ACHILLION PHARMACEUTICALS INC
Form 10-K
February 20, 2013
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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, 2012

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)

Delaware	**52-2113479**
(State or other jurisdiction of incorporation or organization)	**(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	**Name of Exchange on Which Registered**
Common Stock, $0.001 par value per share	**NASDAQ Global Select 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 x

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 x

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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x 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. x

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

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if smaller reporting company)	Smaller reporting company ¨

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

The aggregate market value of the voting stock held by non-affiliates of the Registrant on June 30, 2012 was approximately $332,145,873 based on the closing price of such stock as reported by the NASDAQ Global Select Market on June 29, 2012.

As of February 11, 2013, the registrant had 79,653,417 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) 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, 2012, a definitive proxy statement for our annual meeting of stockholders to be held on May 28, 2013. The information required by Item 5 of Part II relating to our equity compensation plans has been omitted and will be incorporated from our annual report. The information required by Items 10, 11, 12, 13 and 14 of Part III, which will appear in our definitive proxy statement, and the information required by Item 5 of Part II relating to our equity compensation plans, which will appear in our annual report, are incorporated by reference into this report.

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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. There are a number of important risks and uncertainties that could cause our actual results to differ materially from those indicated by forward-looking statements. These risks and uncertainties include those inherent in pharmaceutical research and development, such as adverse results in our drug discovery and clinical development activities, decisions made by the U.S. Food and Drug Administration and other regulatory authorities with respect to the development and commercialization of our drug candidates, our ability to obtain, maintain and enforce intellectual property rights for our drug candidates, the ability of our competitors to clinically advance their competing drug candidates, our ability to obtain any necessary financing to conduct our planned activities, and other risk factors. Please refer to the section entitled Risk Factors in Part I Item 1A of this report for a description of these risks and uncertainties. Unless required by law, 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 that was established to discover, develop and commercialize 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 viral infection, or HCV. Recently, we have been developing our three lead clinical-stage drug candidates for the treatment of HCV, including sovaprevir and ACH-3102, each currently in phase II clinical development, and ACH-2684, currently in phase I clinical development. In the near term, we intend to focus our efforts on (i) initiating clinical development of a combination regimen including sovaprevir and ACH-3102, with and without ribavirin, (ii) continuing our study of ACH-3102 plus ribavirin and (iii) exploring potential development of our drug candidates with other drug developers under cooperative or other study arrangements.

In addition, we have established a pipeline of certain antibacterial product candidates for which we are currently seeking appropriate collaborative partners, but to which we are not devoting significant resources at this time. These product candidates include ACH-702 for the treatment of dermatologic and ophthalmic infections, and ACH-2881 for the treatment of serious resistant bacterial infections, including methicillin-resistant staphylococcus aureus. We have also developed and out licensed certain development and commercialization rights to elvucitabine, for the treatment of both Hepatitis B, or HBV, and human immunodeficiency virus, or HIV.

We have established our current HCV drug candidate pipeline entirely through our internal discovery capabilities. Through these efforts we have identified and are developing the following portfolio of drug candidates which we intend to study in combination with each other and/or potentially in combination with compounds owned by others:

Sovaprevir, a NS3 Protease Inhibitor. We have most recently completed a phase IIa clinical trial conducted in both the United States and Europe to assess the compound s safety, tolerability, pharmacokinetic properties and efficacy when dosed with pegylated interferon and ribavirin (P/R) in treatment-naïve, genotype 1 HCV-infected subjects. In this trial, sovaprevir was demonstrated to achieve a complete early virologic response, or cEVR, after twelve weeks of dosing, in 94% to 100% of patients. Mean viral load, a measurement of the amount of virus in the blood stream, was reduced in HCV-infected patients by 4.56 log10 to 5.08 log10, or reduction of over 99.9% of the virus. Sovaprevir continued to be safe and well-tolerated with no significant drug-related adverse events. Liver enzyme elevations were observed with higher doses of sovaprevir, were transient, and returned to baseline while on treatment. In addition, sustained virologic response twelve weeks (SVR12) after the completion of therapy was achieved in 77% to 85% of patients after completion of 24 weeks of therapy (12 weeks of sovaprevir plus P/R, followed by 12 weeks of P/R). Mutations commonly associated with

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protease inhibitor therapy including mutations at R155, A156 and D168 were not observed with sovaprevir treatment. Sovaprevir has been granted Fast Track status by the United States Food and Drug Administration, or FDA. Our next step in developing sovaprevir is to initiate clinical development of a combination regimen including sovaprevir and ACH-3102, both with and without ribavirin. During the second quarter of 2013, we intend to begin dosing in a randomized, double-blind phase II clinical trial that will evaluate a 12 week treatment consisting of sovaprevir and our NS5A inhibitor, ACH-3102, with ribavirin for the treatment of genotype 1 HCV.

