upon our senior management and scientific staff for our business success. Key members of our senior team include Michael Kishbauch, our president and chief executive officer and Dr. Milind Deshpande, our executive vice president and chief scientific officer. All of our employment agreements with our senior management employees are terminable without notice by the employee. The loss of the service of any of the key members of our senior management may significantly delay or prevent the achievement of drug development and 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 adversely affect our business.





## **Table of Contents**

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

Our business exposes us to significant potential product liability risks that are inherent in the development, manufacturing and sales and marketing of human therapeutic products. Although we do not currently commercialize any products, claims could be made against us based on the use of our drug candidates in clinical trials. Product liability claims could delay or prevent completion of our clinical development programs. We currently have clinical trial insurance in an amount equal to up to \$10.0 million in the aggregate and will seek to obtain product liability insurance prior to the sales and marketing of any of our drug candidates. However, our insurance may not provide adequate coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to maintain current amounts of insurance coverage or obtain additional or sufficient insurance at a reasonable cost to protect against losses that could have a material adverse effect on us. If a claim is brought against us, we might be required to pay legal and other expenses to defend the claim, as well as uncovered damages awards resulting from a successful claim. Furthermore, whether or not we are ultimately successful in defending any such claims, we might be required to direct significant financial and managerial resources to such defense, and adverse publicity is likely to result.

**We may grow through additional acquisitions, which could dilute our existing shareholders and could involve substantial integration risks.**

As part of our business strategy, we may acquire other businesses and/or technologies in the future. We may issue equity securities as consideration for future acquisitions that would dilute our existing stockholders, perhaps significantly depending on the terms of the acquisition. We may also incur additional debt in connection with future acquisitions, which, if available at all, may place additional restrictions on our ability to operate our business. Acquisitions may involve a number of risks, including:

difficulty in transitioning and integrating the operations and personnel of the acquired businesses, including different and complex accounting and financial reporting systems;

potential disruption of our ongoing business and distraction of management;

potential difficulty in successfully implementing, upgrading and deploying in a timely and effective manner new operational information systems and upgrades of our finance, accounting and product distribution systems;

difficulty in incorporating acquired technology and rights into our products and technology;

unanticipated expenses and delays in completing acquired development projects and technology integration;

management of geographically remote units both in the United States and internationally;

impairment of relationships with partners;

entering markets or types of businesses in which we have limited experience;

potential loss of key employees of the acquired company; and

## Edgar Filing: ACHILLION PHARMACEUTICALS INC - Form 10-K

inaccurate assumptions of acquired company's product quality and/or product reliability.

As a result of these and other risks, we may not realize anticipated benefits from any acquisitions. Any failure to achieve these benefits or failure to successfully integrate acquired businesses and technologies could seriously harm our business.

## **Table of Contents**

### **Risks Related to Our Dependence on Third Parties**

**We may not be able to execute our business strategy if we are unable to enter into alliances with other companies that can provide capabilities and funds for the development and commercialization of our drug candidates. If we are unsuccessful in forming or maintaining these alliances on favorable terms, our business may not succeed.**

We have entered into a collaboration arrangement with Gilead for the development and commercialization of certain of our HCV compounds involving NS4A antagonism, and we may enter into additional collaborative arrangements in the future. For example, we currently plan to enter into an alliance for the phase III development and commercialization of elvucitabine. Given the limited number of global pharmaceutical companies which currently develop and market drugs for the treatment of HIV, and the strategic need for elvucitabine to be suitable for co-formulation with drugs already marketed or under development by a potential partner, the number of potential partners is relatively small. To date we have been unsuccessful in partnering with the major pharmaceutical companies with whom we have had on-going discussions. We are continuing partnering efforts with regional companies and institutions, including those in Asia, South America and elsewhere. If we are not successful in forming an alliance before the completion of the currently ongoing trial extensions, we do not plan to enter phase III clinical trials and would not independently pursue further development or commercialization of elvucitabine. In addition, as we continue to assess our strategic and development options for ACH-702, at this time, we do not anticipate moving into clinical development of ACH-702 until we complete this strategic assessment, and even then, we may not significantly invest in the future development of this compound without a collaboration partner. We also may enter into alliances with major biotechnology or pharmaceutical companies to jointly develop other specific drug candidates and to jointly commercialize them if they are approved. In such alliances, we would expect our biotechnology or pharmaceutical collaborators to provide substantial funding, as well as significant capabilities in clinical development, regulatory affairs, marketing and sales. We may not be successful in entering into any such alliances on favorable terms, if at all. Even if we do succeed in securing such alliances, we may not be able to maintain them if, for example, development or approval of a drug candidate is delayed or sales of an approved drug are disappointing. Furthermore, any delay in entering into collaboration agreements could delay the development and commercialization of our drug candidates and reduce their competitiveness even if they reach the market. Any such delay related to our collaborations could adversely affect our business.

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

If Gilead or another, future collaborative partner does not devote sufficient time and resources to collaboration arrangements 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 any existing or future collaboration partner were to breach or terminate its arrangements with us, the development and commercialization of the affected drug candidate could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue development and commercialization of the drug candidate on our own. Under our collaboration agreement with Gilead, Gilead may terminate the collaboration for any reason at any time upon 120 days notice. If Gilead were to exercise this right, the development and commercialization of our HCV compounds would be adversely affected.

In addition, research and development activities under our Gilead collaboration arrangement prior to proof-of-concept are overseen by a research committee comprised of equal numbers of our representatives and representatives from Gilead. The joint research committee assigns research and development tasks, agrees upon a budget for the research program, and shares equally in the related costs. The parties may agree at any time to increase or decrease the research budget. Prior to proof-of-concept, any disputes within the joint research committee that cannot be resolved between designated executives of each party will be resolved by Gilead.

Much of the potential revenue from our existing and future collaborations will consist of contingent payments, such as payments for achieving development milestones and royalties payable on sales of drugs

---

## **Table of Contents**

developed. The milestone and royalty revenues that we may receive under these collaborations will depend upon our collaborator's ability to successfully develop, introduce, market and sell new products. In addition, our collaborators may decide to enter into arrangements with third parties to commercialize products developed under our existing or future collaborations using our technologies, which could reduce the milestone and royalty revenue that we may receive, if any. In many cases we will not be involved in these processes and accordingly will depend entirely on our collaborators. Our collaboration partners may fail to develop or effectively commercialize products using our products or technologies because they:

decide not to devote the necessary resources due to internal constraints, such as limited personnel with the requisite scientific expertise, limited cash resources or specialized equipment limitations, or the belief that other drug development programs may have a higher likelihood of obtaining regulatory approval or may potentially generate a greater return on investment;

do not have sufficient resources necessary to carry the drug candidate through clinical development, regulatory approval and commercialization; or

cannot obtain the necessary regulatory approvals.

In addition, a collaborator may decide to pursue a competitive drug candidate developed outside of the collaboration. In particular, Gilead, our collaborator for our chronic hepatitis C program, currently is developing other products for the treatment of chronic hepatitis C, and the results of its development efforts could affect its commitment to our drug candidate. If a collaboration partner fails to develop or effectively commercialize drug candidates or drugs for any of these reasons, we may not be able to replace the collaboration partner with another partner to develop and commercialize a drug candidate or drugs under the terms of the collaboration. We may also be unable to obtain, on terms acceptable to us, a license from such collaboration partner to any of its intellectual property that may be necessary or useful for us to continue to develop and commercialize a drug candidate.

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

We do not have the ability to independently conduct clinical trials for our drug candidates, and we rely on third parties such as contract research organizations, medical institutions and clinical investigators to enroll qualified patients and conduct our clinical trials. Our reliance on these third parties for clinical development activities reduces our control over these activities. Accordingly, these third-party contractors may not complete activities on schedule, or may not conduct our clinical trials in accordance with regulatory requirements or our trial design. To date, we believe our contract research organizations and other similar entities with which we are working have performed well. However, if these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be required to replace them. Although we believe that there are a number of other third-party contractors we could engage to continue these activities, it may result in a delay of the affected trial. Accordingly, our efforts to obtain regulatory approvals for and commercialize our drug candidates may be delayed.

### **We currently depend on third-party manufacturers to produce our preclinical and clinical drug supplies and intend to rely upon third-party manufacturers to produce commercial supplies of any approved drug candidates. If in the future we manufacture any of our drug candidates, we will be required to incur significant costs and devote significant efforts to establish and maintain these capabilities.**

We rely upon third parties to produce material for preclinical and clinical testing purposes and intend to continue to do so in the future. We also expect to rely upon third parties to produce materials required for the commercial production of our drug candidates 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 drug candidates or market them. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured drug candidates ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing

## **Table of Contents**

agreement by the third party 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 drug candidates 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 of any of our drug candidates. In addition, such failure could be the basis for action by the FDA to withdraw approvals for drug candidates previously granted to us and for other regulatory action.

We currently rely on a single manufacturer for the preclinical and clinical supplies of each of our drug candidates and do not currently have relationships for redundant supply or a second source for any of our drug candidates. To date, our third-party manufacturers have met our manufacturing requirements, but we cannot be assured that they will continue to do so. Any performance failure on the part of our existing or future manufacturers could delay clinical development or regulatory approval of our drug candidates or commercialization of any approved products. If for some reason our current contract manufacturers cannot perform as agreed, we may be required to replace them. Although we believe that there are a number of potential replacements given our manufacturing processes are not manufacturer specific, we may incur added costs and delays in identifying and qualifying any such replacements. Furthermore, although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a drug candidate to complete the trial, any significant delay in the supply of a drug candidate for an ongoing trial due to the need to replace a third-party manufacturer could delay completion of the trial.

We may in the future elect to manufacture certain of our drug candidates in our own manufacturing facilities. If we do so, we will require substantial additional funds and need to recruit qualified personnel in order to build or lease and operate any manufacturing facilities.

### **Risks Related to the Development of Our Drug Candidates**

**All of our drug candidates are still in the early stages of development and remain subject to clinical testing and regulatory approval. If we are unable to successfully develop and test our drug candidates, we will not be successful.**

To date, we have not commercially marketed, distributed or sold any drug candidates. The success of our business depends primarily upon our ability to develop and commercialize our drug candidates successfully. Our most advanced drug candidate is elvucitabine, which is currently in phase II clinical trials. Our drug candidates must satisfy rigorous standards of safety and efficacy before they can be approved for sale. To satisfy these standards, we must engage in expensive and lengthy testing and obtain regulatory approval of our drug candidates. Despite our efforts, our drug candidates may not:

offer therapeutic or other improvement over existing, comparable drugs;

be proven safe and effective in clinical trials;

have the desired effects, or may include undesirable effects or may have other unexpected characteristics;

meet applicable regulatory standards;

be capable of being produced in commercial quantities at acceptable costs; or

be successfully commercialized.

In addition, we may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize our drug candidates, including:

regulators or Institutional Review Boards, or IRBs, may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;

## **Table of Contents**

our preclinical tests or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials, or we may abandon projects that we expect to be promising;

enrollment in our clinical trials may be slower than we currently anticipate or participants may drop out of our clinical trials at a higher rate than we currently anticipate, resulting in significant delays;

our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner;

we might have to suspend or terminate our clinical trials if the participants are exposed to unacceptable health risks;

IRBs or regulators, including the FDA, may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements; and

the supply or quality of our drug candidates or other materials necessary to conduct our clinical trials may be insufficient or inadequate.

We, and a number of other companies in the pharmaceutical and biotechnology industries, have suffered significant setbacks in later stage clinical trials even after achieving promising results in early-stage development. For example, in February 2007, we announced that we discontinued further clinical development of ACH-806 (also known as GS-9132) which was determined to have positive antiviral effect in a proof-of-concept clinical trial in HCV infected patients, but also to elevate serum creatinine levels, a marker of kidney function. There can be no assurance that we have identified the source of the serum creatinine elevation and that we will not see a similar outcome in human clinical trials with that program's successor compound, ACH-1095 (also known as GS-9525). Accordingly, there can be no assurance that this, or another type of toxicity, will not arise in future clinical trials. Additionally, the results from the completed preclinical studies and clinical trials and ongoing clinical trials for elvucitabine, ACH-702, ACH-1625 and our other drug candidates may not be predictive of the results we may obtain in later stage trials. In addition, we have not yet made a final determination regarding the most appropriate therapeutic application or clinical development plan for ACH-702. We continue to assess our strategic and development options for ACH-702 for topical administration and other potential applications including use in medical biofilms and for use against tuberculosis. At this time, we do not anticipate moving into clinical development of ACH-702 until we complete this strategic assessment, and even then, we may not invest significantly in the future development of this compound without a collaboration partner. We do not expect any of our drug candidates to be commercially available for at least several years.

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

Our drug candidates are subject to extensive governmental regulations relating to among other things, research, testing, development, manufacturing, safety, efficacy, record keeping, labeling, marketing and distribution of drugs. Rigorous preclinical testing 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 drug candidates. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that none of the drug candidates we are developing will obtain marketing approval. In connection with the clinical trials for ACH-1095, ACH-1625, ACH-702, elvucitabine and any other drug candidate we may seek to develop in the future, we face risks that:

the drug candidate may not prove to be efficacious;

the drug may not prove to be safe;

the results may not confirm the positive results from earlier preclinical studies or clinical trials; and



the results may not meet the level of statistical significance required by the FDA or other regulatory agencies.

## Table of Contents

We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. The time required to complete clinical trials and for FDA and other countries' regulatory review processes is uncertain and typically takes many years. Our analysis of data obtained from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unanticipated delays or increased costs due to government regulation from future legislation or administrative action or changes in FDA policy during the period of 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 progress the development of a drug candidate and to generate revenues from that drug candidate. In particular, we recently completed a pre-IND consultation with the FDA on the most appropriate clinical development program for ACH-702. Given the complexity of the mechanism of action of ACH-702, which operates via a three-part target including gyrase, topoisomerase IV and primase, the complexity of the preclinical results noted with ACH-702, and the evolving regulatory climate for antibacterials, we decided our development strategy for this compound should be further discussed with the FDA before initiating human clinical studies. While the FDA provided guidance on an appropriate path toward regulatory approval for topical administration for ACH-702, the Division of Anti-Infective and Ophthalmology Products referred our request for additional guidance on systemic administration of ACH-702 to the Division of Special Pathogen and Transplant Products (the DSPTP). We are currently assessing our strategic and development plans for ACH-702 for topical administration and other potential applications including use in medical biofilms and for use against tuberculosis. Even after receiving guidance from the DSPTP, if any, there can be no assurance that the FDA will approve our IND application once filed. Furthermore, any regulatory approval to market a product may be subject to limitations on the indicated uses for which we may market the product and affect reimbursement by third-party payors. These limitations may limit the size of the market for the product. We are also subject to numerous foreign regulatory requirements governing the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process includes all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of foreign regulations. Approval by the FDA does not ensure approval by regulatory authorities outside the United States. Foreign jurisdictions may have different approval procedures than those required by the FDA and may impose additional testing requirements for our drug candidates.

**If clinical trials for our drug candidates are prolonged or delayed, we may be unable to commercialize our drug candidates on a timely basis, which would require us to incur additional costs and delay our receipt of any product revenue.**

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, suspend or terminate clinical trials, or delay the analysis of data from our completed or ongoing clinical trials. Any of the following could delay the clinical development of our drug candidates:

ongoing discussions with the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;

delays in receiving, or the inability to obtain, required approvals from institutional review boards or other reviewing entities at clinical sites selected for participation in our clinical trials;

delays in enrolling volunteers and patients into clinical trials;

a lower than anticipated retention rate of volunteers and patients in clinical trials;

the need to repeat clinical trials as a result of inconclusive or negative results or unforeseen complications in testing;

inadequate supply or deficient quality of drug candidate materials or other materials necessary to conduct our clinical trials;

---

**Table of Contents**

unfavorable FDA inspection and review of a clinical trial site or records of any clinical or preclinical investigation;

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

the placement by the FDA of a clinical hold on a trial.

Our ability to enroll patients in our clinical trials in sufficient numbers and on a timely basis will be subject to a number of factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial. Delays in patient enrollment may result in increased costs and longer development times. For example, we experienced delays in patient enrollment in connection with our phase II trial of elvucitabine in HIV infected patients who have failed a HAART regimen which included Efavir (lamivudine) due to the strict entry criteria for this trial. As a result, we expanded the number of sites at which the trial was conducted and changed the protocol of the trial to include additional treatment with elvucitabine after the initial 14 days of treatment. In addition, subjects may drop out of our clinical trials, and thereby impair the validity or statistical significance of the trials.

We, the FDA or other applicable regulatory authorities or IRBs may suspend clinical trials of a drug candidate at any time if we or they believe the subjects or patients participating in such clinical trials are being exposed to unacceptable health risks or for other reasons.

We cannot predict whether any of our drug candidates will encounter problems during clinical trials which will cause us or regulatory authorities to delay or suspend these trials, or which will delay the analysis of data from these trials. In addition, it is impossible to predict whether legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be. If we experience any such problems, we may not have the financial resources to continue development of the drug candidate that is affected or the development of any of our other drug candidates.

In addition, we, along with our collaborators or subcontractors, may not employ, in any capacity, persons who have been debarred under the FDA's Application Integrity Policy. Employment of such a debarred person (even if inadvertently) may result in delays in the FDA's review or approval of our products, or the rejection of data developed with the involvement of such persons.

**Even if we obtain regulatory approvals, our drug candidates will be subject to ongoing regulatory review. If we fail to comply with continuing U.S. and applicable foreign regulations, we could lose those approvals, and our business would be seriously harmed.**

Even if we receive regulatory approval of any drugs we are developing or may develop, we will be subject to continuing regulatory review, including the review of clinical results which are reported after our drug candidates become commercially available approved drugs. As greater numbers of patients use a drug following its approval, side effects and other problems may be observed after approval that were not seen or anticipated during pre-approval clinical trials. In addition, the manufacturer, and the manufacturing facilities we use to make any approved drugs, will also be subject to periodic review and inspection by the FDA. The subsequent discovery of previously unknown problems with the drug, manufacturer or facility may result in restrictions on the drug, manufacturer or facility, including withdrawal of the drug from the market. If we fail to comply with applicable continuing regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approval, product recalls and seizures, operating restrictions and criminal prosecutions.

Our product promotion and advertising is also subject to regulatory requirements and continuing regulatory review. In particular, the marketing claims we will be permitted to make in labeling or advertising regarding our marketed products will be limited by the terms and conditions of the FDA-approved labeling. We must submit copies of our advertisements and promotional labeling to the FDA at the time of initial publication or dissemination. If the FDA believes these materials or statements promote our products for unapproved indications, or with unsubstantiated claims, or if we fail to provide appropriate safety-related information, the

## **Table of Contents**

FDA could allege that our promotional activities misbrand our products. Specifically, the FDA could issue an untitled letter or warning letter, which may demand, among other things, that we cease such promotional activities and issue corrective advertisements and labeling. The FDA also could take enforcement action including seizure of allegedly misbranded product, injunction or criminal prosecution against us and our officers or employees. If we repeatedly or deliberately fail to submit such advertisements and labeling to the agency, the FDA could withdraw our approvals. Moreover, the Department of Justice can bring civil or criminal actions against companies that promote drugs or biologics for unapproved uses, based on the False Claims Act and other federal laws governing reimbursement for such products under the Medicare, Medicaid and other federally supported healthcare programs. Monetary penalties in such cases have often been substantial, and civil penalties can include costly mandatory compliance programs and exclusion from federal healthcare programs.

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

Our research and development efforts involve the controlled use of hazardous materials, chemicals and various radioactive compounds. Although we believe that our safety procedures for the use, manufacture, storage, handling and disposing of these materials comply with the standards prescribed by federal, state and local 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. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. Although we maintain workers' compensation insurance to cover us for costs we may incur due to injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. In addition, though we have environmental liability insurance, such coverage may not provide for all related losses. We may incur substantial costs to comply with, and substantial fines or penalties if we violate any of these laws or regulations.

## **Risks Related to Commercialization of Our Drug Candidates**

**If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our drug candidates, we may not generate product revenue.**

We have no commercial products, and we do not currently have an organization for the sales and marketing of pharmaceutical products. In order to successfully commercialize any drugs that may be approved in the future by the FDA or comparable foreign regulatory authorities, we must build our sales and marketing capabilities or make arrangements with third parties to perform these services. For certain drug candidates in selected indications where we believe that an approved product could be commercialized by a specialty North American sales force that calls on a limited but focused group of physicians, we intend to commercialize these products ourselves. However, in therapeutic indications that require a large sales force selling to a large and diverse prescribing population and for markets outside of North America, we plan to enter into arrangements with other companies for commercialization. For example, we have entered into an agreement with Gilead for the development and commercialization of certain of our HCV candidates involving NS4A antagonism. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable.

**If physicians and patients do not accept our future drugs, we may be unable to generate significant revenue, if any.**

Even if ACH-1095, ACH-1625, ACH-702, elvucitabine or any other drug candidates we may develop or acquire in the future, obtain regulatory approval, they may not gain market acceptance among physicians, health care payors, patients and the medical community. Factors that we believe could materially affect market acceptance of our product candidates include:

the timing of market introduction of competitive drugs;

## **Table of Contents**

the demonstrated clinical safety and efficacy of our product candidates compared to other drugs;

the cost-effectiveness of our product candidates;

the availability of reimbursement from managed care plans, the government and other third-party payors;

the convenience and ease of administration of our product candidates;

the existence, prevalence and severity of adverse side effects;

other potential advantages of alternative treatment methods; and

the effectiveness of marketing and distribution support.