ACH-3102, a NS5A Inhibitor. We recently completed a proof-of-concept clinical trial of our second-generation, pan-genotypic NS5A inhibitor, ACH-3102, and it is currently being studied in a phase II clinical trial in combination with ribavirin. In phase Ia safety and pharmacokinetic studies, more than 70 healthy volunteers received either a single ascending dose of ACH-3102, or 14 days of once-daily ACH-3102. Data from both the single and multiple ascending dose groups demonstrated that ACH-3102 was well tolerated with no serious adverse events. In phase Ib, ACH-3102 demonstrated proof-of-concept efficacy results after a single dose of ACH-3102 in patients with genotype 1a HCV. In all, 12 patients were treated with a single dose of either 50 mg, 150 mg, or 300 mg of ACH-3102, with a mean maximum decline in HCV RNA of 3.78, 3.52, and 3.93 log10 achieved, respectively. Interim results from an open-label phase IIa pilot trial, initially enrolling 8 patients, evaluating 12-weeks of once-daily ACH-3102 in combination with ribavirin for the treatment of HCV genotype 1b revealed that 75% of patients (6 of 8) who had completed 4 weeks of therapy achieved rapid virologic response, or RVR, meaning undetectable levels of virus at 4 weeks of therapy, and 100% of patients (3 of 3) completing 12 weeks of therapy achieved undetectable levels of virus at end of treatment, or ETR. Further, 100% of patients (3 of 3) receiving 12 weeks of therapy demonstrated undetectable levels of HCV 4 weeks after cessation of therapy, or SVR4. This study remains on-going and we expect that additional data will be available in the second quarter of 2013. ACH-3102 has been granted Fast Track status by the FDA. During the second quarter of 2013, we also expect to expand our trial of ACH-3102 and ribavirin to include an additional eight genotype 1b patients with any genotype subtypes and to report RVR data for this group in the third quarter of 2013. ACH-2928, an NS5A inhibitor we were previously testing, is no longer being developed.

ACH-2684, a NS3 Protease Inhibitor. ACH-2684 has most recently completed phase Ib proof-of-concept clinical studies, including three segments: once-daily dosing in genotype 1, twice-daily dosing in patients with genotype 3 and once-daily dosing in patients with cirrhosis. Once-daily doses of 400mg of ACH-2684 reduced viral load by a mean maximum 3.73 log10 in patients with HCV genotype 1. In addition, twice daily doses of 400mg of ACH-2684 reduced viral load by a maximal 2.03 log10 in patients with HCV genotype 3. Lastly, once-daily doses of 400mg administered for three days to HCV patients with cirrhosis achieved a mean maximum 3.67 log10 reduction in HCV viral load, similar to the antiviral activity achieved in non-cirrhotic genotype 1 HCV patients receiving the same dose of ACH-2684. ACH-2684 demonstrated good safety and tolerability in these phase Ib clinical studies, as well as in phase Ia studies in healthy volunteers. Our current strategic plan does not include the combination development of ACH-2684 with our other drug candidates in the near-term, but we remain interested in combining ACH-2684 with our other drug candidates in the future, or with other compounds under cooperative study arrangements.

We were incorporated on August 17, 1998 in Delaware. Since our 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 $39.0 million, $35.4 million and $20.5 million in research and development costs for the years ended December 31, 2012, 2011, and 2010, respectively.

We intend to continue to focus on the discovery and development of new drug candidates through our extensive expertise in virology, microbiology and synthetic chemistry. Although significant additional funding and research and development will be required to support these efforts, we believe our drug discovery capabilities will allow us to further expand our product candidate portfolio, providing us with strong growth potential and, over time, reducing our reliance on the success of any single drug candidate.

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Our Strategy

Our objective is to become a leading infectious disease-focused biopharmaceutical company. In order to advance toward our objective, we intend to advance our current pipeline of HCV drug candidates in three ways:

Base Case Combination Development Plan: Sovaprevir + ACH-3102 +/- ribavirin. In the second quarter of 2013, we plan to begin dosing in a randomized, double-blind phase II trial that will evaluate combination regimen including sovaprevir and ACH-3102, with ribavirin, over 12 weeks of therapy in treatment-naïve, HCV genotype 1 patients. We plan to make an initial assessment of that combination and announce RVR results in the third quarter of 2013 and SVR results when complete. We plan to conduct a number of pilot clinical studies to assess which populations of HCV patients are most appropriately treated with this combination, both with and without ribavirin. We also intend to initiate planning for phase III clinical trials for this combination therapy, which we anticipate will begin during 2014.

Additional Combination Development Plan: ACH-3102 + ribavirin. We plan to continue to evaluate a regimen of ACH-3102 with ribavirin over 12 weeks of therapy for treatment of HCV genotype 1b. We plan to complete our further assessment of that combination and announce RVR and SVR4 results for a second dosing cohort during the third and fourth quarters of 2013, respectively. We plan to conduct a number of pilot clinical studies to assess which populations of HCV patients are most appropriately treated with this combination. We also intend to initiate planning for phase III clinical trials for this combination, which we anticipate will begin during 2014.

Value-added Combination Development Scenarios. We may establish strategic cooperative study arrangements, or CSAs, with other drug developers where we believe that in doing so we can accelerate the development or maximize the value of our drug candidates by (i) accessing additional drug candidates that may be combinable with our drug candidates for the future treatment of HCV infection, or (ii) utilizing the financial, clinical development, manufacturing and/or commercialization strengths of leading biotechnology, pharmaceutical companies or regional institutions. CSAs typically involve the co-management of cooperative clinical studies utilizing drug candidates from multiple parties in order to determine the efficacy, safety and pharmacokinetics of the combination regimens.

In addition, we intend to continue to leverage our expertise in synthetic chemistry, virology and microbiology to quickly and efficiently discover and develop additional anti-infective compounds. Our research team has discovered multiple clinical candidates in multiple infectious disease programs. For example, in our HCV protease program, we discovered both sovaprevir and ACH-2684. In our HCV NS5A program, we discovered ACH-2928 and ACH-3102. And in our antibacterial program, we discovered ACH-702 and ACH-2881.

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 HCV 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.

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

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schedules and inconvenient methods of administration, such as by 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.

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 deoxyribonucleic acid, or DNA, or ribonucleic acid, 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, over time, may 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. Reduction in viral replication as the result of anti-viral therapy slows disease progression and generally results in improved prognosis. The effect of therapy with antiviral drugs is typically measured by the reduction in circulation of the virus in the blood stream of infected patients. In the case of HCV, the amount of viral particles in circulation is measured in log scale, wherein a reduction of over 2 $\log_{10}$ is generally equivalent to reduction of 99% of the viral RNA in a given blood sample.

The development of resistance to antiviral drugs is a major challenge for the treatment of life-threatening viral infections such as HCV. 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, or DAA, 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

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antiviral 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.

Our Drug Candidates

The following table summarizes key information regarding our lead drug candidates:

Drug Candidate/ Indication	Mechanism	Stage of Development	Current Status	Current Marketing Rights
Core Assets:				
Sovaprevir *Chronic Hepatitis C Infection*	HCV NS3 protease inhibitor	Phase II	Phase IIa clinical trial completed; Dosing of combination regimen with ACH-3102 planned for second quarter 2013	Achillion
ACH-3102 *Chronic Hepatitis C Infection*	HCV NS5A inhibitor	Phase II	Phase IIa clinical trial on-going in combination with ribavirin; Dosing of combination regimen with sovaprevir planned for second quarter 2013	Achillion
ACH-2684 *Chronic Hepatitis C Infection*	HCV NS3 protease inhibitor	Phase I	Phase Ia and 1b clinical trials completed	Achillion

Overview of HCV Market

The hepatitis-C virus is a common cause of viral hepatitis, which leads to inflammation of the liver. HCV infection is contracted by transmission through the blood of an infected person. Hepatitis due to HCV can result in an acute process in which a person is affected for only several months and then the virus is cleared from the body. However, the Department of Health and Human Services Centers for Disease Control, or CDC, estimates that 75% to 85% of newly infected 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.