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

**If third-party payors do not adequately reimburse patients for any of our drug candidates that are approved for marketing, they might not be purchased or used, and our revenues and profits will not develop or increase.**

Our revenues and profits will depend significantly upon the availability of adequate reimbursement for the use of any approved drug candidates from governmental and other third-party payors, both in the United States and in foreign markets. Reimbursement by a third party may depend upon a number of factors, including the third-party payor's determination that use of a product is:

a covered benefit under its health plan;

safe, effective and medically necessary;

appropriate for the specific patient;

cost effective; and

neither experimental nor investigational.

Obtaining reimbursement approval for a product from each third-party and government payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of any approved drugs to each payor. We may not be able to provide data sufficient to gain acceptance with respect to reimbursement. There also exists substantial uncertainty concerning third-party reimbursement for the use of any drug candidate incorporating new technology, and even if determined eligible, coverage may be more limited than the purposes for which the drug is approved by the FDA. Moreover, eligibility for coverage does not imply that any drug will be reimbursed in all cases or at a rate that allows us to make a profit or even cover our costs. Interim payments for new products, if applicable, may also be insufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for lower-cost products that are already reimbursed, may be incorporated into existing payments for other products or services, and may reflect budgetary constraints and/or imperfections in Medicare or Medicaid data used to calculate these rates. Net prices for products may be reduced by mandatory discounts or rebates required by government health care programs

## Edgar Filing: ACHILLION PHARMACEUTICALS INC - Form 10-K

or by any future relaxation of laws that restrict imports of certain medical products from countries where they may be sold at lower prices than in the United States.

There have been, and we expect that there will continue to be, federal and state proposals to constrain expenditures for medical products and services, which may affect payments for any of our approved products. The Centers for Medicare and Medicaid Services frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Third-party payors often follow

---

## **Table of Contents**

Medicare coverage policy and payment limitations in setting their own reimbursement rates and may have sufficient market power to demand significant price reductions. As a result of actions by these third-party payors, the health care industry is experiencing a trend toward containing or reducing costs through various means, including lowering reimbursement rates, limiting therapeutic class coverage and negotiating reduced payment schedules with service providers for drug products.

Our inability to promptly obtain coverage and profitable reimbursement rates from government-funded and private payors for any approved products could have a material adverse effect on our operating results and our overall financial condition.

**Federal legislation has increased the pressure to reduce prices of pharmaceutical products paid for by Medicare, which could adversely affect our revenues, if any.**

The Medicare Prescription Drug Improvement and Modernization Act of 2003, or MMA, changes the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and eventually will introduce a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation provides authority for limiting the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

### **Risks Related to Patents and Licenses**

**If we are unable to adequately protect our drug candidates, or if we infringe the rights of others, our ability to successfully commercialize our drug candidates will be harmed.**

As of December 31, 2008, our patent portfolio included a total of at least 210 patents and patent applications worldwide. We own or hold exclusive licenses to a total of 13 U.S. issued patents and 28 U.S. pending provisional and non-provisional patent applications, as well as at least 170 pending PCT applications and associated non-US patents and patent applications. Our success depends in part on our ability to obtain patent protection both in the United States and in other countries for our drug candidates. Our ability to protect our drug candidates from unauthorized or infringing use by third parties depends in substantial part 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 maintain, 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 our drug candidates or provide sufficient protection to afford us a commercial advantage against competitive products or processes. In addition, we cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us. Even if patents have issued or will issue, we cannot guarantee that the claims of these patents are or will be valid or enforceable or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us. 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 as a U.S. patent. Similarly, publication of discoveries in the scientific or patent literature often lag behind actual discoveries. Consequently, 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 drug candidates or their use as anti-infective drugs. In the event that a third party has also filed a U.S. patent application relating to our drug candidates or a similar invention, we may have to participate in interference proceedings declared by the U.S. Patent Office to determine priority of invention in the United States.

---

## **Table of Contents**

The costs of these proceedings could be substantial and it is possible that our efforts would be unsuccessful, resulting in a loss of our U.S. patent position. Furthermore, we may not have identified all U.S. and foreign patents or published applications that affect our business either by blocking our ability to commercialize our drugs or by covering similar technologies that affect our drug market.

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.

**We license patent rights from third-party owners. If such owners do not properly maintain or enforce the patents underlying such licenses, our competitive position and business prospects will be harmed.**

We are party to a number of licenses that give us rights to third-party intellectual property that is necessary or useful for our business. In particular, we have obtained a sublicense from Vion Pharmaceuticals and a license from Emory University with respect to elvucitabine. We may enter into additional licenses for third-party intellectual property in the future. Our success will depend in part on the ability of our licensors to obtain, maintain and enforce patent protection for their intellectual property, in particular, those patents to which we have secured exclusive rights. Our licensors may not successfully prosecute the patent applications to which we are licensed. Even if patents issue in respect of these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. In addition, our licensors may terminate their agreements with us in the event we breach the applicable license agreement and fail to cure the breach within a specified period of time. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects.

**Litigation regarding patents, patent applications and other proprietary rights may be expensive and time consuming. If we are involved in such litigation, it could cause delays in bringing drug candidates to market and harm our ability to operate.**

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Although we are not currently aware of any litigation or other proceedings or third-party claims of intellectual property infringement related to our drug candidates, the pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may obtain patents in the future and allege that the use of our technologies infringes these patent claims or that we are employing their proprietary technology without authorization. Likewise, third parties may challenge or infringe upon our existing or future patents. Under our license agreements with Vion Pharmaceuticals we have the right, but not an obligation, to bring actions against an infringing third party. If we do not bring an action within a specified number of days, the licensor may bring an action against the infringing party. Pursuant to our license agreement with Emory University and our research collaboration and license agreement with Gilead, Emory and Gilead have the primary right, but not an obligation, to bring actions against an infringing third party. However, if Gilead or Emory elects not to bring an action, we may bring an action against the infringing party.

Proceedings involving our patents or patent applications or those of others could result in adverse decisions regarding:

the patentability of our inventions relating to our drug candidates; and/or

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

Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action



---

## **Table of Contents**

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 do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may:

incur substantial monetary damages;

encounter significant delays in bringing our drug candidates to market; and/or

be precluded from participating in the manufacture, use or sale of our drug candidates or methods of treatment requiring licenses.

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

We rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. In order to protect our proprietary technology and processes, we also rely in part on confidentiality and intellectual property assignment agreements with our corporate partners, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information nor result in the effective assignment to us of intellectual property, and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information or other breaches of the agreements. In addition, others may independently discover our trade secrets and proprietary information, and in such case we could not assert any trade secret rights against such party. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. Costly and time-consuming litigation could be necessary to seek 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.

### **Risks Relating to Our Common Stock**

**We may be required to dilute our existing stockholders further in connection with capital raising activities and certain purchasers may beneficially own significant blocks of our common stock. Additionally, the market price of our common stock may fall due to the increased number of shares available in the public market.**

In connection with capital raising activities, we may be required to dilute our existing stockholders substantially. For example, upon the closing of our private placement on August 12, 2008, we issued to a group of institutional investors a total of 10,714,655 shares of our common stock, plus common stock warrants to purchase a total of 2,678,664 additional shares of common stock. We also issued these investors additional unit warrants which represent the right to purchase 3,679,078 units, consisting of 3,679,078 shares of common stock and common stock warrants to purchase 919,770 shares of our common stock. The issuance of these shares and warrants resulted in substantial dilution to stockholders who held our common stock prior to the private placement.

Pursuant to our obligations under a registration rights agreement for the private placement, on October 6, 2008 we filed a registration statement with the SEC, covering the resale of the 10,714,655 shares of common stock issued in the private placement and the 2,678,664 shares of common stock issuable upon exercise of the warrants which was declared effective on October 30, 2008, making such shares available for immediate resale in the public market. The market price of our common stock could fall due to an increase in the number of shares available for sale in the public market.

**Our executive officers, directors and principal stockholders own a large percentage of our voting common stock and could limit our stockholders' influence on corporate decisions or could delay or prevent a change in corporate control.**

As of March 1, 2009, our directors, executive officers and current holders of more than 5% of our outstanding common stock, together with their affiliates and related persons, beneficially own, in the aggregate, approximately

## **Table of Contents**

86% of our outstanding common stock. As a result, these stockholders, if acting together, have the ability to determine the outcome of all matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets and other extraordinary transactions. The interests of this group of stockholders may not always coincide with our corporate interests or the interest of other stockholders, and they may act in a manner with which you may not agree or that may not be in the best interests of other stockholders. This concentration of ownership may have the effect of:

delaying, deferring or preventing a change in control of our company;

entrenching our management and/or board;

impeding a merger, consolidation, takeover or other business combination involving our company; or

discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company.

**Our stock price is likely to be volatile, and the market price of our common stock may decline in value in the future.**

The market price of our common stock has fluctuated in the past and is likely to fluctuate in the future. During the period from January 1, 2007 to December 31, 2008, our closing stock price has ranged from a low of \$0.68 to a high of \$19.61. Market prices for securities of early stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

the results of preclinical studies and planned clinical trials of our drug candidates, including ACH-1095 and ACH-1625;

the results of our currently on-going phase II trial extensions for elvucitabine;

the entry into, or termination of, key agreements, in particular our collaboration agreement with Gilead or our sublicense agreement with Vion Pharmaceuticals, or any new collaboration agreement we may enter for elvucitabine;

the results of regulatory reviews relating to the approval of our drug candidates;

the initiation of, material developments in, or conclusion of litigation to enforce or defend any of our intellectual property rights;

failure of any of our drug candidates, if approved, to achieve commercial success;

general and industry-specific economic conditions that may affect our research and development expenditures;

the results of clinical trials conducted by others on drugs that would compete with our drug candidates;

the failure or discontinuation of any of our research programs;

issues in manufacturing our drug candidates or any approved products;

the introduction of technological innovations or new commercial products by us or our competitors;

changes in estimates or recommendations by securities analysts, if any, who cover our common stock;

future sales of our common stock;

changes in the structure of health care payment systems;

period-to-period fluctuations in our financial results; and

low trading volume of our common stock.

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 significant impact on the market

## **Table of Contents**

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.

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

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our business operations and reputation.

### **Unstable market and economic conditions may have serious adverse consequences on our business.**

Our general business strategy may be adversely affected by the recent economic downturn and volatile business environment and continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate further, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which would directly affect our ability to attain our operating goals on schedule and on budget.

At December 31, 2008, we had \$8.5 million in cash and \$26.5 million of cash equivalents and marketable securities consisting of U.S. government and agency securities and FDIC guaranteed commercial paper held by a major banking institution.

There is a possibility that our stock price may decline, due in part to the volatility of the stock market and the general economic downturn.

### **Our management is required to devote substantial time and incur additional expense to comply with public company regulations. Our failure to comply with such regulations could subject us to public investigations, fines, enforcement actions and other sanctions by regulatory agencies and authorities and, as a result, our stock price could decline in value.**

Prior to our initial public offering in 2006, as a private company with limited resources, we maintained a small finance and accounting staff. As a public company, the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC, as well as the rules of the Nasdaq Global Market, have required us to implement additional corporate governance practices and adhere to a variety of reporting requirements and complex accounting rules. Compliance with these public company obligations places significant additional demands on our finance and accounting staff and on our financial, accounting and information systems.

In particular, as a public company, our management is required to conduct an annual evaluation of our internal controls over financial reporting and include a report of management on our internal controls in our annual reports on Form 10-K. If we are unable to continue to conclude that we have effective internal controls over financial reporting, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the value of our common stock.

### **We do not anticipate paying cash dividends, and accordingly stockholders must rely on stock appreciation for any return on their investment in us.**

We anticipate that we will retain our earnings, if any, for future growth and therefore do not anticipate paying cash dividends in the future. As a result, only appreciation in the price of our common stock will provide a return to stockholders

**Table of Contents**

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

We currently lease approximately 37,000 square feet of laboratory and office space in New Haven, Connecticut, which we occupy under a ten-year lease expiring in 2011. We believe our existing facilities are adequate for our current needs and that additional space will be available in the future on commercially reasonable terms as needed.

**ITEM 3. LEGAL PROCEEDINGS**

We are currently not a party to any material legal proceedings.

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

No matters were submitted to a vote of our security holders during the fourth quarter of 2008.

**Table of Contents****PART II****ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES*****Market Information***

Our common stock began trading on the NASDAQ Global Market on October 26, 2006 under the symbol ACHN. Prior to that time, there was no established public trading market for our common stock. The following table sets forth the high and low sale prices per share for our common stock on the NASDAQ Global Market for the period indicated:

**Year and Quarter:**

	<b>High</b>	<b>Low</b>
<b>2008</b>		
First Quarter	\$ 6.75	\$ 3.26
Second Quarter	\$ 4.50	\$ 1.96
Third Quarter	\$ 3.02	\$ 0.85
Fourth Quarter	\$ 1.84	\$ 0.68
<b>2007</b>		
First Quarter	\$ 20.00	\$ 5.71
Second Quarter	\$ 7.41	\$ 4.91
Third Quarter	\$ 8.00	\$ 5.61
Fourth Quarter	\$ 6.50	\$ 3.68
<b>2006</b>		
Fourth Quarter (beginning October 26, 2006)	\$ 17.94	\$ 11.57

Information regarding our equity compensation plans and the securities authorized for issuance thereunder is set forth in Item 12 below.

***Holders of record***

As of March 13, 2009, there were approximately 81 holders of record of our common stock.

***Dividends***

We have never paid or declared any cash dividends on our common stock. We currently intend to retain any earnings for future growth and, therefore, do not expect to pay cash dividends in the foreseeable future.

***Sales of Unregistered Equity Securities and Use of Proceeds***

On August 12, 2008, we issued 10,714,655 units to ProQuest Investments, Clarus Ventures and Investor Growth Capital at a price of \$2.9049 per unit, resulting in gross proceeds of \$31.1 million. Each unit consists of one share of our common stock and a warrant to purchase 0.25 shares of common stock at an exercise price of \$3.53 per share. Additionally, the investors may have the option to purchase an additional 3,679,078 units between February 2009 and August 2009, subject to certain contingencies. We have agreed to seek stockholder approval for the transaction in accordance with NASDAQ Marketplace Rules.

We received aggregate net proceeds of approximately \$29.2 million, after deducting expenses of the offering of approximately \$2.0 million. These expenses consisted of payments of:

- i. \$1.7 million in fees and commissions; and

- ii. \$289,000 in legal and accounting fees.

## **Table of Contents**

The net proceeds of approximately \$29.2 million are invested in short-term investment grade securities and money market accounts. We currently plan to use the net proceeds for general corporate purposes and to fund our research operations including: (i) to initiate clinical testing of ACH-1095 and ACH-1625 and to begin clinical testing for both candidates, (ii) to complete our strategic and development assessment of ACH-702 data and if appropriate, prepare for clinical testing, (iii) to complete the open-label extension phases of our phase II clinical trials for elvucitabine, and (iv) to progress additional drug candidates.

Pursuant to our obligations under a registration rights agreement for the private placement, on October 6, 2008 we filed a registration statement with the SEC, covering the resale of the 10,714,655 shares of common stock issued in the private placement and the 2,678,664 shares of common stock issuable upon exercise of the warrants. This registration statement was declared effective on October 30, 2008.

### ***Issuer Purchases of Equity Securities***

Neither we nor any affiliated purchaser or anyone acting on behalf of us or an affiliated purchaser made any purchases of shares of our common stock in the fourth quarter of 2008.

### ***Comparative Stock Performance***

The following graph and related information should not be deemed soliciting material or to be filed with the Securities and Exchange Commission, nor shall such information be incorporated by reference into any future filing under the Securities Act of 1933 or Securities Exchange Act of 1934, each as amended, except to the extent that we specifically incorporate it by reference into such filing.



## **Table of Contents**

The following graph compares the cumulative total stockholder return on our common stock from October 26, 2006 (the first trading date following our initial public offering) to December 31, 2008 with the cumulative total return of (i) the NASDAQ Market Index and (ii) the NASDAQ Biotechnology Index. This graph assumes the investment of \$100.00 on October 26, 2006 in our common stock, the NASDAQ Market Index and the NASDAQ Biotechnology Index, and assumes any dividends are reinvested.

	10/26/06	12/31/06	12/31/07	12/31/08
ACHILLION PHARMACEUTICALS, INC.	100.00	130.02	40.27	5.49
NASDAQ BIOTECHNOLOGY INDEX	100.00	96.92	98.29	91.72
NASDAQ MARKET INDEX	100.00	102.03	112.16	66.19

**Table of Contents****ITEM 6. SELECTED FINANCIAL DATA**

The following selected financial data should be read together with the information under Management's Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and the notes to those financial statements included elsewhere in this Annual Report on Form 10-K. The selected statements of operations data for the years ended December 31, 2008, 2007 and 2006 and balance sheet data as of December 31, 2008 and 2007 set forth below have been derived from our audited financial statements included elsewhere in this Annual Report. The selected statement of operations data for the years ended December 31, 2005 and 2004 and balance sheet data as of December 31, 2006, 2005 and 2004 set forth below have been derived from the audited financial statements for such years not included in this Annual Report. The historical results presented here are not necessarily indicative of future results.

	2008	Years Ended December 31,			
		2007	2006	2005	2004
		(in thousands, except per share amounts)			
Statement of Operations Data:					
Total operating revenue	\$ (234)	\$ 4,038	\$ 3,292	\$ 8,526	\$ 807
Research and development	21,150	28,120	22,741	18,112	14,841
General and administrative	6,546	6,476	4,865	3,101	3,181
Total operating expenses	27,696	34,596	27,606	21,213	18,022
Loss from operations	(27,930)	(30,558)	(24,314)	(12,687)	(17,215)
Interest income (expense)	(353)	1,496	179	(976)	(509)
Tax benefit	132	960	49	88	264
Net loss	(28,151)	(28,102)	(24,086)	(13,575)	(17,460)
Net loss applicable to common shareholders	\$ (28,151)	\$ (28,102)	\$ (28,249)	\$ (16,514)	\$ (20,048)
Net loss per share basic and diluted	\$ (1.42)	\$ (1.80)	\$ (9.35)	\$ (32.96)	\$ (43.77)
Weighted average number of shares outstanding basic and diluted	19,812	15,583	3,022	501	458
	2008	2007	2006	2005	2004
Balance Sheet Data:					
Cash and cash equivalents	\$ 11,060	\$ 8,971	\$ 22,662	\$ 9,583	\$ 9,481
Marketable Securities	24,297	22,138	39,904		4,897
Working capital	24,359	20,224	53,190	654	6,264
Total assets	38,561	35,632	67,146	13,750	19,291
Long-term liabilities	1,361	1,402	8,102	5,021	14,811
Total liabilities	13,540	14,094	19,776	15,418	24,230
Convertible preferred stock				94,354	74,740
Total stockholders' (deficit) equity	25,021	21,538	47,370	(96,022)	(79,679)

## **Table of Contents**

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

We are a biopharmaceutical company focused on the discovery, development and commercialization of innovative treatments for infectious diseases. Within the anti-infective market, we are currently concentrating on the development of antivirals for the treatment of chronic hepatitis C and the development of antibacterials for the treatment of resistant bacterial infections. We are currently focusing our efforts on advancing two late-stage preclinical candidates: ACH-1095, an NS4A antagonist for the treatment of chronic hepatitis C, being developed in collaboration with Gilead Sciences, Inc., or Gilead, and ACH-1625, a protease inhibitor also for the treatment of chronic hepatitis C. In addition, we have established a pipeline of certain other product candidates for which we are currently seeking appropriate collaborative partners or for which we are considering to seek appropriate collaborative partners but to which we are not devoting significant resources at this time. These product candidates include elvucitabine for the treatment of HIV infection, and ACH-702 for the treatment of serious bacterial infections.

We have devoted and are continuing to devote substantially all of our efforts toward product research and development. We have incurred losses of \$166 million from inception through December 31, 2008 and had an accumulated deficit of \$180 million through December 31, 2008. Our net losses were \$28.2 million, \$28.1 million and \$24.1 million for the years ended December 31, 2008, 2007 and 2006, respectively. We have funded our operations primarily through:

proceeds of \$192.4 million from the sale of equity securities, including our initial public offering in October 2006 and a private placement of our common stock in August 2008;

borrowings of \$22.1 million from debt facilities; and

receipts of \$10.0 million from up-front and milestone payments, as well as \$9.1 million in cost-sharing receipts, from our collaboration partner, Gilead.

We expect to incur substantial and increasing losses for at least the next several years as we seek to:

complete late-stage preclinical studies and initiate clinical testing of ACH-1095;

initiate clinical testing of ACH-1625;

complete the open-label extension phases of our phase II clinical trials for elvucitabine; and

progress additional drug candidates.

We will need substantial additional financing to obtain regulatory approvals, fund operating losses, and, if deemed appropriate, establish manufacturing and sales and marketing capabilities, which we will seek to raise through public or private equity or debt financings, collaborative or other arrangements with third parties or through other sources of financing. There can be no assurance that such funds will be available on terms favorable to us, if at all. In addition to the normal risks associated with early-stage companies, there can be no assurance that we will successfully complete our research and development, obtain adequate patent protection for our technology, obtain necessary government regulatory approval for drug candidates we develop or that any approved drug candidates will be commercially viable. In addition, we may not be profitable even if we succeed in commercializing any of our drug candidates.

On August 12, 2008, in a private placement we issued to certain institutional investors 10,714,655 units at a price of \$2.9049 per unit, resulting in gross proceeds of \$31.1 million, or \$29.2 million net of offering expenses. Each unit consists of one share of our common stock and a warrant to purchase 0.25 shares of common stock at an exercise price of \$3.53 per share. Additionally, the investors may have the option to purchase an additional 3,679,078 units between February 2009 and August 2009, potentially resulting in additional proceeds and subject to certain

contingencies. We have agreed to seek stockholder approval for the transaction in accordance with NASDAQ Marketplace Rules.

## **Table of Contents**

### **Financial Operations Overview**

#### ***Revenue***

To date, we have not generated revenue from the sale of any drugs. The majority of our revenue recognized to date has been derived from our collaboration with Gilead to develop compounds for use in treating chronic hepatitis C. During the years ended December 31, 2008, 2007 and 2006 we recognized \$(234,000), \$4.0 million and \$3.0 million, respectively, under this collaboration agreement.

Upon initiating our collaboration with Gilead, we received a payment of \$10.0 million, which included an equity investment by Gilead determined to be worth approximately \$2.0 million. The remaining \$8.0 million is being accounted for as a nonrefundable up-front fee recognized under the proportionate performance model. Revenue under the proportionate performance model is recognized as our effort under the collaboration is incurred. Payments made by us to Gilead in connection with this collaboration are being recognized as a reduction of revenue. When our performance obligation is complete, we will recognize milestone payments, if any, when the corresponding milestone is achieved. We will recognize royalty payments, if any, upon product sales.

Effective April 1, 2007, each party provides for the costs of their own full-time equivalents. External research costs continue to be shared equally by both parties. Through March 31, 2007 research and development expenses under our collaboration with Gilead, including internal full-time equivalent costs and external research costs, incurred by both companies prior to proof-of-concept, were borne equally by both parties. As we were providing the majority of those services and were incurring the majority of those expenses, we were the net recipient of funds under this cost-sharing portion of the arrangement and therefore recognized the reimbursed costs as revenue rather than research expense. For the quarter ended December 31, 2008, Gilead incurred a greater amount of external costs, therefore we were a net payor of funds to Gilead under this portion of the arrangement.

We recognize revenue related to our Gilead arrangement using the proportionate performance method. Under the proportionate performance method, periodic revenue related to up-front license payments is recognized as the percentage of actual effort expended in that period to total effort expected for all of our performance obligations under the arrangement. Actual effort is generally determined based upon actual direct labor hours or full-time equivalents incurred and include research and development activities performed by internal scientists. Total expected effort is generally based upon the total direct labor hours of full-time equivalents incorporated into the detailed budget and project plan that is agreed to by both parties to the collaboration. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which we expect to complete the related performance obligations. Under our arrangement with Gilead Sciences, the joint research committee periodically reviews and updates the project plan. In the event that a change in estimate occurs, the change will be accounted for using the cumulative catch-up method which provides for an adjustment to revenue in the current period. Estimates of our level of effort may change in the future, resulting in a material change in the amount of revenue recognized in future periods. For example, the most recent project plan agreed upon by the joint research committee resulted in an increase to our total efforts under the collaboration and extended our estimated obligation period under the collaboration to the second half of 2010, resulting in an adjustment to our proportion of completed performance. This change in estimate caused a non-cash reduction in amounts previously recognized as revenue under the collaboration resulting in negative revenue for the fourth quarter of 2008.

#### ***Research and Development***

Our research and development expenses reflect costs incurred for our proprietary research and development projects as well as costs for research and development projects conducted as part of collaborative arrangements we establish. These costs consist primarily of salaries and benefits for our research and development personnel, costs of services by clinical research organizations, other outsourced research, materials used during research and development activities, facility-related costs such as rent and utilities associated with our laboratory and clinical development space, operating supplies and other costs associated with our research and development activities.

**Table of Contents**

We expect a slight reduction in research and development expenses over the next twelve months as a result of the reduction of expenses related to the near completion of the phase II clinical program for elvucitabine, the reduction of expenses relating to ACH-702 and the termination of our collaboration agreement with FOB Synthesis, offset by increased expenses related to the initiation of human clinical trials for ACH-1095 and ACH-1625.

All costs associated with internal research and development, and research and development services for which we have externally contracted, are expensed as incurred. The costs of obtaining and maintaining patents for our candidates are expensed as incurred as indirect costs. Our research and development expenses are outlined in the table below.

	For the Years Ended		
	2008	2007	2006
	(in thousands)		
Direct external costs:			
NS4A Antagonists (including ACH-806 and ACH-1095)	\$ 1,106	\$ 1,793	\$ 3,001
ACH-1625	3,470		
ACH-702	262	3,055	3,141
Elvucitabine	3,416	10,728	5,204
	8,254	15,576	11,346
Direct internal personnel costs	7,037	7,206	6,337
Sub-total direct costs	15,291	22,782	17,683
Indirect costs and overhead	5,859	5,338	5,058
Total research and development	\$ 21,150	\$ 28,120	\$ 22,741

Currently, we are initiating clinical studies for ACH-1095 and ACH-1625 and completing the open-label extension phases of two phase II clinical trials for elvucitabine. From inception through December 31, 2008, we incurred approximately \$29.3 million in total costs for our NS4A antagonist program, including both ACH-1095 and ACH-806, approximately \$10.7 million for ACH-1625, approximately \$19.2 million in total costs for ACH-702 and approximately \$49.4 million in total costs for elvucitabine. These figures include our internal research and development personnel costs and related facilities overhead.

We anticipate that the future expense associated with early clinical development through proof-of-concept of ACH-1095, our next generation NS4A antagonist, will total approximately \$4.0 million, exclusive of internal personnel costs. Our portion of this expense is anticipated to be \$2.0 million, which represents one-half of the external costs associated with those activities, as we share such external costs with Gilead. We estimate that the costs associated with early clinical development of ACH-1625, our HCV protease inhibitor, will be approximately \$3.0 million, exclusive of internal personnel costs. We are currently assessing our strategic and development plans for ACH-702 and considering whether to undertake such development independently or with a collaborative partner. We currently estimate that the clinical trial costs for two phase III clinical trials of elvucitabine in different HIV populations will be approximately \$50.0 million, exclusive of the internal personnel costs associated with conducting these trials; however, we currently do not plan to undertake these two Phase III trials for elvucitabine unless or until we enter into a collaboration agreement.

The successful development of our drug candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the remainder of the development of our drug candidates. We are also unable to predict when, if ever, material net cash inflows will commence from elvucitabine or any early stage programs. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

the scope, rate of progress and expense of our clinical trials and other research and development activities;

## **Table of Contents**

the potential benefits of our drug candidates over other therapies;

in the case of our HCV inhibitors involving NS4A antagonism, the rate at which our collaboration partner, Gilead, is able to complete preclinical and clinical trials, and the degree to which Gilead prioritizes those trials over its other development efforts;

our ability to market, commercialize and achieve market acceptance for any of our drug candidates that we are developing or may develop in the future;

future clinical trial results;

the terms and timing of any collaborative, licensing and other arrangements that we may establish;

the expense and timing of regulatory approvals; and

the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

A change in the outcome of any of these variables with respect to the development of any of our drug candidates would significantly change the costs and timing associated with the development of that drug candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those which we currently anticipate will be required to complete clinical development of a drug candidate, or if we experience significant delays in enrollment in any of our clinical trials, we would be required to expend significant additional financial resources and time on the completion of clinical development.

We expect expenses associated with the completion of these programs to be substantial and increase. We do not believe, however, that it is possible at this time to accurately project total program-specific expenses through commercialization. There exist numerous factors associated with the successful commercialization of any of our drug candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will evolve and therefore impact our clinical development programs and plans over time.

### ***General and Administrative***

Our general and administrative expenses consist primarily of salaries and benefits for management and administrative personnel, professional fees for legal, accounting and other services, travel costs and facility-related costs such as rent, utilities and other general office expenses. We expect that general and administrative expenses will remain substantially unchanged over the next twelve months.

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

The discussion and analysis of our financial condition and results of operations set forth below are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, we evaluate our estimates and assumptions, including those described below. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Management makes estimates and exercises judgment in revenue recognition, research and development costs, stock-based compensation and accrued expenses. Actual results may differ from these estimates under different assumptions or conditions.

**Table of Contents**

We believe the following critical accounting policies affect management's more significant judgments and estimates used in the preparation of our financial statements:

***Revenue Recognition***

We recognize revenue from contract research and development and research progress payments in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition*, or SAB No. 104, and Financial Accounting Standards Board, or FASB, Emerging Issue Task Force, or EITF, Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*, or EITF No. 00-21. Revenue-generating research and development collaborations are often multiple element arrangements, providing for a license as well as research and development services. Such arrangements are analyzed to determine whether the deliverables, including research and development services, can be separated or whether they must be accounted for as a single unit of accounting in accordance with EITF No. 00-21. We recognize upfront license payments as revenue upon delivery of the license only if the license has standalone value and the fair value of the undelivered performance obligations can be determined. If the fair value of the undelivered performance obligations can be determined, such obligations would then be accounted for separately as performed. If the license is considered to either (i) not have standalone value or (ii) have standalone value but the fair value of any of the undelivered performance obligations cannot be determined, the arrangement would then be accounted for as a single unit of accounting and the upfront license payments are recognized as revenue over the estimated period of when our performance obligations are performed.

When we determine that an arrangement should be accounted for as a single unit of accounting, we must determine the period over which the performance obligations will be performed and revenue related to upfront license payments will be recognized. Revenue will be recognized using either a proportionate performance or straight-line method. We recognize revenue using the proportionate performance method provided that we can reasonably estimate the level of effort required to complete our performance obligations under an arrangement and such performance obligations are provided on a best-efforts basis. Under the proportionate performance method, periodic revenue related to up-front license payments is recognized as the percentage of actual effort expended in that period to total effort expected for all of our performance obligations under the arrangement. Actual effort is generally determined based upon actual direct labor hours or full-time equivalents incurred and include research and development activities performed by internal scientists. Total expected effort is generally based upon the total direct labor hours of full-time equivalents incorporated into the detailed budget and project plan that is agreed to by both parties to the collaboration. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which we expect to complete the related performance obligations. For example, under our arrangement with Gilead Sciences, the joint research committee periodically reviews and updates the project plan. In the event that a change in estimate occurs, the change will be accounted for using the cumulative catch-up method which provides for an adjustment to revenue in the current period. Estimates of our level of effort may change in the future, resulting in a material change in the amount of revenue recognized in future periods, including negative revenue in some periods. We revised our joint research program with Gilead in the first quarter of 2007 to focus on next-generation NS4A antagonists. At that time, we extended the period over which our remaining obligations under the arrangement would be completed. We and Gilead also agreed to continue to equally share external costs, but effective April 1, 2007, internal full-time equivalents would no longer be subject to a cost sharing arrangement. Instead, each party bears the costs of their respective full-time equivalents. In addition, we also revised our joint research program with Gilead in the first quarter of 2009 to include a more complete series of preclinical studies, thereby increasing our total estimated efforts under the collaboration and extending the estimated period over which our remaining obligations under the arrangement would be completed to the second half of 2010. This change in estimate caused a non-cash reduction in amounts previously recognized as revenue under the collaboration resulting in negative revenue for the fourth quarter of 2008.

Generally under collaboration arrangements, payments received during the period of performance may include up-front payments, time-or performance-based milestones and reimbursement of internal and external



## **Table of Contents**

costs. The proportion of actual performance to total expected performance is applied to these payments in determining periodic revenue, but will be limited by the aggregate cash received or receivable to date by us.

Substantive milestone payments are considered to be performance bonuses that are recognized upon achievement of the milestone only if all of the following conditions are met: (1) the milestone payments are non-refundable, (2) achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement, (3) substantive effort is involved in achieving the milestone, (4) the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone and (5) a reasonable amount of time passes between the upfront license payment and the first milestone payment as well as between each subsequent milestone payment.

Reimbursement of costs is recognized as revenue provided the provisions of EITF Issue No. 99-19, *Reporting Revenue Gross as Principal Versus Net as an Agent*, are met, the amounts are determinable and collection of the related receivable is reasonably assured.

### ***Stock-Based Compensation Employee Stock-Based Awards***

We apply the Statement of Financial Accounting Standards No. 123 as revised in 2004, *Share-Based Payment*, or SFAS No. 123R, which requires measurement and recognition of compensation expense for all stock-based awards made to employees and directors, including employee stock options and employee stock purchases under our 2006 ESPP Plan based on estimated fair values. In December 2007, the SEC issued Staff Accounting Bulletin No. 110, or SAB No. 110, which extends the use of the simplified method in developing an estimate of the expected term of plain vanilla share options beyond December 31, 2007. Due to our limited exercise history and period of time that our shares have been publicly traded, we utilize the provisions of SAB 110 in our application of SFAS 123R.

We primarily grant qualified stock options for a fixed number of shares to employees with an exercise price equal to the market value of the shares at the date of grant. To the extent that the amount of the aggregate fair market value of qualified stock options that become exercisable for an individual exceeds \$100,000 during any tax year, those stock options are treated as non qualified stock options. Under the fair value recognition provisions of SFAS No. 123R, stock-based compensation cost is based on the value of the portion of stock-based awards that is ultimately expected to vest during the period. Stock-based compensation expense recognized during the years ended December 31, 2008 and 2007 includes compensation expense for stock-based awards granted prior to, but not yet vested as of December 31, 2005, based on the fair value on the grant date estimated in accordance with the pro forma provisions of SFAS No. 123. Compensation expense also includes amounts related to the stock-based awards granted subsequent to December 31, 2005, based on the fair value on the grant date, estimated in accordance with the provisions of SFAS No. 123R.

We utilize the Black-Scholes option pricing model for determining the estimated fair value for stock-based awards. The Black-Scholes model requires the use of assumptions which determine the fair value of the stock-based awards. Determining the fair value of stock-based awards at the grant date requires judgment, including estimating the expected term of stock options, the expected volatility of our stock and expected dividends. In addition, we previously accounted for forfeitures as they occurred. In accordance with SFAS No. 123R, we are required to estimate forfeitures at the grant date and recognize compensation costs for only those awards that are expected to vest. Judgment is required in estimating the amount of stock-based awards that are expected to be forfeited.

If factors change and we employ different assumptions in the application of SFAS No. 123R in future periods, the compensation expense that we record under SFAS No. 123R may differ significantly from what we have recorded in the current period. Therefore, we believe it is important for investors to be aware of the degree of subjectivity involved when using option pricing models to estimate share-based compensation under SFAS No. 123R. There is risk that our estimates of the fair values of our share-based compensation awards on the grant

## **Table of Contents**

dates may differ from the actual values realized upon the exercise, expiration, early termination or forfeiture of those share-based payments in the future. Certain share-based payments, such as employee stock options, may expire worthless or otherwise result in zero intrinsic value as compared to the fair values originally estimated on the grant date and reported in our financial statements. Alternatively, value may be realized from these instruments that is significantly in excess of the fair values originally estimated on the grant date and reported in our financial statements. Although the fair value of employee share-based awards is determined in accordance with SFAS No. 123R and SAB No. 110 using an option pricing model, that value may not be indicative of the fair value observed in a willing buyer/willing seller market transaction.

Total compensation expense recorded in the accompanying statements of operations associated with option grants made to employees for the years ended December 31, 2008, 2007 and 2006 was \$2.1 million, \$1.7 million and \$968,000, respectively. We recorded no tax benefit related to these options since we currently maintain a full valuation allowance.

As of December 31, 2008, the total compensation cost related to nonvested options not yet recognized in the financial statements is approximately \$3.7 million, net of estimated forfeitures, and the weighted average period over which it is expected to be recognized is 1.34 years.

As of December 31, 2008, the intrinsic value of the options outstanding was \$0.

### ***Accrued Expenses***

As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves identifying services which have been performed on our behalf and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date in our financial statements.

In accruing service fees, we estimate the time period over which services will be provided and the level of effort in each period. If the actual timing of the provision of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. The majority of our service providers invoice us monthly in arrears for services performed. Some of our service providers require upfront or milestone payments. If our estimate of services performed is less than the upfront or milestone payments, the difference is accounted for as a prepaid expense. In the event that we do not identify costs that have been incurred or we underestimate or overestimate the level of services performed or the costs of such services, our actual expenses could differ from such estimates. The date on which some services commence, the level of services performed on or before a given date and the cost of such services are often subjective determinations. We make judgments based upon facts and circumstances known to us in accordance with U.S. GAAP.

### ***Income Taxes***

We use an asset and liability approach for financial accounting and reporting of income taxes. Deferred tax assets and liabilities are determined based on temporary differences between financial reporting and tax basis assets and liabilities and are measured by applying enacted rates and laws to taxable years in which differences are expected to be recovered or settled. Further, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that the rate changes.

Effective January 1, 2007, we adopted Financial Accounting Standards Board ( FASB ) Interpretation No. 48, *Accounting for Uncertainty in Income Taxes - an Interpretation of FASB Statement No. 109*, or FIN 48. FIN 48 prescribes a comprehensive model for how a company should recognize, measure, present and disclose in its financial statements uncertain tax positions that the company has taken or expects to take on a tax return, including a decision whether to file or not file a return in a particular jurisdiction. Under FIN 48, the financial statements reflect expected future tax consequences of such positions presuming the taxing authorities' full knowledge of the position and all relevant facts.

**Table of Contents**

We do not have any unrecognized tax benefits as of the date of adoption or December 31, 2008. We review all tax positions to ensure the tax treatment selected is sustainable based on its technical merits and that the position would be sustained if challenged.

**Results of Operations**

Results of operations may vary from period to period depending on numerous factors, including the timing of payments received under existing or future strategic alliances, joint ventures or financings, if any, the progress of our research and development projects, technological advances and determinations as to the commercial potential of proposed products.

**Revenues:**

Our sources of revenue during the years ended December 31, 2008, 2007 and 2006 consist primarily of Gilead collaboration revenue. During the years ended December 31, 2007 and 2006 we also recognized revenue under a Small Business Innovation Research, or SBIR, grant. No additional grant revenue is currently anticipated. Revenue consisted of the following:

	For the Years Ended			Change	
	2008	2007	2006	2008 vs. 2007	2007 vs. 2006
	(in thousands)				
Gilead collaboration revenue	\$ (234)	\$ 4,003	\$ 2,979	\$ (4,237)	\$ 1,024
Grant revenue		35	313	(35)	(278)
Total revenue	\$ (234)	\$ 4,038	\$ 3,292	\$ (4,272)	\$ 746

Through the completion of our performance obligations in 2010, we expect to recognize additional collaboration revenue of approximately \$2.5 million, offset by any payments we are obligated to make to Gilead in satisfaction of external costs paid by Gilead under our external cost-sharing agreement. It is possible that we will recognize negative revenue in future quarters based upon the timing of our performance under the collaboration, and on the timing and magnitude of external costs borne by Gilead.

***Comparison of the Years Ended December 31, 2008 and 2007***

The decrease in revenue in 2008 is primarily due to a change in estimate of our remaining performance obligations under our collaboration with Gilead. Under the proportionate performance method, periodic revenue related to up-front license and milestone payments is recognized as the percentage of actual effort expended in that period to total effort expected for all of our performance obligations under the arrangement. The most recent project plan agreed upon by the joint research committee resulted in an increase to our total efforts under the collaboration and extended our estimated obligation period under the collaboration to the second half of 2010, resulting in an adjustment to our proportion of completed performance.

Accordingly, in the fourth quarter of 2008, we recorded a decrease to revenue under the cumulative catch up method to reflect the Company's proportionate performance through December 31, 2008. This adjustment reflected our increased remaining performance obligations, which effectively reduced the proportion of our performance obligations that have been completed to date. This change in estimate caused a non-cash reduction in amounts previously recognized as revenue under the collaboration resulting in negative revenue for the fourth quarter of 2008.

***Comparison of the Years Ended December 31, 2007 and 2006***

The increase in revenue in 2007 is primarily due to lower revenue recognized in 2006 resulting from a significant change in estimate of our remaining performance obligations as of December 31, 2006, under our collaboration with Gilead. In February 2007, we discontinued further development of ACH-806. We also revised

**Table of Contents**

our research program with Gilead to focus on next-generation NS4A antagonists. Additionally, our efforts under the collaboration, which were previously estimated to be complete in March 2007, were extended through mid 2009. In March 2007, we and Gilead agreed to continue to equally share external costs, but effective April 1, 2007, internal full-time equivalents would no longer be subject to this cost sharing arrangement. Instead, each party would bear the costs of their respective full-time equivalents. Accordingly, in the fourth quarter of 2006, we recorded a reduction of revenue under the cumulative catch-up method to reflect our proportionate performance through December 31, 2006. This adjustment reflected our increased remaining performance obligations, which effectively reduced the proportion of our performance obligations that had been completed to date.