Until 2011, the standard of care for patients with chronic HCV infection consisted of treatment with a combination of long-acting, pegylated forms of interferon alpha, a modified version of a protein that occurs naturally in the human body and boosts the immune system s ability to fight viral infection, administered through weekly injections, coupled with daily, oral doses of ribavirin, together referred to as P/R. 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 only successful in approximately 40-50% of patients receiving a full course of treatment.

Treatment with P/R is further complicated by significant adverse side effects, including flu-like symptoms, anemia, depression, fatigue, suicidal tendencies and abnormal fetal development. Since HCV, 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, many patients require dosage adjustments, and many may discontinue therapy altogether. In addition, current treatments are administered by injection, which is inconvenient, painful, and particularly problematic for patients who are afraid of needles.

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

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treat HCV focuses on the inhibition of viral proteins essential to the completion of the HCV replication cycle. Many drug developers have focused on three of the HCV proteins: protease or NS3, polymerase or NS5B, and more recently, another protein, NS5A. The goal of HCV drug development is to discover and develop molecules that have a high affinity for binding to these enzymes thereby inhibiting enzymatic activity and, in turn, inhibiting viral replication. Each of these inhibitor types have demonstrated in clinical trials a 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.

In 2011, two DAA protease inhibitors were introduced to the market. These compounds, Victrelis (boceprevir) and Incivek (telaprevir), were approved only for the treatment of patients with HCV genotype 1, and are dosed in combination with P/R. This treatment regimen for HCV offers improved SVR rates for those genotype 1 patients who can tolerate the triple combination therapy. However, a majority of individuals with HCV are unable to be treated with this regimen due to contraindications to one or more of the drugs used, such as advanced liver disease or psychiatric conditions. Further, the occurrence of side effects, both from P/R and the newly marketed DAAs, some of which can be serious and dose-limiting, combined with the inconvenient treatment regimen can result in many patients being non-compliant with their therapy or not completing therapy at all.

Despite the challenges of suboptimal efficacy, poor tolerability by some patients, and inability to combine with certain concomitant medications, sales for these existing DAAs totaled $1.1 billion and $1.2 billion in the United States and worldwide, respectively, in 2011 and $1.5 billion and $2.3 billion in the United States and worldwide, respectively, in 2012. It is anticipated that with the introduction of all-oral combination regimens in 2014 and beyond, the HCV DAA worldwide market will grow to over $10 billion by 2020. The United States, European Union and Japan are anticipated to comprise roughly $3.5 billion, $2.5 billion and $1.4 billion, respectively, of this global market.

The less than optimal antiviral efficacy, potential for dose-limiting side effects, contraindications and inconvenient dosing regimen of the currently available P/R/DAA combination therapy illustrate the unmet medical need of the HCV patient population. Therefore, important goals for new HCV therapies are to:

- improve efficacy against the genotype 1 virus, particularly the more-challenging genotype 1a, and to develop all oral treatments for patients infected with HCV genotypes 2, 3, 4, 5 and 6;
- offer interferon-free therapies;
- offer a treatment response in patients who have failed a P/R-containing regimen;
- offer a treatment response in patients who have failed a telaprevir or boceprevir-containing regimen;
- offer therapies to which patients do not develop drug resistance;
- reduce the magnitude of treatment-related adverse side effects; and
- offer a more convenient, orally available, treatment option.

We believe our NS3 protease inhibitors can be used in combination with our NS5A inhibitor for the treatment of HCV patients, and that this combination therapy has the potential to address many of these treatment goals.

Protease Inhibitors for Chronic Hepatitis C Infection

Our HCV protease inhibitors, sovaprevir and ACH-2684, were discovered by our internal research team. The compounds have demonstrated strong *in vitro* potency and good safety profiles in animals. In recently announced clinical trials completed to date, the compounds have

demonstrated efficacy and safety in human subjects infected with HCV.

HCV Protease Inhibitor Sovaprevir

We believe combination therapy for the treatment of chronic HCV infection will benefit from drugs that inhibit HCV replication through complementary mechanisms of action. Therefore, we have leveraged our experience in HCV drug discovery to identify NS3 protease inhibitors, and NS5 inhibitors that are distinct in their efficacy, resistance profile and/or pharmacokinetic profile. The first of our NS3 protease inhibitors is sovaprevir.