**Research and Development Expenses:**

Our research and development expenses reflect costs incurred for our proprietary research and development projects as well as costs for research and development projects conducted as part of collaborative arrangements we establish. These costs consist primarily of salaries and benefits for our research and development personnel, costs of services by clinical research organizations, other outsourced research, materials used during research and development activities, facility-related costs such as rent and utilities associated with our laboratory and clinical development space, operating supplies and other costs associated with our research and development activities. Research and development expenses consisted of the following:

	For the Years Ended			Change	
	2008	2007	2006	2008 vs. 2007	2007 vs. 2006
	(in thousands)				
Personnel costs	\$ 6,135	\$ 6,565	\$ 6,031	(430)	\$ 534
Stock based compensation	912	676	330	236	346
Outsourced research and supplies	9,404	16,266	11,758	(6,862)	4,508
Professional and consulting fees	1,691	1,646	1,525	45	121
Facilities costs	2,738	2,657	2,808	81	(151)
Travel and other costs	270	310	289	(40)	21
Total	\$ 21,150	\$ 28,120	\$ 22,741	\$ (6,970)	\$ 5,379

**Comparison of the Years Ended December 31, 2008 and 2007**

The decrease in research and development expenses from 2007 to 2008 was primarily due to lower outsourced research costs related to phase II trials for elvucitabine and the completion of preclinical testing of ACH-702 in 2007, partially offset by increased costs associated with ACH-1625 preclinical studies and an upfront license fee under our collaboration with FOB Synthesis. We expect a slight reduction in research and development expenses over the next twelve months as a result of the reduction of expenses related to the near completion of the phase II clinical program for elvucitabine, the reduction of expenses relating to ACH-702 and the termination of our collaboration agreement with FOB Synthesis, offset by increased expenses related to the initiation of human clinical trials for ACH-1095 and ACH-1625.

**Comparison of the Years Ended December 31, 2007 and 2006**

The increase in research and development expenses from 2006 to 2007 was the result of: (i) increased personnel costs for our research and development staff, including an increase in headcount as well as increased wages, combined with increased non-cash stock based compensation (ii) the costs associated with three clinical trials using elvucitabine during 2007, two of which had longer durations and greater number of patients than those conducted during 2006, and (iii) the costs associated with additional preclinical testing of ACH-702.

**Table of Contents****General and Administrative Expenses:**

General and administrative expenses consist primarily of salaries and benefits for management and administrative personnel, professional fees for legal, accounting and other services, travel costs and facility-related costs such as rent, utilities and other general office expenses. General and administrative expenses consisted of the following:

	For the Years Ended			Change	
	2008	2007	2006	2008 vs. 2007	2007 vs. 2006
	(in thousands)				
Personnel costs	\$ 1,857	\$ 1,968	\$ 1,785	\$ (111)	\$ 183
Stock based compensation	1,269	1,076	695	193	381
Professional and consulting fees	1,625	1,744	1,206	(119)	538
Facilities costs	1,191	1,179	811	12	368
Travel and other costs	604	509	368	95	141
Total	\$ 6,546	\$ 6,476	\$ 4,865	\$ 70	\$ 1,611

***Comparison of the Years Ended December 31, 2008 and 2007***

The slight increase in general and administrative expenses from 2007 to 2008 was primarily due to increased non-cash stock compensation, offset by a decrease in professional costs associated with certain market studies performed during 2007 that were not repeated in 2008. We expect that general and administrative expenses will remain substantially unchanged over the next twelve months.

***Comparison of the Years Ended December 31, 2007 and 2006***

The increase in general and administrative expenses from 2006 to 2007 was primarily due to increased professional fees related to certain market studies and increased insurance premiums, combined with increased recognition of non-cash stock based compensation.

**Other Income and Expense:*****Comparison of the Years Ended December 31, 2008 and 2007***

*Interest income (expense).* Interest income was \$707,000 and \$2.5 million for the years ended December 31, 2008 and 2007, respectively. The \$1.8 million decrease from 2007 to 2008 was primarily due to decreased average cash balances combined with lower interest rates paid on those balances. Interest expense was \$1.1 million and \$964,000 for the years ended December 31, 2008 and 2007, respectively.

*Tax benefit.* The State of Connecticut provides companies with the opportunity to forego certain research and development tax credit carryforwards in exchange for cash. The program provides for such exchange of the research and development credits at a rate of 65% of the annual incremental and non-incremental research and development credits, as defined. The amount of tax benefit we recognized in connection with this exchange program was \$132,000 and \$960,000 for the years ended December 31, 2008 and 2007, respectively. The \$828,000 decrease from 2007 to 2008 is due to the decrease in the incremental portion of the credit resulting from comparable eligible research and development expenditures in 2008 and 2007.

***Comparison of the Years Ended December 31, 2007 and 2006***

*Interest income (expense).* Interest income was \$2.5 million and \$1.1 million for the years ended December 31, 2007 and 2006, respectively. The \$1.4 million increase from 2006 to 2007 was primarily due to increased average cash balances due to the receipt of \$18.4 million in proceeds from our Series C-2 financing in

**Table of Contents**

March and May of 2006 and \$53.4 million in net proceeds from our initial public offering in October 2006. Interest expense was \$1.0 million and \$1.0 million for the years ended December 31, 2007 and 2006, respectively.

*Tax benefit.* The State of Connecticut provides companies with the opportunity to forego certain research and development tax credit carryforwards in exchange for cash. The program provides for such exchange of the research and development credits at a rate of 65% of the annual incremental and non-incremental research and development credits, as defined. The amount of tax benefit we recognized in connection with this exchange program was \$960,000 and \$49,000 for the years ended December 31, 2007 and 2006, respectively. The \$911,000 increase from 2006 to 2007 is due to an overall increase in eligible research and development costs for the year, resulting primarily from the lack of reimbursement for internal full-time equivalent costs from Gilead, under our amended agreement which became effective April 1, 2007, combined with an increase in clinical trial costs. The reimbursement previously received by Gilead reduced the amount of research and development expense eligible for the tax credit.

*Accretion of preferred stock dividends.* Accretion of preferred stock dividends was \$0 and \$4.2 million for the years ended December 31, 2007 and 2006, respectively. Since the conversion of our preferred stock in connection with our initial public offering, there is no further accretion of dividends.

**Liquidity and Capital Resources**

Since our inception in August 1998, we have financed our operations primarily through the issuance of stock, borrowings under debt facilities, as well as through receipts from our collaboration with Gilead. Through December 31, 2008, we had received approximately \$192.4 million in aggregate net proceeds from stock issuances, including convertible preferred stock, our initial public offering and our private placement, \$19.1 million from Gilead under our collaboration agreement with them and approximately \$22.1 million under debt facilities. As of December 31, 2008, the following debt facilities remain outstanding:

<b>Lender</b>	<b>Date</b>	<b>Interest Rate (per annum)</b>	<b>Principal Amount</b>	<b>Maturity Date</b>
Connecticut Innovations, Inc.	November 2000	7.5%	\$ 1,400,000	September 2010
Webster Bank	May 2003	6.72%-9.27	972,185	June 2006-Dec 2009
Oxford Finance Corporation	May 2006	11.56	2,500,000	April 2009
General Electric Capital Corporation	May 2006	11.56	2,500,000	April 2009
Oxford Finance Corporation	June 2007	11.58	400,000	June 2010
General Electric Capital Corporation	June 2007	11.58	400,000	June 2010
Webster Bank	December 2007	7.46	414,623	December 2010
Oxford Finance Corporation	February 2008	9.97	2,500,000	March 2011
General Electric Capital Corporation	February 2008	9.97%	\$ 2,500,000	March 2011

The amounts reflected above represent original maturities under our debt agreements. As of December 31, 2008, our debt balance due to borrowings is \$6.2 million with a weighted average interest rate of 10.0%.

We had \$35.4 million, \$31.1 million and \$62.6 million in cash, cash equivalents and marketable securities as of December 31, 2008, 2007 and 2006, respectively.

On August 12, 2008, in a private placement we issued to certain institutional investors 10,714,655 units at a price of \$2.9049 per unit, resulting in gross proceeds of \$31.1 million, or \$29.2 million net of offering expenses. Each unit consists of one share of our common stock and a warrant to purchase 0.25 shares of common stock at an exercise price of \$3.53 per share. Additionally, the investors may have the option to purchase an additional 3,679,078 units between February 2009 and August 2009, subject to certain contingencies. We have agreed to seek stockholder approval for the transaction in accordance with NASDAQ Marketplace Rules.

## **Table of Contents**

In February 2008, we entered into a credit facility with GE Capital Corporation and Oxford Finance Corporation. The new facility has substantially the same terms as the 2005 Credit Facility. At the same time, we combined the amounts outstanding under the 2005 Credit Facility with the newly issued notes (collectively the 2008 Credit Facility). The 2008 Credit Facility provides an incremental \$5.0 million to fund our working capital needs, and is secured by substantially all of our tangible assets. In connection with the 2008 Credit Facility, we issued warrants to purchase 43,000 shares of common stock at an exercise price of \$4.68 per share.

On May 12, 2006, we received \$13.8 million in gross proceeds from the sale of 9,166,167 additional shares of our series C-2 convertible preferred stock at \$1.50 per share, and \$5.0 million in proceeds from the issuance of promissory notes under existing debt facilities. In October 2006, we received \$53.4 million in net proceeds from our initial public offering of 5,175,000 shares of common stock, at a public offering price of \$11.50 per share.

Cash used in operating activities was \$24.9 million for the year ended December 31, 2008 and was primarily attributable to our \$28.2 million net loss, offset primarily by \$3.2 million in non cash charges related to depreciation, amortization and non-cash interest and stock based compensation. Cash used in operating activities was \$29.9 million for the year ended December 31, 2007 and was primarily attributable to our \$28.1 million net loss and \$2.7 million amortization of deferred revenue, offset primarily by \$2.5 million in non cash charges related to depreciation, amortization and non-cash stock based compensation. Cash used in operating activities was \$21.1 million for the year ended December 31, 2006 and was primarily attributable to our \$24.1 million net loss, offset by our \$1.7 million increase in accounts payable and \$1.8 million in non-cash charges related to depreciation, amortization and non-cash stock based compensation.

Cash used in investing activities was \$1.8 million for the year ended December 31, 2008 and was primarily attributable to purchases of marketable securities offset by maturities of marketable securities. Cash provided by investing activities was \$18.3 million for the year ended December 31, 2007 and was primarily attributable to maturities of marketable securities offset by purchases of marketable securities and \$1.2 million in property and equipment purchases. Cash used in investing activities was \$40.1 million for the year ended December 31, 2006 and was primarily attributable to the purchase of marketable securities.

Cash provided by financing activities was \$28.8 million for the year ended December 31, 2008 and was primarily attributable to \$29.2 million in net proceeds from the sale of \$10,714,655 units and an incremental \$5.0 million in borrowings under our 2008 credit facility, offset by \$5.3 million used for repayments of debt. Cash used in financing activities was \$2.1 million for the year ended December 31, 2007 and was attributable to \$3.7 million used for repayments of debt, offset primarily by \$1.2 million in receipt of proceeds under a debt facility. Cash provided by financing activities was \$74.2 million for the year ended December 31, 2006 and was primarily attributable to \$18.2 million in proceeds from the sale of 12,270,815 shares of our Series C-2 Preferred Stock, \$53.4 million in net proceeds from our initial public offering of 5,175,000 shares of common stock and \$5.4 million in proceeds from the issuance of debt, offset by \$3 million used for repayments of debt.

We expect to incur continuing and increasing losses from operations for at least the next several years as we seek to:

complete late-stage preclinical studies and initiate clinical testing of ACH-1095;

initiate clinical testing of ACH-1625;

complete the open-label extension phases of our phase II clinical trials for elvucitabine; and

progress additional drug candidates.

We do not expect our existing capital resources, together with the milestone payments and research and development funding we expect to receive, to be sufficient to fund the completion of the development of any of our drug candidates. As a result, we will need to raise additional funds prior to being able to market any drug

## **Table of Contents**

candidates, to, among other things, obtain regulatory approvals, fund operating losses, and, if deemed appropriate, establish manufacturing and sales and marketing capabilities. We will seek to raise such additional financing through (i) public or private equity or debt financings, (ii) collaborative or other arrangements with third parties or (iii) through other sources of financing.

We believe that our existing cash and cash equivalents will be sufficient to meet our projected operating requirements for at least the next twelve months. However, our funding resources and requirements may change and will depend upon numerous factors, including but not limited to:

the outcome of future clinical trials of ACH-1095, which will determine our ability to earn future milestone payments from our partner Gilead Sciences;

the costs involved in the preclinical and clinical development, manufacturing and formulation of ACH-1625;

the costs involved in the preclinical and clinical development of ACH-1095 and other NS4A antagonists, certain portions of which we share with Gilead Sciences;

the outcome of our strategic and development assessment of ACH-702;

our ability to enter into corporate collaborations and the terms and success of these collaborations;

the costs involved in obtaining regulatory approvals for our drug candidates;

the scope, prioritization and number of programs we pursue;

the costs involved in preparing, filing, prosecuting, maintaining, enforcing and defending patent and other intellectual property claims;

our ability to raise incremental debt or equity capital;

our acquisition and development of new technologies and drug candidates; and

competing technological and market developments currently unknown to us.

We intend to augment our cash balance in 2009 through financing transactions, including the issuance of debt or equity securities, and/or further corporate alliances. No arrangements have been entered into for any future financing and there can be no assurance that we will be able to obtain adequate levels of additional funding or favorable terms, if at all. If adequate funds are not available during 2009, we will be required to:

delay, reduce the scope of or eliminate our research and development programs;



reduce our planned commercialization efforts;

obtain funds through arrangements with collaborators or others on terms unfavorable to us or that may require us to relinquish rights to certain drug candidates that we might otherwise seek to develop or commercialize independently; and/or

pursue merger or acquisition strategies.

Additionally, any future equity funding may dilute the ownership of our equity investors.

We have developed a contingency plan which provides for changes in our operations in the event that we are unable to secure additional funding within the next twelve months. We believe that this plan would reduce its operating expenses and believe that implementation of this contingency plan, if necessary, would permit us to conduct our operations for at least the next twelve months.

#### **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements or relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities.

**Table of Contents****Contractual Obligations and Commitments**

The following table sets forth a summary of our commitments as of December 31, 2008:

	Total	Payment Due by Period			More than 5 Years
		Less Than 1 Year	1-3 Years (in thousands)	3-5 Years	
Long-term debt, including interest	\$ 6,247	\$ 6,247	\$	\$	\$
Operating lease obligations	1,650	991	659		
Clinical research obligations	1,287	1,287			
Other research obligations and licenses	3,885	3,411	371	103	
<b>Total</b>	<b>\$ 13,069</b>	<b>\$ 11,936</b>	<b>\$ 1,030</b>	<b>\$ 103</b>	<b>\$</b>

The above amounts exclude potential payments that are based on the progress of our drug candidates in development, to be made under our license agreements, as these payments are not yet determinable.

Each of the Company's debt agreements contains certain subjective acceleration clauses, which upon the occurrence of a material adverse change in the financial condition, business or operations of Achillion in the view of the respective lenders, may cause amounts due under the agreements to become immediately due and payable. As stated previously, we will need additional financing to fund operations which we will seek to raise through public or private equity or debt financings, collaborative or other arrangements with third parties or through other sources of financing. There can be no assurance that such funding will be available on terms favorable us, if at all. As such funding cannot be assured, our debt balances have been classified as short term at December 31, 2008. We are not in default with respect to any debt agreements and none of our lenders have accelerated scheduled loan payments.

**Related Party Transactions**

Our board of directors is committed to upholding the highest legal and ethical conduct in fulfilling its responsibilities and recognizes that related party transactions can present a heightened risk of potential or actual conflicts of interest. Accordingly, as a general matter, it is our preference to avoid related party transactions.

In accordance with our audit committee charter, members of the audit committee, all of whom are independent directors, review and approve all related party transactions for which approval is required under applicable laws or regulations, including SEC and the NASDAQ Stock Market rules. Current SEC rules define a related party transaction to include any transaction, arrangement or relationship in which we are a participant and the amount involved exceeds \$120,000, and in which any of the following persons has or will have a direct or indirect interest:

our executive officers, directors or director nominees;

any person who is known to be the beneficial owner of more than 5% of our common stock;

any person who is an immediate family member, as defined under Item 404 of Regulation S-K, of any of our executive officers, directors or director nominees or beneficial owner of more than 5% of our common stock; or

any firm, corporation or other entity in which any of the foregoing persons is employed or is a partner or principal or in a similar position or in which such person, together with any other of the foregoing persons, has a 5% or greater beneficial ownership interest.

In addition, the audit committee reviews and investigates any matters pertaining to the integrity of management, including conflicts of interest and adherence to our Code of Business Conduct and Ethics. Under our Code of Business Conduct and Ethics, our directors, officers and

## Edgar Filing: ACHILLION PHARMACEUTICALS INC - Form 10-K

employees are expected to avoid any relationship, influence or activity that would cause or even appear to cause a conflict of interest. Under our Code of Business Conduct and Ethics, a director is required to promptly disclose to our board of directors any potential

## **Table of Contents**

or actual conflict of interest involving him or her. In accordance with our Code of Business Conduct and Ethics, the board of directors will determine an appropriate resolution on a case-by-case basis. All directors must recuse themselves from any discussion or decision affecting their personal, business or professional interests.

We have entered into or engaged in the following transactions with the following directors, officers and stockholders who beneficially owned more than 5% of our outstanding common stock at the time of these transactions, as well as affiliates or immediate family members of those directors, officers stockholders. We believe that the terms of the transactions described below were no less favorable than those that we could have obtained from unaffiliated third parties.

### *Gilead*

In November 2004, we entered into the Gilead Arrangement with Gilead to jointly develop and commercialize compounds for use in treating hepatitis C infection which inhibit viral replication through a specified novel mechanism of action. Commercialization efforts will commence only if such compounds are found to be commercially viable and all appropriate regulatory approvals have been obtained. In addition to being a collaboration partner, Gilead Inc. is also a shareholder of Achillion. As of December 31, 2008, Gilead holds 1,116 shares, representing 4.2% of total shares outstanding.

### *Nicholas Simon*

On August 19, 2008, the Board of Directors of the Company elected Nicholas Simon as a Class I member of the Board of Directors to serve until the Company's 2010 Annual Meeting of Stockholders or until his successor is duly elected and qualified. Mr. Simon is a managing director of Clarus Ventures LLC (Clarus). In connection with Clarus' agreement to invest in the Company, the Company agreed that Mr. Simon would be appointed to the Company's Board of Directors upon a vacancy, which occurred on August 19, 2008. On August 12, 2008, Clarus purchased units consisting of 5,163,689 shares of common stock and common stock warrants to purchase 1,290,922 shares of common stock for an aggregate purchase price of \$15 million. In addition, pursuant to warrants issued to Clarus, Clarus may have the right to purchase an additional 1,773,050 units between February 2009 and August 2009. Clarus is currently the beneficial owner of approximately 19.6% of the Company's total issued and outstanding shares, excluding the shares that may be acquired upon exercise of the warrants held by Clarus.

## **Recently Issued Accounting Pronouncements**

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. The standard is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. We adopted SFAS No. 157 for financial assets and liabilities effective January 1, 2008. There was no impact to our financial statements upon adoption. On February 12, 2008, the FASB issued FASB Staff Position (FSP) FAS No. 157-2. This FSP permits a delay in the effective date of SFAS No. 157 to fiscal years beginning after November 15, 2008, for nonfinancial assets and nonfinancial liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis, at least annually. We do not believe that adoption of SFAS No. 157 for nonfinancial assets and nonfinancial liabilities will have a material impact on our financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, or SFAS No. 159. SFAS No. 159 permits an entity to elect to report many financial assets and liabilities at fair value. Entities electing the fair value option are required to recognize changes in fair value in earnings and are required to distinguish, on the face of the statement of financial position, the fair value of assets and liabilities for which the fair value option has been elected and similar assets and liabilities measured using another measurement attribute. The initial adjustment to reflect the difference between the fair value and the carrying amount is accounted for as a cumulative-effect adjustment to retained earnings as of the date of initial adoption. SFAS No. 159 was effective as of the beginning of an entity's first fiscal year beginning after November 15, 2007. We did not elect to adopt the fair value option.

## **Table of Contents**

In December 2007, the EITF reached a consensus on EITF Issue No. 07-01, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*, or EITF No. 07-01. EITF No. 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 No. 07-01 is effective for our collaborations existing after January 1, 2009. We are currently evaluating the impact this standard will have on our financial statements.

In December 2007, the FASB issued SFAS No. 141R, *Business Combinations*, which changes the accounting for business acquisitions. SFAS No. 141R requires the acquiring entity in a business combination to recognize all the assets acquired and liabilities assumed in the transaction and establishes the acquisition-date fair value as the measurement objective for all assets acquired and liabilities assumed in a business combination. Certain provisions of this standard will, among other things, impact the determination of acquisition-date fair value of consideration paid in a business combination, including contingent consideration; exclude transaction costs from acquisition accounting; and change accounting practices for acquired contingencies, acquisition-related restructuring costs, in-process research and development, indemnification assets, and tax benefits. SFAS No. 141R is effective for business combinations and adjustments to an acquired entity's deferred tax asset and liability balances occurring after December 31, 2008. Adoption of SFAS No. 141R will likely have a material impact on our financial position and results of operations in the event that we enter into a business combination that falls within the scope of this pronouncement.

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

*Interest Rate Risk.* Our exposure to market risk is confined to our cash, cash equivalents and marketable securities. We regularly review our investments and monitor the financial markets. The recent distress in the financial markets has not had a significant impact on our financial position. We invest in high-quality financial instruments, primarily money market funds, government sponsored bond obligations and corporate debt securities, with the effective duration of the portfolio less than six months and no security with an effective duration in excess of 12 months, which we believe are subject to limited credit risk. We currently do not hedge interest rate exposure. Due to the short-term nature of our investments, we do not believe that we have any material exposure to interest rate risk or changes in credit ratings arising from our investments.

*Capital Market Risk.* We currently have no product revenues and depend on funds raised through other sources. One source of funding is through future equity offerings. Our ability to raise funds in this manner depends upon capital market forces affecting our stock price.

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

The information required by this Item is included in our Financial Statements and Supplementary Data listed in Item 15 of Part IV of this annual report on Form 10-K.

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

None.

### **ITEM 9A. CONTROLS AND PROCEDURES**

#### *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, 2008. 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



## **Table of Contents**

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 officers, 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, 2008, the Company's 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 Rule 13a-15(f) and 15d-15(f) promulgated under the Securities Exchange Act of 1934 as a process designed by, or under the supervision of, the Company's principal executive and principal financial officers and effected by the Company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles 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 the assets of the company;

Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and

Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. 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 the Company's internal control over financial reporting as of December 31, 2008. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control-Integrated Framework*.

Based on this assessment, management concluded that, as of December 31, 2008, our internal control over financial reporting is effective based on the criteria set forth in *Internal Control - Integrated Framework* issued by the COSO. This annual report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this annual report.

### *Changes in Internal Control over Financial Reporting*

No change in our internal control over financial reporting occurred during the fiscal quarter ended December 31, 2008 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **ITEM 9B. OTHER INFORMATION**

None.





**Table of Contents**

**PART III**

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

We intend to file with the Securities and Exchange Commission a definitive Proxy Statement, which we refer to herein as the Proxy Statement, not later than 120 days after the close of the fiscal year ended December 31, 2008. The information required by this item is incorporated herein by reference to the information contained under the sections captioned Election of Class II Directors, Section 16(a) Beneficial Ownership Reporting Compliance and Corporate Governance of the Proxy Statement. The information required by this item relating to executive officers is included in Part I, Item 1 Business Executive Officers of the Registrant of this Annual Report on Form 10-K on page 18 and is incorporated by reference.

We have adopted a written code of business conduct and ethics, which applies to our principal executive officer, principal financial or accounting officer or person serving similar functions and all of our other employees and members of our board of directors. The text of our amended code of ethics is available on our website at [www.achillion.com](http://www.achillion.com). We did not waive any provisions of the code of business ethics during the year ended December 31, 2008. If we amend, or grant a waiver under, our code of business ethics that applies to our principal executive officer, principal financial or accounting officer, or persons performing similar functions, we intend to post information about such amendment or waiver on our website at [www.achillion.com](http://www.achillion.com).

**ITEM 11. EXECUTIVE COMPENSATION**

The information required by this item is incorporated herein by reference to the information contained under the sections captioned Executive Compensation, Compensation of Directors, Compensation Committee Interlocks and Insider Participation and Employment Arrangements of the Proxy Statement.

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

The information required by this item is incorporated herein by reference to the information contained under the sections captioned Security Ownership of Certain Beneficial Owners and Management and Equity Compensation Plan Information of the Proxy Statement.

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

The information required by this item is incorporated herein by reference to the information contained under the sections captioned Employment Arrangements and Certain Relationships and Related Transactions of the Proxy Statement.

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The information required by this item is incorporated herein by reference to the information contained under the sections captioned Auditor's Fees and Pre-Approval Policies and Procedures of the Proxy Statement.

**Table of Contents**

**PART IV**

**ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

(a)(1) Financial Statements

The following documents are included on pages F-1 through F-26 attached hereto and are filed as part of this annual report on Form 10-K.

<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Balance Sheets at December 31, 2008 and 2007</u>	F-3
<u>Statements of Operations for the Years Ended December 31, 2008, 2007 and 2006</u>	F-4
<u>Statements of Stockholders' Equity (Deficit) and Comprehensive Loss for the Years Ended December 31, 2006, 2007 and 2008</u>	F-5
<u>Statements of Cash Flows for the Years Ended December 31, 2008, 2007 and 2006</u>	F-6
<u>Notes to Financial Statements</u>	F-7

(a)(2) Financial Statement Schedules

Not applicable

(a)(3) List of Exhibits

The exhibits which are filed with this report or which are incorporated herein by reference are set forth in the Exhibit Index hereto.

Table of Contents**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 27, 2009.

**ACHILLION PHARMACEUTICALS, INC.**

By: */s/* MICHAEL D. KISHBAUCH  
**Michael D. Kishbauch**  
**President and Chief Executive Officer**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Report has been signed below by the following persons on behalf of the Registrant and in the capacities indicated as of March 27, 2009.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<i>/s/</i> MICHAEL D. KISHBAUCH  <b>Michael D. Kishbauch</b>	President and Chief Executive Officer and Director (Principal executive officer)	March 27, 2009
<i>/s/</i> MARY KAY FENTON  <b>Mary Kay Fenton</b>	Vice President and Chief Financial Officer (Principal financial and accounting officer)	March 27, 2009
<i>/s/</i> JASON FISHERMAN, M.D.  <b>Jason Fisherman, M.D.</b>	Director	March 27, 2009
<i>/s/</i> GARY E. FRASHIER  <b>Gary E. Frashier</b>	Director	March 27, 2009
<i>/s/</i> MICHAEL GREY  <b>Michael Grey</b>	Director	March 27, 2009
<i>/s/</i> DENNIS LIOTTA  <b>Dennis Liotta</b>	Director	March 27, 2009
<i>/s/</i> DAVID SCHEER  <b>David Scheer</b>	Director	March 27, 2009
<i>/s/</i> NICHOLAS SIMON  <b>Nicholas Simon</b>	Director	March 27, 2009
<i>/s/</i> ROBERT VAN NOSTRAND  <b>Robert Van Nostrand</b>	Director	March 27, 2009
<i>/s/</i> DAVID WRIGHT	Director	March 27, 2009

David Wright

**Table of Contents**

**INDEX TO FINANCIAL STATEMENTS**

	<b>Page</b>
<b><u>Report of Independent Registered Public Accounting Firm</u></b>	F-2
<b><u>Financial Statements:</u></b>	
<u>Balance Sheets at December 31, 2008 and 2007</u>	F-3
<u>Statements of Operations for the Years Ended December 31, 2008, 2007 and 2006</u>	F-4
<u>Statements of Stockholders' Equity (Deficit) and Comprehensive Loss for the Years Ended December 31, 2006, 2007 and 2008</u>	F-5
<u>Statements of Cash Flows for the Years Ended December 31, 2008, 2007 and 2006</u>	F-6
<b><u>Notes to Financial Statements</u></b>	F-7

F-1

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders

of Achillion Pharmaceuticals, Inc.

In our opinion, the accompanying balance sheets and the related statements of operations, of stockholders' equity (deficit) and comprehensive loss and of cash flows present fairly, in all material respects, the financial position of Achillion Pharmaceuticals, Inc. at December 31, 2008 and December 31, 2007, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2008 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

As discussed in Note 15 to the financial statements, the Company changed the manner in which it accounts for uncertain tax positions, effective January 1, 2007.

/s/ PricewaterhouseCoopers LLP

March 27, 2009

Hartford, CT

F-2

**Table of Contents****Achillion Pharmaceuticals, Inc.****Balance Sheets**

(in thousands, except per share amounts)

	<b>As of December 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 11,060	\$ 8,971
Marketable securities	24,297	22,138
Accounts receivable		136
Prepaid expenses and other current assets	1,181	1,671
Total current assets	36,538	32,916
Fixed assets, net	1,770	2,475
Deferred financing costs	100	36
Restricted cash	153	205
Total assets	\$ 38,561	\$ 35,632
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 2,544	\$ 2,083
Accrued expenses	2,260	2,748
Deferred revenue	1,128	1,298
Current portion of long-term debt	6,247	6,563
Total current liabilities	12,179	12,692
Accrued expenses, net of current portion		130
Deferred revenue	1,361	1,272
Total liabilities	13,540	14,094
Commitments (Notes 10, 13 and 14)		
<b>Stockholders' Equity:</b>		
Preferred Stock, undesignated, \$.01 par value; 5,000 shares authorized at December 31, 2008 and 2007; no shares issued or outstanding		
Common Stock, \$.001 par value; 100,000 shares authorized at December 31, 2008 and 2007; 26,399 and 15,637 shares issued and outstanding at December 31, 2008 and 2007, respectively	26	16
Additional paid-in capital	204,861	173,301
Accumulated deficit	(179,981)	(151,830)
Accumulated other comprehensive income	115	51
Total stockholders' equity	25,021	21,538
Total liabilities and stockholders' equity	\$ 38,561	\$ 35,632

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

F-3



**Table of Contents****Achillion Pharmaceuticals, Inc.****Statements of Operations****(in thousands, except per share amounts)**

	<b>Years Ended December 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
Revenue	\$ (234)	\$ 4,038	\$ 3,292
Operating expenses			
Research and development	21,150	28,120	22,741
General and administrative	6,546	6,476	4,865
Total operating expenses	27,696	34,596	27,606
Loss from operations	(27,930)	(30,558)	(24,314)
Other income (expense)			
Interest income	707	2,460	1,144
Interest expense	(1,060)	(964)	(965)
Net loss before tax benefits	(28,283)	(29,062)	(24,135)
Tax benefit	132	960	49
Net loss	(28,151)	(28,102)	(24,086)
Accretion of preferred stock dividends			(4,163)
Loss attributable to common stockholders	\$ (28,151)	\$ (28,102)	\$ (28,249)
Basic and diluted net loss per share attributable to common stockholders (Note 4)	\$ (1.42)	\$ (1.80)	\$ (9.35)
Weighted average shares used in computing basic and diluted net loss per share attributable to common stockholders	19,812	15,583	3,022

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

**Table of Contents****Achillion Pharmaceuticals, Inc.****Statements of Stockholders' Equity (Deficit) and Comprehensive Loss for the Years Ended December 31, 2006, 2007 and 2008**

(in thousands)

	Common Stock		Additional	Stock	Accumulated	Accumulated	Total
	Shares	Amount	Paid-In	Subscription	Deficit	Other	Stockholders
			Capital	Receivable		Income	Equity (Deficit)
Balances at December 31, 2005	513	\$ 4	\$ 341	\$ (181)	\$ (96,186)	\$	\$ (96,022)
Net loss					(24,086)		(24,086)
Unrealized gain on marketable securities						18	18
Comprehensive loss							(24,068)
Stock compensation			1,025				1,025
Exercise of stock options	13	1	21				22
Conversion of preferred warrants to common warrants			303				303
Repayment of stock subscriptions receivable				131			131
Issuance of common stock in initial public offering, net of issuance costs of	5,175	5	53,395				53,400
Conversion of preferred stock into common stock	9,834	6	116,736				116,742
Convertible preferred stock dividends			(527)		(3,636)		(4,163)
Balances at December 31, 2006	15,535	16	171,294	(50)	(123,908)	18	47,370
Net loss					(28,102)		(28,102)
Unrealized gain on marketable securities						33	33
Comprehensive loss							(28,069)
Adoption of FASB Interpretation No. 48					180		180
Stock compensation			1,752				1,752
Issuance of common stock upon exercise stock options	59		101				101
Issuance of common stock upon exercise of warrants	9						
Issuance of common stock under ESPP Plan	34		154				154
Repayment of stock subscriptions receivable				50			50
Balances at December 31, 2007	15,637	16	173,301		(151,830)	51	21,538
Net loss					(28,151)		(28,151)
Unrealized gain on marketable securities						64	64
Comprehensive loss							(28,087)
Stock compensation			2,182				2,182
Issuance of common stock and warrants in connection with the private placement, net of issuance costs	10,715	10	29,143				29,153
Issuance of common stock upon exercise stock options	13		21				21
Issuance of common stock under ESPP Plan	34		59				59
Warrants issued in connection with debt financing			155				155
Balances at December 31, 2008	26,399	\$ 26	\$ 204,861	\$	\$ (179,981)	\$ 115	\$ 25,021

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



**Table of Contents****Achillion Pharmaceuticals, Inc.****Statements of Cash Flows****(in thousands)**

	<b>Years Ended December 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
<b>Cash flows from operating activities</b>			
Net loss	\$ (28,151)	\$ (28,102)	\$ (24,086)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	828	773	785
Noncash stock-based compensation	2,182	1,752	1,025
Noncash interest expense	159	116	92
Noncash interest income on debt warrant adjustment			24
Loss(gain) on disposal of equipment	4	(19)	3
Amortization of discount on securities	(320)	(1,782)	(173)
Changes in operating assets and liabilities:			
Accounts receivable	136	660	(35)
Prepaid expenses and other current assets	490	(169)	(783)
Accounts payable	461	(550)	1,737
Accrued expenses	(618)	79	317
Deferred revenue	(81)	(2,695)	63
Net cash (used in) operating activities	(24,910)	(29,937)	(21,031)
<b>Cash flows from investing activities</b>			
Purchase of property and equipment	(77)	(1,240)	(436)
Release of restriction on cash	52	52	53
Purchase of available for sale marketable securities	(40,239)	(59,479)	(40,713)
Maturities of marketable securities	38,464	79,060	1,000
Net cash provided by (used in) investing activities	(1,800)	18,393	(40,096)
<b>Cash flows from financing activities</b>			
Proceeds from issuance of Series C-2 Preferred Stock, net of issuance costs of \$182			18,224
Proceeds from issuance of Common Stock in initial public offering, net of issuance costs of \$1,900			53,400
Proceeds from issuance of Common Stock and warrants in connection with the private placement offering, net of issuance costs of \$1,972	29,153		
Proceeds from exercise of stock options	21	101	23
Proceeds from sale of stock under the Employee Stock Purchase Plan	59	154	
Proceeds from repayment of stock subscription receivable		50	131
Borrowings under notes payable	5,000	1,215	5,381
Repayments of notes payable	(5,320)	(3,667)	(2,953)
Payment of deferred financing costs	(114)		
Net cash provided by (used in) financing activities	28,799	(2,147)	74,206
Net increase (decrease) in cash and cash equivalents	2,089	(13,691)	13,079
Cash and cash equivalents, beginning of period	8,971	22,662	9,583
Cash and cash equivalents, end of period	\$ 11,060	\$ 8,971	\$ 22,662

**Supplemental disclosure of cash flow information**

# Edgar Filing: ACHILLION PHARMACEUTICALS INC - Form 10-K

Cash paid for interest	\$ 854	\$ 848	\$ 847
Cash received from tax credits	\$ 1,008	\$	\$ 336
<b>Supplemental disclosure of noncash financing activities</b>			
Issuance of warrants in connection with debt financing	\$ 155	\$	\$ 174
Conversion of Preferred stock into Common stock in connection with initial public offering	\$	\$	\$ 116,742
Conversion of preferred warrants to common warrants	\$	\$	\$ 303
Cashless exercise of warrants	\$	\$ 288	\$

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

F-6

**Table of Contents**

**Achillion Pharmaceuticals, Inc.**

**Notes to Financial Statements**

**(in thousands, except per share amounts)**

**1. Nature of the Business**

Achillion Pharmaceuticals, Inc. (the Company) was incorporated on August 17, 1998 in Delaware. The Company was established to discover, develop and commercialize innovative anti-infective drug therapies. The Company is devoting substantially all of its efforts towards product research and development.

The Company incurred losses of \$166,118 from inception through December 31, 2008 and had an accumulated deficit of \$179,981 through December 31, 2008. The Company has funded its operations primarily through the sale of equity securities, borrowings from debt facilities, and the receipt of milestone and cost-sharing receipts from its collaboration partner, Gilead Sciences, Inc. (Gilead).

The Company believes that its existing cash and cash equivalents will be sufficient to support its current operating plan through at least the next twelve months. However, its operating plan may change as a result of many factors, including:

the outcome of future clinical trials of ACH-1095, which will determine the Company's ability to earn future milestone payments from its collaboration partner Gilead;

the costs involved in the clinical development, manufacturing and formulation of ACH-1625;

the outcome of the Company's strategic and development assessment of ACH-702;

the costs involved in the preclinical and clinical development of ACH-1095 and other NS4A antagonists, certain portions of which are shared with Gilead;

the Company's ability to enter into corporate collaborations and the terms and success of these collaborations; and

the Company's ability to raise incremental debt or equity capital, including any changes in the credit market that may impact its ability to obtain capital in the future.

In the event that the Company is unable to secure additional funding within the next twelve months, the Company has developed a contingency plan which provides for changes in its operations. The Company believes that this plan would reduce its operating expenses and believes that implementation of this contingency plan, if necessary, would permit it to conduct its operations for at least the next twelve months.

The Company expects to incur substantial and increasing losses for at least the next several years and will need substantial additional financing to obtain regulatory approvals, fund operating losses, and, if deemed appropriate, establish manufacturing and sales and marketing capabilities, which the Company will seek to raise through public or private equity or debt financings, collaborative or other arrangements with third parties or through other sources of financing. There can be no assurance that such funding will be available on terms favorable to the Company, if at all.

In addition to the normal risks associated with early-stage companies, there can be no assurance that the Company will successfully complete its research and development, obtain adequate patent protection for its technology, obtain necessary government regulatory approval for drug candidates the Company develops or that any approved drug candidates will be commercially viable. In addition, the Company may not be profitable even if it succeeds in commercializing any of its drug candidates.

**2. Private Placement Financing**

On August 12, 2008, the Company issued 10,715 units, with each unit consisting of one share of the Company's common stock plus a common stock warrant to purchase 0.25 shares of common stock (the

F-7

## **Table of Contents**

Common Stock Warrants ), at a price of \$2.9049 per unit (the Units ). The Common Stock Warrants, which represent the right to acquire 2,679 shares of common stock, have a seven-year term from the date of issuance, are exercisable at a price of \$3.53 per share and are exercisable for cash or by net share settlement.

Additionally, the Company issued certain unit warrants in connection with the Purchase Agreement, pursuant to which the investors may have the option to purchase an additional 3,679 Units at an exercise price of \$2.82 between February 2009 and August 2009 (the Unit Warrants ). The Unit Warrants are exercisable for Units consisting of up to an additional 3,679 shares of the Company s common stock and Common Stock Warrants to purchase up to 920 shares of the Company s common stock at an exercise price of \$2.82. The Unit Warrants are exercisable beginning February 12, 2009 for a minimum of \$1,000 worth of Units per exercise. The Unit Warrants expire on August 12, 2009.

No investor is permitted to exercise a Common Stock Warrant or Unit Warrant, or part thereof, if, upon such exercise, the number of shares of common stock beneficially owned by the investor would exceed 19.99% of the number of shares of the Company s common stock then issued and outstanding unless and until such limitation is no longer required by applicable NASDAQ Marketplace Rules.

The Company agreed to seek stockholder approval for the transaction. Additionally, pursuant to the Company s obligations under a registration rights agreement, on October 6, 2008 the Company filed a registration statement with the Securities and Exchange Commission covering the resale of the 10,715 shares of common stock issued in the private placement and the 2,679 shares of common stock issuable upon the exercise of the warrants.

### **3. Summary of Significant Accounting Policies**

#### ***Use of Estimates***

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

#### ***Revenue Recognition***

The Company recognizes revenue from contract research and development and research progress payments in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition*, or SAB No. 104, and Financial Accounting Standards Board, or FASB, Emerging Issue Task Force, or EITF, Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*, or EITF No. 00-21. Revenue-generating research and development collaborations are often multiple element arrangements, providing for a license as well as research and development services. Such arrangements are analyzed to determine whether the deliverables, including research and development services, can be separated or whether they must be accounted for as a single unit of accounting in accordance with EITF No. 00-21. The Company recognizes upfront license payments as revenue upon delivery of the license only if the license has standalone value and the fair value of the undelivered performance obligations can be determined. If the fair value of the undelivered performance obligations can be determined, such obligations would then be accounted for separately as performed. If the license is considered to either (i) not have standalone value or (ii) have standalone value but the fair value of any of the undelivered performance obligations cannot be determined, the arrangement would then be accounted for as a single unit of accounting and the upfront license payments are recognized as revenue over the estimated period of when our performance obligations are performed.

When the Company determines that an arrangement should be accounted for as a single unit of accounting, it must determine the period over which the performance obligations will be performed and revenue related to



**Table of Contents**

upfront license payments will be recognized. Revenue will be recognized using either a proportionate performance or straight-line method. The Company recognizes revenue using the proportionate performance method provided that it can reasonably estimate the level of effort required to complete its performance obligations under an arrangement and such performance obligations are provided on a best-efforts basis. Under the proportionate performance method, periodic revenue related to up-front license payments is recognized as the percentage of actual effort expended in that period to total effort expected for all of the Company's performance obligations under the arrangement. Actual effort is generally determined based upon actual direct labor hours or full-time equivalents incurred and include research and development activities performed by internal scientists. Total expected effort is generally based upon the total direct labor hours of full-time equivalents incorporated into the detailed budget and project plan that is agreed to by both parties to the collaboration. Generally under collaboration arrangements, payments received during the period of performance may include up-front payments, time- or performance-based milestones and reimbursement of internal and external costs. The proportion of actual performance to total expected performance is applied to these payments in determining periodic revenue, but will be limited by the aggregate cash received or receivable to date by the Company. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which the Company expects to complete the related performance obligations. For example, under the Company's arrangement with Gilead, the joint research committee periodically reviews and updates the project plan. In the event that a change in estimate occurs, the change will be accounted for using the cumulative catch-up method which provides for an adjustment to revenue in the current period. Estimates of the Company's level of effort may change in the future, resulting in a material change in the amount of revenue recognized in future periods.

The Company revised its joint research program with Gilead in the first quarter of 2007 to focus on next-generation NS4A antagonists. At that time, the Company extended the period over which its remaining obligations under the arrangement would be completed. The Company and Gilead also agreed to continue to equally share external costs, but effective April 1, 2007, internal full-time equivalents would no longer be subject to a cost sharing arrangement. Instead, each party bears the costs of their respective full-time equivalents. In addition, the Company revised its joint research plan with Gilead in the first quarter of 2009. Under this revised plan, the Company's total level of effort is estimated to increase and the estimated period over which the Company's remaining obligations under the arrangement would be completed was extended through 2010. As a result, the Company's proportion of actual effort expended through December 31, 2008 to total effort expected for all periods decreased, which resulted in the quarter ended December 31, 2008 in a non-cash reduction to amounts previously recognized as revenue earned under the arrangement.

Substantive milestone payments are considered to be performance bonuses that are recognized upon achievement of the milestone only if all of the following conditions are met: (1) the milestone payments are non-refundable, (2) achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement, (3) substantive effort is involved in achieving the milestone, (4) the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone and (5) a reasonable amount of time passes between the upfront license payment and the first milestone payment as well as between each subsequent milestone payment.

Reimbursement of costs is recognized as revenue provided the provisions of EITF Issue No. 99-19, *Reporting Revenue Gross as Principal Versus Net as an Agent*, are met, the amounts are determinable and collection of the related receivable is reasonably assured.

***Stock-Based Compensation Employee Stock-Based Awards***

The Company applies the Statement of Financial Accounting Standards No. 123 as revised in 2004, *Share-Based Payment*, or SFAS No. 123R, which requires measurement and recognition of compensation expense for all stock-based awards made to employees and directors, including employee stock options and employee stock purchases under the Company's 2006 ESPP Plan based on estimated fair values. In December 2007, the SEC issued Staff Accounting Bulletin No. 110, or SAB No. 110, which extends the use of the simplified method in developing an estimate of the expected term of plain vanilla share options beyond December 31, 2007. Due to

## **Table of Contents**

the Company's limited exercise history and period of time that its shares have been publicly traded, the Company utilizes the provisions of SAB 110 in its application of SFAS No. 123R.

The Company primarily grants qualified stock options for a fixed number of shares to employees with an exercise price equal to the market value of the shares at the date of grant. To the extent that the amount of the aggregate fair market value of qualified stock options that become exercisable for an individual exceeds \$100 during any tax year, those stock options are treated as non qualified stock options. Under the fair value recognition provisions of SFAS No. 123R, stock-based compensation cost is based on the value of the portion of stock-based awards that is ultimately expected to vest during the period. Stock-based compensation expense recognized during the years ended December 31, 2008, 2007 and 2006 includes compensation expense for stock-based awards granted prior to, but not yet vested as of December 31, 2005, based on the fair value on the grant date estimated in accordance with the pro forma provisions of SFAS No. 123. Compensation expense also includes amounts related to the stock-based awards granted subsequent to December 31, 2005, based on the fair value on the grant date, estimated in accordance with the provisions of SFAS No. 123R.

The Company utilizes the Black-Scholes option pricing model for determining the estimated fair value for stock-based awards. The Black-Scholes model requires the use of assumptions which determine the fair value of the stock-based awards. Determining the fair value of stock-based awards at the grant date requires judgment, including estimating the expected term of stock options, the expected volatility of our stock and expected dividends. In addition, the Company previously accounted for forfeitures as they occurred. In accordance with SFAS No. 123R, the Company is required to estimate forfeitures at the grant date and recognize compensation costs for only those awards that are expected to vest. Judgment is required in estimating the amount of stock-based awards that are expected to be forfeited.

The Company uses the straight-line attribution method for allocating compensation cost under SFAS No. 123R which allocates expense on a straight-line basis over the requisite service period of the last separately vesting portion of an award.

During the fourth quarter of 2007, the Company changed its calculation of volatility from peer group volatility to incorporate both a weighted average rate of historical volatility, and the volatility of its peer group. The Company's actual volatility from the end of its lock-up period to the end of the current reporting period is weighted as a percentage of actual time to the 6.1 year term, determined under the simplified method. The Company will continue to monitor these and other relevant factors used to measure expected volatility for future option grants.

The risk-free rate utilized when valuing share-based payment arrangements is based on the U.S. Treasury yield curve in effect at the time of grant for the expected term of the particular instrument being valued.

If factors change and the Company employs different assumptions in the application of SFAS No. 123R in future periods, the compensation expense that is recorded under SFAS No. 123R may differ significantly from what the Company has recorded in the current period. Therefore, the Company believes it is important for investors to be aware of the degree of subjectivity involved when using option pricing models to estimate share-based compensation under SFAS No. 123R. There is risk that the Company's estimates of the fair values of its share-based compensation awards on the grant dates may differ from the actual values realized upon the exercise, expiration, early termination or forfeiture of those share-based payments in the future. Certain share-based payments, such as employee stock options, may expire worthless or otherwise result in zero intrinsic value as compared to the fair values originally estimated on the grant date and reported in the Company's financial statements. Alternatively, value may be realized from these instruments that is significantly in excess of the fair values originally estimated on the grant date and reported in the financial statements. Although the fair value of employee share-based awards is determined in accordance with SFAS No. 123R and SAB No. 110 using an option pricing model, that value may not be indicative of the fair value observed in a willing buyer/willing seller market transaction.

## **Table of Contents**

### ***Accrued Expenses***

As part of the process of preparing financial statements, the Company is required to estimate accrued expenses. This process involves identifying services which have been performed on its behalf and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date in its financial statements.

In accruing service fees, the Company estimates the time period over which services will be provided and the level of effort in each period. If the actual timing of the provision of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. The majority of service providers invoice the Company monthly in arrears for services performed. Some service providers require upfront or milestone payments. If the estimate of services performed is less than the upfront or milestone payments, the difference is accounted for as a prepaid expense. In the event that the Company does not identify costs that have begun to be incurred or the Company underestimates or overestimates the level of services performed or the costs of such services, actual expenses could differ from such estimates. The date on which some services commence, the level of services performed on or before a given date and the cost of such services are often subjective determinations. The Company makes judgments based upon facts and circumstances known to it in accordance with GAAP.

### ***Cash, Cash Equivalents and Restricted Cash***

Cash and cash equivalents are stated at cost, which approximates market, and include short-term, highly-liquid investments with original maturities of less than three months. The Company also holds certificates of deposit, which collateralize the Company's facility lease which are classified as restricted cash in the accompanying balance sheets. The restricted cash will be released from restriction at various dates through 2010.

### ***Marketable Securities and Equity Investments***

The Company adopted SFAS No. 157, *Fair Value Measurements*, or SFAS No. 157, effective January 1, 2008 for financial assets and liabilities measured on a recurring basis. There was no impact to the Company's financial statements upon the adoption of SFAS No. 157. SFAS No. 157 requires disclosure that establishes a framework for measuring fair value and expands disclosures in the financial statements. The statement requires that fair value measurements be classified and disclosed in one of the three categories:

Level 1: Quoted prices in active markets for identical assets and liabilities that the reporting entity has the ability to access at the measurement date;

Level 2: Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly; or

Level 3: Unobservable inputs.

The fair value of the Company's securities as of December 31, 2008 is valued based on level 2 inputs as defined in SFAS No. 157. The Company classifies its entire investment portfolio as available for sale as defined in SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. As of December 31, 2008, the Company's investment portfolio consisted of U.S. government and agency securities and short term FDIC guaranteed commercial paper held by a major banking institution. The maturities of all marketable securities held at December 31, 2008 are less than one year. Securities are carried at fair value with the unrealized gains (losses) reported as a separate component of stockholders equity.

As of December 31, 2008, none of the Company's investments were determined to be other than temporarily impaired.

### ***Fair Value of Financial Instruments***

The Company's financial instruments, including cash, cash equivalents, accounts receivable, and accounts payable are carried at cost, which approximates their fair value because of the short-term maturity of these instruments.

## **Table of Contents**

### ***Concentration of Risk***

Concentration of credit risk exists with respect to cash and cash equivalents, accounts receivable, and investments. The Company maintains its cash and cash equivalents and investments with high quality financial institutions. At times, amounts may exceed federally insured deposit limits.

For the years ended December 31, 2008, 2007 and 2006, 100%, 99% and 90% of the Company's revenue was generated from an agreement with one collaboration partner (see Note 5). At December 31, 2007, 100% of accounts receivable was due from the same collaboration partner.

### ***Fixed Assets***

Property and equipment are recorded at cost and are depreciated and amortized over the shorter of their remaining lease term or their estimated useful lives on a straight-line basis as follows:

Laboratory equipment	4-7 years
Office equipment	3-5 years
Leasehold improvements	Earlier of life of improvement or lease

Expenditures for maintenance and repairs, which do not improve or extend the useful lives of the respective assets, are expensed as incurred. When assets are sold or retired, the related cost and accumulated depreciation are removed from their respective accounts and any resulting gain or loss is included in income (loss).

### ***Long-lived Assets***

SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, addresses the financial accounting and reporting for impairment or disposal of long-lived assets. The Company reviews the recorded values of long-lived assets for impairment whenever events or changes in business circumstance indicate that the carrying amount of an asset or group of assets may not be fully recoverable.

### ***Research and Development Expenses***

All costs associated with internal research and development, research and development services for which the Company has externally contracted and licensed technology are expensed as incurred. Research and development expense includes direct costs for salaries, employee benefits, subcontractors, including clinical research organizations (CROs), operating supplies, facility-related expenses and depreciation.

### ***Patent Costs***

The Company expenses the costs of obtaining and maintaining patents.

### ***Convertible Preferred Stock***

The carrying value of convertible preferred stock was increased by periodic accretion to account for accrued but unpaid dividends (see Note 11). These increases were effected through charges against additional paid-in-capital, if any, and then accumulated deficit.

In connection with the 2006 initial public offering, the Company's outstanding shares of Series A, Series B, Series C, Series C-1 and Series C-2 Convertible Preferred Stock were converted into 9,834 shares of common stock, including shares issued in satisfaction of \$15,400 of accrued but unpaid dividends on the Preferred Stock as of October 31, 2006, the closing date of the initial public offering.

### ***Comprehensive Loss***

The Company reports and presents comprehensive loss in accordance with SFAS No. 130, *Reporting Comprehensive Income*, which establishes standards for reporting and display of comprehensive loss and its

F-12

## **Table of Contents**

components in a full set of general purpose financial statements. The objective of the statement is to report a measure of all changes in equity of an enterprise that result from transactions and other economic events of the period other than transactions with owners (comprehensive loss). The Company's other comprehensive income arises from net unrealized gains on marketable securities.

### ***Income Taxes***

The Company uses an asset and liability approach for financial accounting and reporting of income taxes. Deferred tax assets and liabilities are determined based on temporary differences between financial reporting and tax basis of assets and liabilities and are measured by applying enacted rates and laws to taxable years in which differences are expected to be recovered or settled. Further, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that the rate change is enacted. A valuation allowance is required when it is more likely than not that all or a portion of deferred tax assets will not be realized.

Effective January 1, 2007, the Company adopted Financial Accounting Standards Board ( FASB ) Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* an interpretation of FASB Statement No. 109, or FIN 48. FIN 48 prescribes a comprehensive model for how a company should recognize, measure, present, and disclose in its financial statements uncertain tax positions that the company has taken or expects to take on a tax return (including a decision whether to file or not file a return in a particular jurisdiction). Under FIN 48, the financial statements reflect expected future tax consequences of such positions presuming the taxing authorities' full knowledge of the position and all relevant facts.

As a result of implementation of FIN 48, the Company recognized a decrease of \$180 in its liability for unrecognized tax benefits, which was accounted for as a decrease to the January 1, 2007 retained deficit. The Company does not have any unrecognized tax benefits as of the date of adoption or December 31, 2008. The Company reviews all tax positions to ensure the tax treatment selected is sustainable based on its technical merits and that the position would be sustained if challenged.

### ***Segment Information***

The Company is engaged solely in the discovery and development of innovative anti-infective drug therapies. Accordingly, the Company has determined that it operates in one operating segment.

### ***Recently Issued Accounting Pronouncements***

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, or SFAS No. 157. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. The standard is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The Company adopted SFAS No. 157 for financial assets and liabilities effective January 1, 2008. There was no impact to the Company's financial statements upon adoption. On February 12, 2008, the FASB issued FASB Staff Position (FSP) FAS No. 157-2. This FSP permits a delay in the effective date of SFAS No. 157 to fiscal years beginning after November 15, 2008 for nonfinancial assets and nonfinancial liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis, at least annually. The Company does not believe that its adoption of SFAS No. 157 for nonfinancial assets and nonfinancial liabilities will have a material impact on the Company's financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, or SFAS No. 159. SFAS No. 159 permits an entity to elect to report many financial assets and liabilities at fair value. Entities electing the fair value option are required to recognize changes in fair value in earnings and are required to distinguish, on the face of the statement of financial position, the fair value of assets and liabilities for which the fair value option has been elected and similar assets and liabilities measured

**Table of Contents**

using another measurement attribute. The initial adjustment to reflect the difference between the fair value and the carrying amount is accounted for as a cumulative-effect adjustment to retained earnings as of the date of initial adoption. SFAS No. 159 was effective as of the beginning of an entity's first fiscal year beginning after November 15, 2007. The Company did not elect to adopt the fair value option.

In December 2007, the EITF reached a consensus on EITF Issue No. 07-01, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*, or EITF No. 07-01. EITF No. 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 No. 07-01 is effective for the Company's collaborations existing after January 1, 2009. The Company is currently evaluating the impact this standard will have on its financial statements.

In December 2007, the FASB issued SFAS No. 141R, *Business Combinations*, or SFAS No. 141R, which changes the accounting for business acquisitions. SFAS No. 141R requires the acquiring entity in a business combination to recognize all the assets acquired and liabilities assumed in the transaction and establishes the acquisition-date fair value as the measurement objective for all assets acquired and liabilities assumed in a business combination. Certain provisions of this standard will, among other things, impact the determination of acquisition-date fair value of consideration paid in a business combination, including contingent consideration; exclude transaction costs from acquisition accounting; and change accounting practices for acquired contingencies, acquisition-related restructuring costs, in-process research and development, indemnification assets, and tax benefits. SFAS No. 141R is effective for business combinations and adjustments to an acquired entity's deferred tax asset and liability balances occurring after December 31, 2008. Adoption of SFAS No. 141R may have a material impact on the Company's financial position and results of operations in the event that the Company enters into a business combination that falls within the scope of this pronouncement.

**4. Earnings (Loss) Per Share ( EPS )**

Basic EPS is calculated in accordance with SFAS No. 128, *Earnings per Share*, by dividing net income or loss attributable to common stockholders by the weighted average common stock outstanding. Diluted EPS is calculated in accordance with SFAS No. 128 by adjusting weighted average common shares outstanding for the dilutive effect of common stock options, warrants, convertible preferred stock and accrued but unpaid convertible preferred stock dividends. In periods where a net loss is recorded, no effect is given to potentially dilutive securities, since the effect would be antidilutive. Total securities that could potentially dilute basic EPS in the future that were not included in the computation of diluted EPS because to do so would have been antidilutive (prior to consideration of the treasury stock method) were as follows:

	<b>Years Ended December 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
Options	2,596	1,857	1,208
Warrants	6,711	311	336
<b>Total potentially dilutive securities outstanding</b>	<b>9,307</b>	<b>2,168</b>	<b>1,544</b>

**5. Collaboration Arrangements*****Gilead Sciences, Inc.***

In November 2004, the Company entered into a collaboration arrangement with Gilead (the "Gilead Arrangement") to jointly develop and commercialize compounds for use in treating hepatitis C infection which inhibit viral replication through a specified novel mechanism of action. Commercialization efforts will commence only if such compounds are found to be commercially viable and all appropriate regulatory approvals have been obtained. In connection with this arrangement, Gilead paid the Company \$10,000 as payment for both a non-refundable upfront license fee and 2,300 shares of Series C-1 Convertible Preferred Stock ("Series C-1").

## **Table of Contents**

Under the Gilead Arrangement, the Company and Gilead are working together to develop one or more compounds for use in treating hepatitis C infection until proof-of-concept in one compound, as defined in the Gilead Arrangement, is achieved (the Research Period). Subsequent to the achievement of proof-of-concept, the Company has no further obligation to continue providing services to Gilead but, at Gilead's request, the Company may elect to extend the Research Period for up to an additional two years after proof-of-concept is established, based upon good faith negotiations at that point in time. Further, if it is agreed that potential back-up compounds should continue to be researched, good faith negotiations would also be conducted to determine the specifics of any arrangement to continue to research backup compounds.

Gilead has agreed to make milestone payments to the Company upon the achievement of various defined clinical, regulatory and commercial milestones, such as regulatory approval in the United States, the European Union or Japan. The Company could receive up to \$157,500 in development, regulatory and sales milestone payments, assuming the successful simultaneous development of a lead and back-up compound, and annual sales in excess of \$600,000. The Company could also receive royalties on net sales of products if commercialization is achieved.

The up-front payment of \$10,000, received in 2004, was first allocated to the fair value of the Series C-1, as determined by management after considering a valuation analysis performed by an unrelated third-party valuation firm, Fletcher Spaght, at the direction of the Company, in which each share of the Series C-1 was determined to be worth \$0.88 per share, or approximately \$2,000 in aggregate. The remaining \$8,000 balance of the \$10,000 is being accounted for as a non-refundable up-front license fee. Due to certain provisions contained within the Gilead Arrangement relating to services to be performed on both the primary and backup compounds, as defined in the Gilead Arrangement, the non-refundable up-front license fee of \$8,000, as well as a \$2,000 milestone achieved during the Research Period, is being accounted for under the proportionate performance model. Future milestones, if any, will occur after the Research Period and are not accounted for under the proportionate performance model. Revenue recognized under the proportionate performance model is limited by the aggregate cash received or receivable to date by the Company. Milestones achieved, if any, after the termination of the Research Period, will be recognized when the milestone is achieved as the Company has no further research or development obligations after the Research Period.

Under the Gilead Arrangement, through March 31, 2007, agreed upon research or development expenses, including internal full-time equivalent ( FTE ) costs and external costs, incurred by both companies during the period up to proof-of-concept were borne equally by both parties. Prior to March 31, 2007, the Company was incurring the majority of those expenses and, therefore, was the net receiver of funds under this cost-sharing portion of the arrangement. Effective April 1, 2007, internal FTE costs are no longer subject to this cost-sharing arrangement. Instead, each party bears its own internal costs, including FTE costs. External costs continue to be shared equally by both parties. In March 2007, the Company and Gilead also revised their joint research program to focus on next-generation NS4A antagonists, after discontinuing clinical trials for ACH-806, an NS4A antagonist the Company was previously evaluating. The Company also revised its joint research plan with Gilead in the first quarter of 2009, thereby extending the period over which the Company's remaining obligations under the arrangement would be completed to the second half of 2010. As a result, the Company's percentage of actual effort expended through December 31, 2008 to total effort expected for all periods decreased, which resulted in the quarter ended December 31, 2008 in a non-cash reduction to amounts previously recognized as revenue earned under the arrangement. Generally under collaboration arrangements, payments received during the period of performance may include up-front payments, time-or performance-based milestones and reimbursement of internal and external costs. The proportion of actual performance to total expected performance is applied to these payments in determining periodic revenue, but will be limited by the aggregate cash received or receivable to date by the Company.

Gilead has the right to terminate the agreement without cause upon 120 days written notice to the Company. Upon termination of the Gilead Arrangement for any reason, all cost share amounts due and payable through the date of termination shall be paid by the appropriate party and no previously paid amounts will be refundable.



## **Table of Contents**

During the years ended December 31, 2008, 2007 and 2006, the Company recognized revenue of \$(234), \$4,003 and \$2,978, respectively, under the Gilead Arrangement, respectively, of which \$51, \$2,091 and \$1,511, respectively, related to the recognition of the non-refundable upfront fee and a pre-proof-of-concept milestone under the proportionate performance model. The remaining \$(285), \$1,912 and \$1,468 recognized during the years ended December 31, 2008, 2007 and 2006, relate to FTE reimbursements recognized under the proportionate performance model and external costs billed under the Gilead Arrangement, net of Gilead billings to the Company of \$1,126, \$462 and \$1,646 for the years ended December 31, 2008, 2007 and 2006, respectively. Payments to Gilead under this collaboration are recognized as a reduction in revenue.

Included in the accompanying 2008 and 2007 balance sheets as of December 31, 2008 and 2007 are \$0 and \$136 respectively, of accounts receivable resulting from this collaboration agreement, \$260 and \$0, respectively, of accrued expenses, and \$2,489 and \$2,570, respectively, of deferred revenue resulting from the up-front fee, a milestone payment, and FTE costs. In addition to Gilead's rights to unilaterally terminate this agreement, each party has the right to terminate for material breach; however, the Company may terminate for Gilead's breach only on a market-by-market basis, and, if applicable, a product-by-product basis.

### ***FOB Synthesis, Inc.***

In April 2008, the Company entered into a license and research agreement with FOB Synthesis, Inc. ( "FOB" ) granting the Company an exclusive worldwide license for the research, development and commercialization of certain FOB compounds for the treatment of serious bacterial infections.

Under the terms of the agreement, the Company paid to FOB a \$500 upfront license payment. The Company also provided FOB with funding at specified levels to collaborate with the Company on the further characterization and development of the compounds for a period of at least one year. The Company had the option to extend the research term for an additional one year period with 30 days written notice to FOB prior to the end of the first year of the research term. In accordance with the terms of the agreement, in February 2009, the company terminated this agreement effective April 4, 2009.

## **6. Marketable Securities**

The Company adopted SFAS No. 157, *Fair Value Measurements*, or SFAS No. 157, effective January 1, 2008 for financial assets and liabilities measured on a recurring basis. There was no impact to the Company's financial statements upon the adoption of SFAS No. 157. SFAS No. 157 requires disclosure that establishes a framework for measuring fair value and expands disclosures in the financial statements. The statement requires that fair value measurements be classified and disclosed in one of the three categories:

Level 1: Quoted prices in active markets for identical assets and liabilities that the reporting entity has the ability to access at the measurement date;

Level 2: Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly; or

Level 3: Unobservable inputs.

The fair value of the Company's securities of \$24,297 as of December 31, 2008 is valued based on level 2 inputs as defined in SFAS No. 157. The Company classifies its entire investment portfolio as available for sale as defined in SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. As of December 31, 2008 and 2007, the Company's investment portfolio consisted of U.S. government and agency securities and short term FDIC guaranteed commercial paper held by a major banking institution. The maturities of all marketable securities held at December 31, 2008 and 2007 are less than one year. Securities are carried at fair value with the unrealized gains (losses) reported as a separate component of stockholders' equity.

The unrealized gain from marketable securities was \$115 and \$51 at December 31, 2008 and 2007, respectively.

As of December 31, 2008 and 2007, none of the Company's investments were determined to be other than temporarily impaired.

**Table of Contents**

The following table summarizes our investments:

	As of December 31,					
	Amortized	2008 Unrealized	Estimated	Amortized	2007 Unrealized	Estimated
	Cost	Gain (Loss)	Fair Value	Cost	Gain (Loss)	Fair Value
Commercial Paper	\$ 3,484	\$ 16	\$ 3,500	\$ 18,330	\$ 53	\$ 18,383
Corporate bonds				3,757	(2)	3,755
U.S. Government and Agency securities	20,698	99	20,797			
Total	\$ 24,182	\$ 115	\$ 24,297	\$ 22,087	\$ 51	\$ 22,138

**7. Other Current Assets**

A summary of other current assets is as follows:

	As of December 31,	
	2008	2007
Prepaid research and development costs	\$ 304	\$ 160
Tax credit receivable	160	1,036
Maintenance agreements	265	289
Interest receivable	152	89
Prepaid insurance	175	29
Prepaid other	125	68
Total	\$ 1,181	\$ 1,671

**8. Fixed Assets**

A summary of property and equipment is as follows:

	As of December 31,	
	2008	2007
Laboratory equipment	\$ 3,490	\$ 3,695
Office equipment	570	601
Leasehold improvements	3,495	3,495
	7,555	7,791
Less accumulated depreciation and amortization	(5,785)	(5,316)
Total	\$ 1,770	\$ 2,475

Depreciation expense was \$778, \$750 and \$762 for the years ended December 31, 2008, 2007 and 2005, respectively.

**9. Accrued Expenses**

Current and long-term accrued expenses consist of the following:

	<b>As of December 31,</b>	
	<b>2008</b>	<b>2007</b>
Accrued compensation	\$ 472	\$ 720
Accrued research and development expenses	1,233	1,618
Accrued professional	355	294
Other accrued expenses	200	246
<b>Total</b>	<b>\$ 2,260</b>	<b>\$ 2,878</b>

F-17

**Table of Contents**

Accrued clinical trial and preclinical trial expenses are comprised of amounts owed to third-party contract research organizations or CROs, clinical investigators, laboratories and data managers for research and development work performed on behalf of the Company.

**10. Debt**

Debt consists of the following:

	As of December 31,	
	2008	2007
CII Term Loan, payable in monthly installments of \$13 through September 2010 with a final balloon payment of \$686, with interest at 7.5% per annum	\$ 844	\$ 933
2003 Credit Facility, payable in monthly installments as the individual notes mature through December 2010, with interest ranging from 7.75% to 9.06% per annum	394	675
2005 Credit Facility, payable in monthly installments as notes mature through December 2009, with interest of 10.92% to 11.58% per annum		4,955
2008 Credit Facility, payable in monthly installments as notes mature through March 2011, with interest of 9.97% to 11.58% per annum	5,009	
<b>Total long-term debt</b>	<b>6,247</b>	<b>6,563</b>
<b>Less: current portion</b>	<b>(6,247)</b>	<b>(6,563)</b>
<b>Total long-term debt, net of current portion</b>	<b>\$</b>	<b>\$</b>

During November 2000, the Company entered into a \$1,400 term loan ( CII Term Loan ) with Connecticut Innovations, Inc. (CII), a stockholder of the Company. The CII Term Loan is collateralized by personal and real property located at the Company's facility in New Haven, Connecticut. The current carrying value of the personal and real property located at the Company's facility that acts as collateral for the loan was \$487 as of December 31, 2007. The CII Term Loan contains certain non-financial covenants, including the requirement that the Company maintain its principal place of business and conduct the majority of its operations in Connecticut ( Connecticut Presence ). If the Company fails to maintain its Connecticut Presence, all amounts due under the CII Term Loan shall be immediately due and payable. Maintaining a Connecticut Presence is within management's control, and the Company currently has no plans to relocate the majority of its operations.

In 2003, the Company entered into a credit facility with Webster Bank ( 2003 Credit Facility ) for the purchase of capital equipment. In December 2007, the Company expanded the 2003 Credit Facility, drawing down an additional \$415 for the purchase of capital equipment. The purchased equipment serves as collateral for the credit facility.

On December 30, 2005, the Company entered into a credit facility with two lenders ( 2005 Credit Facility ). In connection therewith, the Company issued warrants to purchase 167 shares of Series C-2 at an exercise price of \$1.50 per share. Following the Company's initial public offering, these automatically converted to warrants to purchase 21 shares of common stock at an exercise price of \$12.00 (See Note 11).

In May 2006, the Company expanded the 2005 Credit Facility, drawing down an additional \$5,000 to fund the Company's working capital needs and issued warrants to purchase an additional 167 shares of Series C-2 at an exercise price of \$1.50 per share. Following the Company's initial public offering, these automatically converted to warrants to purchase 21 shares of common stock at an exercise price of \$12.00 (See Note 11). In June 2007, the Company again expanded the 2005 Credit Facility, drawing down an additional \$800 to fund an office and lab expansion project. Substantially all of the Company's tangible assets are collateral for the 2005 Credit Facility.

**Table of Contents**

In February 2008, the Company entered into a credit facility with GE Capital Corporation and Oxford Finance Corporation. The new facility has substantially the same terms as the 2005 Credit Facility. At the same time, the Company combined the amounts outstanding under the 2005 Credit Facility with the newly issued notes (collectively the 2008 Credit Facility). The 2008 Credit Facility provides an incremental \$5,000 to fund the Company's working capital needs, and is secured by substantially all of the Company's tangible assets. In connection with the 2008 Credit Facility, the Company issued warrants to purchase 43 shares of common stock at an exercise price of \$4.68 per share. The fair value of the warrants at the date of issuance was estimated to be \$155, utilizing the Black Scholes method and was recorded as a debt discount. This amount will be amortized as interest expense over the term of the loan.

Each of the Company's debt agreements contains certain subjective acceleration clauses, such that upon the occurrence of a material adverse change in the financial condition, business or operations of the Company in the view of the lenders (Material Adverse Change), amounts outstanding under the agreement may become immediately due and payable. As stated in Note 1, the Company will need additional financing to fund operations which the Company will seek to raise through public or private equity or debt financings, collaborative or other arrangements with third parties or through other sources of financing. There can be no assurance that such funding will be available on terms favorable to the Company, if at all. As such funding cannot be assured, the Company's debt balances have been classified as short term at December 31, 2008. The Company has no indication that it is in default of any such clauses and none of the Company's lenders have accelerated scheduled loan payments as a result of these provisions.

**11. Capital Structure*****Preferred Stock***

At December 31, 2008, the Company had 5,000 authorized shares of undesignated Preferred Stock of which no shares were issued and outstanding. Immediately prior to the Company's initial public offering, the Company had 80,620 authorized shares of Convertible Preferred Stock, of which 250, 15,817, 22,436, 2,300 and 24,000 were designated as Series A, Series B, Series C, Series C-1 and Series C-2 shares, respectively, and 250, 15,817, 22,418, 2,300 and 23,425, respectively, were issued and outstanding.

In October 2006, the Company completed an initial public offering of its common stock. In connection with the initial public offering, the then outstanding shares of Series A, Series B, Series C, Series C-1 and Series C-2 Convertible Preferred Stock (the Preferred Stock) were converted into 9,834 shares of common stock, including shares issued in satisfaction of \$15,400 of accrued but unpaid dividends on the Preferred Stock as of October 31, 2006, the closing date of the initial public offering transaction. In addition, outstanding warrants to purchase Series C preferred stock were automatically converted into a warrant to purchase 3 shares of the Company's common stock at an exercise price of \$12.11 per share, and outstanding warrants to purchase Series C-2 preferred stock were automatically converted into warrants to purchase 42 shares of the Company's common stock at an exercise price of \$12.00 per share.

In March 2006 and May 2006, the Company raised \$18,224, net of \$182 of issuance costs, through the issuance of 12,271 shares of Series C-2 Preferred Stock, under a second and third closing of the Series C-2 financing. Per share price, rights and preferences were the same as those offered in a November 2005 close of the Series C-2 financing.

During 2005, the Company issued 3,563 shares of Series C-2 Preferred stock, raising \$5,289, net of issuance costs. As part of this issuance, holders of convertible notes converted all outstanding principal and interest, totaling \$11,400, into an additional 7,592 shares of Series C-2 Preferred Stock at a conversion price of \$1.50 per share. As part of this issuance, the purchasers of the Series C-2 Preferred Stock committed to purchase, subject to the satisfaction of certain representations and warranties, an additional 3,104 shares of Series C-2 at identical terms during a second closing to be held before June 30, 2006. The Company determined that the fair value of this option to purchase additional shares was de minimus both at the time of issuance and at December 31, 2005.

**Table of Contents**

During 2004, the Company issued 2,300 shares of Series C-1 Preferred Stock in connection with the collaboration agreement with Gilead. The Company determined, after considering an unrelated third party valuation, that the fair value of these newly issued shares of the Company's Series C-1 Convertible Preferred Stock was \$0.88 per share, or \$2,000 in aggregate. The stated terms of the agreement with Gilead provided that accrued dividends, liquidation rights, and conversion rights related to these shares be based upon a \$2.17 per share price, as discussed in the significant terms section below.

The significant terms of the Series A, Series B, Series C, Series C-1 and Series C-2 were as follows, prior to the conversion of the preferred into common stock in connection with the company's initial public offering.

*Dividends.* Through October 31, 2006, cumulative dividends accrued whether or not declared, except with respect to the Series A. When and if declared by the board of directors, such accrued but unpaid dividends would be payable in cash. Upon an optional conversion at the option of the holder, or a mandatory conversion in connection with a firm commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, all such accrued but unpaid dividends on the Series B, Series C, Series C-1 and Series C-2 preferred stock would be payable in additional shares of Series B, Series C, Series C-1 and Series C-2 preferred stock calculated by dividing the accrued but unpaid dividends by \$1.81, \$1.81, \$2.17 and \$1.50, respectively. Upon the Company's initial public offering, such shares of Series B, Series C, Series C-1 and Series C-2 would then automatically convert into shares of common stock. Given that conversion of the preferred stock was at the option of the holder at any time, and that upon conversion the holder was entitled to receive cumulative accrued but unpaid dividends, and given that the Company had the option to declare and pay such dividends in cash, the Company's policy had been to accrue dividends at the stated dividend rates.

Each share of Series B, Series C and Series C-1 earned cumulative dividends at 4% per annum. Each share of Series C-2 earned cumulative dividends at 8% per annum. No dividends or other distributions were made with respect to the Series A or the common stock. The following reflects dividends accrued prior to the Company's initial public offering:

	<b>Year ended December 31, 2006</b>
Series B	\$ 792
Series C	1,349
Series C-1	166
Series C-2	1,856
<b>Total</b>	<b>\$ 4,163</b>

Upon the closing of the Company's initial public offering 8,722 shares of convertible preferred stock were issued to the holders of our series B, series C, series C-1 and series C-2 convertible preferred stock in satisfaction of \$15,442 of accumulated dividends.

*Conversion.* At the option of the holder, the Series A, Series B, Series C, Series C-1 and Series C-2 stockholders could elect to convert their preferred shares into common stock at an initial conversion price of \$1.00, \$1.50, \$1.81, \$2.17 and \$1.50 per share, respectively, subject to certain anti-dilution adjustments, as defined.

The Company had determined that none of its preferred stock required liability classification under SFAS 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*, as the preferred stock outstanding had no date certain mandatory redemption that was unconditional. In addition, the Company had determined there had been no beneficial conversion features related to any of its outstanding preferred stock from each date of issuance through October 31, 2006, the date of conversion.

**Table of Contents****Common Stock**

At December 31, 2008 and 2007, the Company had 100,000 authorized shares of \$0.001 par value common stock. As of December 31, 2008 there are 10,415 shares reserved for future exercise of outstanding stock options, warrants and shares available for issuance under the Company's 2006 Stock Incentive Plan and 2006 Employee Stock Purchase Plan.

In October 2006, the Company amended its articles of incorporation to effect a 1-for-8 reverse stock split of outstanding common stock. Such reverse stock split had been previously approved by the Company's Board of Directors in September 2006. Such reverse stock split has been retroactively reflected within the accompanying financial statements. As a result of the reverse stock split, the conversion ratios of the Company's preferred stock changed as follows:

	Prior	After
Series A	1 : 1	1 : 0.1250
Series B	1 : 1	1 : 0.1250
Series C	1 : 1.196	1 : 0.1495
Series C-1	1 : 1.196	1 : 0.1495
Series C-2	1 : 1	1 : 0.1250

**Warrants**

A summary of the Company's warrants outstanding as of December 31, 2008, is presented in converted amounts below:

	Warrants Outstanding	Common Shares Attributable to Warrants	Weighted Average Exercise price
Common stock warrants	3,032	3,032	\$ 3.76
Unit warrants	3,679	4,599	2.82
<b>Total</b>	<b>6,711</b>	<b>7,631</b>	<b>\$ 3.25</b>

In May 2006, the Company expanded the 2005 Credit Facility and issued warrants to purchase an additional 167 shares of Series C-2 at an exercise price of \$1.50 per share. Following the Company's initial public offering, these automatically converted to a warrant to purchase 21 shares of Common Stock at an exercise price of \$12.00 per share. The relative fair value of such warrants at the date of issuance was estimated to be \$174, utilizing the Black-Scholes method. Such value was recorded as a debt discount which is being amortized as interest expense over the life of the related obligation.

In February 2008, the Company entered into a credit facility with GE Capital Corporation and Oxford Finance Corporation. In connection with the 2008 Credit Facility, the Company issued warrants to purchase 43 shares of common stock at an exercise price of \$4.68 per share. The fair value of the warrants at the date of issuance was estimated to be \$155, utilizing the Black Scholes method and was recorded as a debt discount. This amount is being amortized as interest expense over the term of the loan.

On August 12, 2008, in a private placement the Company issued to certain institutional investors 10,715 units, with each unit consisting of one share of the Company's common stock plus a common stock warrant to purchase 0.25 shares of common stock (the "Common Stock Warrants"), at a price of \$2.9049 per unit (the "Units"). The Common Stock Warrants, which represent the right to acquire 2,679 shares of common stock, have a seven-year term from the date of issuance, are exercisable at a price of \$3.53 per share and are exercisable for cash or by net share settlement.

Additionally, the Company issued certain unit warrants in connection with the Purchase Agreement, pursuant to which the investors may have the option to purchase an additional 3,679 Units at an exercise price of \$2.82 between February 2009 and August 2009 (the "Unit Warrants"). The Unit Warrants are exercisable for





## **Table of Contents**

Units consisting of up to an additional 3,679 shares of the Company's common stock and Common Stock Warrants to purchase up to 920 shares of the Company's common stock at an exercise price of \$2.82. The Unit Warrants are exercisable beginning February 12, 2009 for a minimum of \$1 million worth of Units per exercise. The Unit Warrants expire on August 12, 2009. No investor is permitted to exercise a Common Stock Warrant or Unit Warrant, or part thereof, if, upon such exercise, the number of shares of common stock beneficially owned by the Investor would exceed 19.99% of the number of shares of the Company's common stock then issued and outstanding unless and until such limitation is no longer required by applicable NASDAQ Marketplace Rules.

## **12. Stock-Based Compensation**

### *1998 Stock Option Plan*

The Company's 1998 stock option plan, or the 1998 Plan, as amended and restated, was adopted by the Company's board of directors in January 2000 and approved by its stockholders in March 2000. A maximum of 1,094 shares of common stock were authorized for issuance under the 1998 Plan.

The 1998 Plan, as amended, provided for the grant of options intended to qualify as incentive stock options under Section 422 of the Internal Revenue Code of 1986, as amended, and nonqualified stock options. The Company's employees, officers, directors, consultants and advisors were eligible to receive options under the 1998 plan. Under present law, however, incentive stock options may only be granted to the Company's employees. The Plan was administered by the Company's board of directors.

Following the adoption of the 2006 stock incentive plan described below, the Company no longer grants stock options or other awards under the 1998 Plan.

### *2006 Stock Incentive Plan*

The Company's 2006 stock incentive plan, or the 2006 Plan, was adopted by the Company's board of directors in May 2006, amended by its board of directors in September 2006, approved by its stockholders in September 2006 and became effective in October 2006, upon the closing of our initial public offering. The Company originally reserved for issuance 750 shares of common stock under the 2006 Plan. In addition, the Plan contains an evergreen provision, which allows for an annual increase in the number of shares available for issuance under the plan on the first day of each fiscal year during the period beginning on the first day of fiscal year 2007 and ending on the second day of fiscal year 2010. The annual increase in the number of shares shall be equal to the lowest of:

750 shares;

a number of shares that, when added to the number of shares already reserved under the plan, equals 5% of our outstanding shares as of such date; or

an amount determined by the Company's board of directors.

The 2006 Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights and other stock-based awards. The Company's officers, employees, consultants, advisors and directors, and those of any subsidiaries, are eligible to receive awards under the 2006 Plan; however, incentive stock options may only be granted to employees.

The Company's board of directors administers the 2006 Plan, although it may delegate its authority to a committee. The board, or a committee to which it has delegated its authority, will select the recipients of awards and determine, subject to any limitations in the 2006 Plan:

the number of shares of common stock covered by options and the dates upon which those options become exercisable;

the exercise prices of options;

F-22

**Table of Contents**

the duration of options;

the methods of payment of the exercise price; and

the number of shares of common stock subject to any restricted stock or other stock-based awards and the terms and conditions of those awards, including the conditions for repurchase, issue price and repurchase price.

Options granted under the Company's 1998 Stock Option Plan and 2006 Stock Option Plan (the "Plans"), are exercisable for a period determined by the Company, but in no event longer than ten years from the date of the grant. Options generally vest ratably over four years.

Under the evergreen provision, the Company registered an additional 735 and 438 share of common stock to be issued under the Company's 2006 plan in March 2008 and 2007, respectively.

There were 7 shares available to be granted under the Plans as of December 31, 2008.

A summary of the status of the Company's stock option activity for the year ended December 31, 2008 is presented in the table and narrative below:

	<b>Options</b>	<b>2008 Weighted Average Exercise Price</b>
Outstanding at January 1, 2008	1,857	\$ 5.97
Granted	849	1.26
Exercised	(13)	1.72
Forfeited/Cancelled	(97)	5.90
Outstanding at December 31, 2008	2,596	\$ 4.45
Options exercisable at December 31, 2008	1,163	\$ 4.93
Options vested and expected to vest at December 31, 2008	2,442	\$ 4.50

The following table summarizes information about stock options outstanding at December 31, 2008:

<b>Range of Exercise Prices</b>	<b>Number Outstanding</b>	<b>Options Outstanding Weighted Average Remaining Contractual Life (Years)</b>	<b>Weighted Average Exercise Price</b>	<b>Options Vested Number Vested</b>	<b>Weighted Average Exercise Price</b>
\$ 0.00 \$2.00	1,233	8.0	\$ 1.26	502	\$ 1.56
\$ 2.01 \$4.00	280	7.7	3.63	227	3.55
\$ 4.01 \$6.00	695	8.8	5.00	210	5.04
\$ 6.01 \$8.00	30	8.7	7.37	30	7.37
\$ 12.01 \$14.00	2	7.8	14.00	1	14.00
\$ 14.01 \$16.00	351	8.0	14.75	191	14.75
\$ 18.01 \$20.00	5	8.1	19.00	2	19.00
	2,596	8.3	\$ 4.45	1,163	\$ 4.93

## Edgar Filing: ACHILLION PHARMACEUTICALS INC - Form 10-K

As of December 31, 2008, the intrinsic value of the options outstanding was \$0. The intrinsic value for stock options is calculated based on the difference between the exercise prices of the underlying awards and the quoted stock price of the Company's common stock as of the reporting date.

F-23

**Table of Contents**

The total intrinsic value, the amount by which the stock price exceeds the exercise of the option on the date of exercise, of stock options exercised for the years ended December 31, 2008, 2007 and 2006 was \$15, \$254 and \$172, respectively.

The weighted-average grant-date fair value of options granted during the years ended December 31, 2008 and 2007 was \$0.84 and \$3.03, respectively. The weighted-average grant-date fair value of options vested at December 31, 2008 and 2007 was \$4.09 and \$3.97, respectively.

The weighted average remaining contractual life is 6.9 years for options exercisable and 8.2 years for options vested and expected to vest.

*Stock Based Compensation*

The Company applies the provisions of SFAS 123R, *Share-Based Payment*, which requires measurement and recognition of compensation expense for all stock-based awards made to employees and directors, including employee stock options and employee stock purchases under our 2006 ESPP Plan based on estimated fair values. In December 2007, the SEC issued Staff Accounting Bulletin No. 110 ( *SAB 110* ) which extends the use of the simplified method in developing an estimate of expected term of plain vanilla share options beyond December 31, 2007. Due to the Company's limited exercise history and period of time that its shares have been publicly traded, the Company utilizes the provisions of SAB 110 in its application of SFAS 123R.

Under the fair value recognition provisions of SFAS No. 123R, stock-based compensation cost is based on the value of the portion of stock-based awards that is ultimately expected to vest during the period. Stock-based compensation expense recognized during the years ended December 31, 2008, 2007 and 2006 includes compensation expense for stock-based awards granted prior to, but not yet vested as of December 31, 2005, based on the fair value on the grant date estimated in accordance with the pro forma provisions of SFAS 123, and compensation expense for the stock-based awards granted subsequent to December 31, 2005, based on the fair value on the grant date, estimated in accordance with the provisions of SFAS 123R.

Upon adoption of SFAS 123R, the Company selected the Black-Scholes option pricing model as the most appropriate method for determining the estimated fair value for stock-based awards. The Black-Scholes model requires the use of assumptions which determine the fair value of the stock-based awards. Determining the fair value of stock-based awards at the grant date requires judgment, including estimating the expected term of stock options, the expected volatility of our stock and expected dividends. In addition, the Company previously accounted for forfeitures as they occurred. In accordance with SFAS 123R, the Company is required to estimate forfeitures at the grant date and recognize compensation costs for only those awards that are expected to vest. Judgment is required in estimating the amount of stock-based awards that are expected to be forfeited. The assumptions used to value options granted are as follows:

	<b>For the Years Ended December 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
Expected term of option	6.1 years	6.1 years	6.1 years
Expected volatility	64% - 79%	64% - 70%	70%
Risk free interest rate	1.71 - 3.48%	3.58 - 4.94%	4.69 - 4.83%
Expected dividend yield	0%	0%	0%

Total compensation expense recorded in the accompanying statements of operations associated with option grants made to employees for the years ended December 31, 2008, 2007 and 2006 was \$2,129, \$1,662 and \$968, respectively. The Company recorded no tax benefit related to these options since the Company currently maintains a full valuation allowance.

**Table of Contents**

As of December 31, 2008, the total compensation cost related to options not yet recognized in the financial statements is approximately \$3,713, net of estimated forfeitures, and the weighted average period over which it is expected to be recognized is 1.34 years.

*2006 Employee Stock Purchase Plan*

The Company established an Employee Stock Purchase Plan effective December 1, 2006 (the 2006 ESPP Plan). A total of 250 shares of common stock are available for issuance under the 2006 ESPP Plan. Eligible employees can purchase common stock pursuant to payroll deductions at a price equal to 85% of the lower of the fair market value of the common stock at the beginning or end of each six-month offering period.

The Company measures the fair value of issuances under the employee stock purchase plan using the Black-Scholes option pricing model at the end of each reporting period. The compensation cost for the Plan consists of the 15% of the grant date stock price discount and the fair value of the option features. The assumptions used to value issuances under the Plan are as follows:

	<b>For the Years Ended December 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
Expected term of option	6 months	6 months	6 months
Expected volatility	99% - 135%	46% - 56%	70%
Risk free interest rate	1.71 - 3.48%	4.69 - 4.83%	5.05%
Expected dividend yield	0%	0%	0%

The Company recorded compensation cost of \$42, \$54 and \$12 for the years ended December 31, 2008, 2007 and 2006, respectively. As of December 31, 2008, 181 shares remained available for future issuance under the 2006 ESPP Plan.

**13. Other License and Research and Development Agreements**

The Company has entered into certain license and collaborative research agreements with third parties relating to the Company's drug discovery and development initiatives. Under these agreements, the Company has been granted certain worldwide exclusive licenses to use the licensed compounds or technologies. Included in the accompanying 2008, 2007 and 2006 statements of operations is \$145, \$95 and \$27, respectively, of research and development expense resulting from these arrangements, respectively. In order to maintain its rights under these agreements, and provided that the Company does not terminate such agreements, the Company may also be required to pay an additional \$475 of aggregate minimum payments over the next five years. The Company may also be required to make future payments to these licensors upon achievement of certain product development milestones for anti-viral products utilizing the third party's intellectual property, as well as pay royalties on future net sales, if any.

**14. Commitments***401(k) Retirement Plan*

The Company has a 401(k) defined contribution retirement plan covering substantially all full-time employees. The Company currently matches employee contributions at a rate of \$0.50 cents for each dollar contribution, up to 6% of salary deferrals. However, the decision to match any employee contributions is at the sole discretion of the Company. The Company made matching contributions of \$167, \$180 and \$0 for the years ended December 31, 2008, 2007 and 2006.

*Operating Leases*

The Company leases its operating facility located in New Haven, Connecticut. The lease agreements require monthly lease payments through March 2011. The Company is recording the expense associated with the lease on a straight-line basis over the expected ten-year minimum term of the lease and, as a result, has accrued \$95 and \$130 at December 31, 2008 and 2007, respectively.

**Table of Contents**

The future minimum annual lease payments under these operating leases at December 31, 2008 are as follows:

Years Ended December 31,	
2009	\$ 991
2010	637
2011	21

Rent expense under operating leases was approximately \$982, \$978 and \$991 for the years ended December 31, 2008, 2007 and 2006, respectively.

**15. Income Taxes**

The Company uses an asset and liability approach for financial accounting and reporting of income taxes. Deferred tax assets and liabilities are determined based on temporary differences between financial reporting and tax basis of assets and liabilities and are measured by applying enacted rates and laws to taxable years in which differences are expected to be recovered or settled. Further, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that the rate changes.

Effective January 1, 2007, the Company adopted Financial Accounting Standards Board ( FASB ) Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* an Interpretation of FASB Statement No. 109, or FIN 48. FIN 48 prescribes a comprehensive model for how a company should recognize, measure, present, and disclose in its financial statements uncertain tax positions that the company has taken or expects to take on a tax return (including a decision whether to file or not file a return in a particular jurisdiction). Under FIN 48, the financial statements reflect expected future tax consequences of such positions presuming the taxing authorities' full knowledge of the position and all relevant facts.

The Company does not have any interest or penalties accrued related to uncertain tax positions as it does not have any unrecognized tax benefits. In the event the Company determines that accrual of interest or penalties is necessary in the future, the amount will be presented as a component of income taxes.

The income tax provision (benefit) consists of the following:

	2008	As of December 31, 2007	2006
<b>Current:</b>			
Federal	\$	\$	\$
State	(132)	(960)	(49)
Total Current	\$ (132)	\$ (960)	\$ (49)
<b>Deferred:</b>			
Federal and state	\$ (12,762)	\$ (12,974)	\$ (10,882)
Valuation allowance	12,762	12,974	10,882
Total deferred	\$	\$	\$
Total provision	\$ (132)	\$ (960)	\$ (49)

## Table of Contents

A reconciliation of the provision for income taxes at statutory rates to the provision in the financial statements is as follows:

	Years Ended December 31,		
	2008	2007	2006
Federal statutory rate	(34.0)%	(34.0)%	(34.0)%
State tax, net of federal benefit	(5.0)	(5.0)	(5.0)
Other	0.1	0.1	0.1
Share-based compensation	1.9	2.4	2.3
Valuation allowance	37.0	36.5	36.6
Research & development credit saleback	(.5)	(3.4)	(0.2)
	(.5)%	(3.4)%	(0.2)%

Future tax benefits (deferred tax assets) related to temporary differences are as follows:

	As of December 31,	
	2008	2007
<b>Gross deferred tax assets:</b>		
Net operating losses	\$ 64,668	\$ 54,076
Tax credits (Federal and State)	6,692	5,564
Deferred revenue	1,033	1,067
Other	2,413	1,337
	\$ 74,806	\$ 62,044
Less valuation allowance	(74,806)	(62,044)
Net deferred tax asset	\$	\$

At December 31, 2008 and 2007, the Company had gross deferred income tax assets of approximately \$74,806 and \$62,044, respectively, which result primarily from net operating loss and tax credit carryforwards. Statement of Financial Standards No. 109 *Accounting for Income Taxes* (SFAS 109) requires that a valuation allowance be established when it is more likely than not that all or a portion of deferred tax assets will not be realized. A review of all positive and negative evidence is required when measuring the need for a valuation allowance. The Company's cumulative loss from inception represents sufficient negative evidence to require a valuation allowance. The Company concluded that it is appropriate to maintain a full valuation allowance for its net deferred tax assets. Additionally, the Company intends to maintain a valuation allowance until sufficient positive evidence exists to support its reversal.

At December 31, 2008 and 2007, the Company had available the following net operating loss and credit carryforwards:

	As of December 31,	
	2008	2007
Federal net operating loss carryforwards	\$ 155,423	\$ 130,186
State net operating loss carryforwards	157,622	131,774
Federal research and development carryforwards	4,347	3,672
State research and development carryforwards	2,345	1,892

The Company's federal net operating loss carryforwards expire commencing in fiscal 2018 through 2028 and state net operating loss carryforwards which expire commencing in fiscal 2020 through 2028.

Utilization of the net operating losses and research and development credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986, or Section 382, due to



F-27

## **Table of Contents**

changes in ownership of the Company that have occurred previously or that could occur in the future. These ownership changes may limit the amount of net operating losses and research and development credit carryforwards that can be utilized annually to offset future taxable income and tax. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. Since the Company's formation, the Company has raised capital through the issuance of capital stock on several occasions which, combined with the purchasing shareholders subsequent disposition of those shares, may have resulted in a change of control, as defined by Section 382. Due to the significant complexity and cost associated with a change in control study, and because there could be additional changes in control in the future, the Company has not assessed whether there has been one or more changes in control since the Company's formation. If the Company has experienced a change of control at any time since Company formation, utilization of its net operating losses or research and development credit carryforwards would be subject to an annual limitation under Section 382. Any limitation may result in expiration of a portion of the net operating loss or research and development credit carryforwards before utilization which would reduce the Company's gross deferred tax assets.

The State of Connecticut provides companies with the opportunity to exchange certain research and development credit carryforwards for cash in exchange for foregoing the carryforward of the research and development credit. The program provides for such exchange of the research and development credits at a rate of 65% of the annual research and development credit, as defined. During the years ended December 31, 2008, 2007 and 2006, the Company had recorded a benefit of approximately \$132, \$960 and \$49, respectively, for the estimated proceeds from this exchange.

The Company believes that it is entitled to a larger cash refund for tax credit carryovers from the State of Connecticut for certain prior years. The Company filed complaints with the Superior Court for the tax year 2003 seeking cash refunds of certain unused research and development tax credits that the Company alleges were wrongfully disallowed by the State of Connecticut. The Company and the State have filed cross-motions for partial judgment. Additionally, the Company has filed appeals for this matter to keep the statute of limitations open for subsequent periods. The Company has not recorded a receivable related to this pending judgment.

The federal and state tax authorities could challenge tax positions taken by the Company for the periods for which there are open tax years. Years subject to audit are years in which unused net operating losses were generated that remain open by the statute of limitations. The Company is open to challenge for the periods of 1998 through 2008 in federal and the State of Connecticut jurisdictions.

As a result of implementation of FIN 48, the Company recognized a decrease of \$180 in its liability for uncertain tax positions, which was accounted for as a decrease to the January 1, 2007 accumulated deficit. The Company did not have any unrecognized tax benefits as of the date of adoption or December 31, 2008.

## **16. Related Party**

### *Gilead*

In November 2004, the Company entered into the Gilead Arrangement with Gilead to jointly develop and commercialize compounds for use in treating hepatitis C infection which inhibit viral replication through a specified novel mechanism of action. Commercialization efforts will commence only if such compounds are found to be commercially viable and all appropriate regulatory approvals have been obtained. In addition to being a collaboration partner, Gilead Inc. is also a shareholder of Achillion. As of December 31, 2008, Gilead holds 1,116 shares, representing 4.2% of total shares outstanding.

### *Nicholas Simon*

On August 19, 2008, the Board of Directors of the Company elected Nicholas Simon as a Class I member of the Board of Directors to serve until the Company's 2010 Annual Meeting of Stockholders or until his successor

**Table of Contents**

is duly elected and qualified. Mr. Simon is a managing director of Clarus Ventures LLC ( "Clarus" ). In connection with Clarus' agreement to invest in the Company, the Company agreed that Mr. Simon would be appointed to the Company's Board of Directors upon a vacancy, which occurred on August 19, 2008. On August 12, 2008, Clarus purchased units consisting of 5,164 shares of common stock and common stock warrants to purchase 1,291 shares of common stock for an aggregate purchase price of \$15,000. In addition, pursuant to warrants issued to Clarus, Clarus may have the right to purchase an additional 1,773 units between February 2009 and August 2009. Clarus is currently the beneficial owner of approximately 19.6% of the Company's total issued and outstanding shares, excluding the shares that may be acquired upon exercise of the warrants held by Clarus.

**17. Unaudited Quarterly Results**

The following tables summarize unaudited quarterly financial data for the years ended December 31, 2008 and 2007. This data has been derived from unaudited financial statements that, in the Company's opinion, include all adjustments necessary for a fair presentation of such information. The operating results for any quarter are not necessarily indicative of results for any future period.

	<b>2008 Quarters</b>			
	<b>First</b>	<b>Second</b>	<b>Third</b>	<b>Fourth</b>
Total operating revenue	\$ 627	\$ 398	\$ 25	\$ (1,284)
Total operating expenses	6,687	7,091	6,630	7,288
Net loss	(5,998)	(6,789)	(6,665)	(8,699)
Net loss per share - basic and diluted	\$ (.38)	\$ (.43)	\$ (.31)	\$ (.33)
Weighted average number of shares outstanding - basic and diluted	15,638	15,646	21,485	26,386

	<b>2007 Quarters</b>			
	<b>First</b>	<b>Second</b>	<b>Third</b>	<b>Fourth</b>
Total operating revenue	\$ 1,550	\$ 1,195	\$ 900	\$ 393
Total operating expenses	9,915	9,442	7,461	7,778
Net loss	(7,670)	(7,653)	(5,894)	(6,885)
Net loss per share - basic and diluted	\$ (.49)	\$ (.49)	\$ (.38)	\$ (.44)
Weighted average number of shares outstanding - basic and diluted	15,540	15,556	15,607	15,628

**Table of Contents**

**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Exhibit</b>
3.1(2)	Amended and Restated Certificate of Incorporation of the Registrant, as amended.
3.2(2)	Amended and Restated Bylaws.
4.1(3)	Specimen Certificate evidencing shares of common stock.
10.1(5)	License and Research Agreement, dated April 4, 2008, by and between Registrant and FOB Synthesis, Inc.
10.2(3)	Research Collaboration and License Agreement, dated November 24, 2004, by and between the Registrant and Gilead, Inc.
10.3(2)	Amendment Number 1 to Research Collaboration and License Agreement, dated November 24, 2004 by and between the Registrant and Gilead, Inc., dated March 26, 2007.
10.4(3)	License Agreement, dated February 3, 2000, by and between Vion Pharmaceuticals, Inc. and the Registrant, as amended on January 28, 2002.
10.5(3)	Letter Agreement, dated September 22, 2006, by and between the Registrant and Yale University.
10.6(3)	License Agreement, dated July 19, 2002 by and between the Registrant and Emory University.
10.7*(3)	Employment Agreement between the Registrant and Michael Kishbauch, dated as of July 19, 2004.
10.8*(3)	Employment Agreement between the Registrant and Milind Desphande, dated as of September 10, 2003, as amended January 1, 2006.
10.9*(3)	Employment Agreement between the Registrant and Elizabeth Olek, dated as of November 6, 2007.
10.10*(2)	Employment Agreement between the Registrant and Mary Kay Fenton, dated as of September 10, 2003, as amended January 1, 2006.
10.11*(3)	Employment Agreement between the Registrant and Gautam Shah, dated as of May 26, 2004, as amended January 1, 2006.
10.12(3)	Second Amended and Restated Investor Rights Agreement, dated as of November 17, 2005, by and among the Registrant and the Holders named therein.
10.13(4)	Third Amended and Restated Investor Rights Agreement, dated as of August 11, 2008, by and among the Registrant and the Holders named therein.
10.14(3)	Third Amended and Restated Stockholders Agreement, dated as of November 17, 2005, by and among the Registrant and the Stockholders named therein.
10.15(4)	Securities Purchase Agreement, dated as of August 5, 2008, by and among the Registrant and the Purchasers named therein.
10.16(4)	Form of Common Warrant pursuant to the Securities Purchase Agreement.
10.17(4)	Form of Unit Warrant pursuant to the Securities Purchase Agreement.
10.18(4)	Registration Rights Agreement, dated as of August 11, 2008, by and among the Registrant and the Purchasers named therein.
10.19(1)	Master Security Agreement and Promissory Notes by and between the Registrant and GE Capital Corporation and Oxford Finance Corporation, dated as of February 26, 2008.
10.20(1)	Form of Common Stock Warrant under Loan and Security Agreement of GE Capital Corporation and Oxford Finance Corporation

## **Table of Contents**

<b>Exhibit No.</b>	<b>Exhibit</b>
10.21(3)	Lease Agreement by and between the Registrant and WE George Street LLC for Suite 202, dated as of March 6, 2002.
10.22(3)	Lease Agreement by and between the Registrant and WE George Street LLC, dated as of May, 2000.
10.23(3)	Lease Agreements and subsequent Assignment and Assumption of Lease Agreements by and between the Registrant, Yale University and WE George Street LLC for Suites 802, 803, 804.
10.24*(3)	1998 Stock Option Plan, as amended, dated March 30, 2001.
10.25*(3)	2006 Stock Incentive Plan as amended.
10.26*(3)	Form of Incentive Stock Option Agreement under the 1998 Stock Option Plan.
10.27*(3)	Form of Incentive Stock Option Agreement for Non-Executives under the 1998 Stock Option Plan.
10.28*(3)	Form of Nonstatutory Stock Option Agreement under the 1998 Stock Option Plan.
10.29*(3)	Form of Incentive Stock Option Agreement under the 2006 Stock Incentive Plan.
10.30*(3)	Form of Nonstatutory Stock Option Agreement under the 2006 Stock Incentive Plan.
10.31*(3)	2006 Employee Stock Purchase Plan as amended.
10.32(3)	Form of Common Stock Warrant.
10.33(3)	Form of Series C-2 Convertible Preferred Stock Warrant.
10.34(1)	Promissory Notes and Master Security Agreement by and between the Registrant and Webster  Bank, dated as of May 15, 2003, as amended by the First, Second, Third, Fourth and Fifth Amendments to Master Security Agreement, dated May 15, 2003, October 29, 2004, March 24, 2005, August 7, 2006 and December 7, 2007, respectively.
10.35(3)	Loan Agreement by and between the Registrant and Connecticut Innovations, Incorporated, dated March 30, 2001.
10.36(3)	Common Stock Warrants issued to Connecticut Innovations, Inc. on March 29, 2001 and November 7, 2000.
23.1#	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
23.2#	Consent of Fletcher Spaght, Inc.
31.1#	Certification of Chief Executive Officer pursuant to Rule 13a- 14(a)/Rule 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)/Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1#	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 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. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

\* Management contracts or compensatory plans or arrangement  
Indicates confidential treatment requested as to certain portions, which portions were omitted and filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Request.

# Filed herewith

- (1) Incorporated herein by reference to our annual report on Form 10-K filed on March 5, 2008.
- (2) Incorporated herein by reference to our annual report on Form 10-K filed on March 29, 2007.
- (3) Incorporated herein by reference to our Registration Statement on Form S-1 filed on March 31, 2006, as amended (File No. 333-132921).
- (4) Incorporated herein by reference to our Registration Statement on Form S-3 filed on October 6, 2008 (File No. 333-153870).
- (5) Incorporated herein by reference to our Quarterly Report on Form 10-Q filed on May 7, 2007.