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We believe sovaprevir has the following benefits:

Potency and Specificity. Data obtained in the standard laboratory assays used to determine anti-HCV activity against the genotype 1 virus, the most common HCV virus subtype found in the United States, demonstrated that sovaprevir has several times greater potency *in vitro* than either the Victrelis (boceprevir) or Incivek (telaprevir), HCV protease inhibitors recently approved. In addition, in preclinical studies, sovaprevir demonstrated no cross resistance with other classes of inhibitors in development, meaning that sovaprevir could ultimately be dosed in combination with those other classes of drugs. In human clinical studies, sovaprevir was demonstrated to reduce viral load by up to 5.12 $\log_{10}$ and achieve 100% cEVR in patients dosed over 12 weeks in combination with P/R.

Safety and Tolerability. In laboratory and animal studies, sovaprevir 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. In human clinical trials, sovaprevir was demonstrated to be safe and well-tolerated over multiple dosing periods up to 12 weeks duration.

Durability. A clinical virology analysis revealed that treatment with sovaprevir does not give rise to certain viral mutations commonly seen with treatment with other protease inhibitors and patients did not demonstrate rebound of viral load or breakthrough during treatment. For this reason, we believe sovaprevir can provide a more durable treatment option for HCV patients.

Pharmacokinetics. In laboratory and animal studies, sovaprevir is rapidly and extensively partitioned to the liver, the organ of infection in HCV. After oral dosing, the liver concentration of sovaprevir at the twenty-four hour time point exceeds the EC_{50} observed in the replicon assay, the standard analysis used to determine the amount of drug necessary to inhibit a viral pathogen. Based upon these data, we designed clinical trials to test once daily oral doses of sovaprevir. Clinical studies subsequently confirm that sovaprevir can be successfully dosed once-daily.

Potential for Combination Treatment. Because sovaprevir is a member of a known and extensively studied drug class, we believe sovaprevir is well positioned for evaluation as a treatment for HCV in combination with the current standard of care and/or in combination with other direct acting antivirals. Further, sovaprevir demonstrates *in vitro* synergy with our NS5A compounds.

Clinical Development History

Phase Ia/Ib Clinical Trials. In June 2009, we initiated dosing in a randomized, double-blind, placebo-controlled phase Ia/Ib clinical trial to investigate the safety, tolerability, pharmacokinetic profile and antiviral activity of sovaprevir after single and multiple ascending oral doses in healthy volunteers and oral repeat doses for 5 days in subjects with hepatitis C infection. The trial was conducted in Europe and dosed 83 subjects, including both healthy volunteers and HCV-infected patients.

In September 2009, we announced positive results from the phase Ia, healthy subject segment of the study. Subjects in the phase Ia single ascending dose (SAD) segment of the study received single doses of sovaprevir ranging from 50 mg to 2000 mg. Subjects in the phase Ia multiple ascending dose (MAD) segment of the study received 5 days of sovaprevir up to a maximal dose of 2000 mg per day. Preliminary data from the SAD and MAD trial segments demonstrated sovaprevir was well tolerated at all doses and there were no serious adverse events, no clinically significant changes in vital signs, electrocardiograms (ECGs), or laboratory evaluations. All reported adverse events were classified as mild or moderate, were transient and showed no apparent dose relationship.

In December 2009, we announced proof-of-concept data from the phase Ib segment of this study. Subjects in the first dosing cohort of HCV-infected patients received doses of 600 mg twice daily (n=9, randomized to 6 active drug, 3 placebo). Preliminary results showed that a mean reduction in viral load of 3.94 $\log_{10}$ was achieved in the treatment group, as compared to a mean reduction of 0.22 $\log_{10}$ in the placebo group. All subjects

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in the treatment group had viral load decline between 3.0 and 4.5 log_{10}, and two subjects reached undetectable levels of HCV RNA. Safety results from this dosing group were similar to those observed in the phase Ia segment of the trial. There were no serious adverse events, no clinically significant changes in vital signs, ECGs, or laboratory evaluations. All reported adverse events were classified as mild or moderate, were transient and showed no apparent dose relationship. Furthermore, all patients had viral loads that remained suppressed for at least 7 days after dosing was completed, maintaining a mean reduction of more than 2.0 log_{10} from baseline through day 12, the last day of viral load measurement in the study.

In January 2010, we announced additional results from the phase Ib clinical study of sovaprevir. HCV-infected subjects in this second dosing cohort (n=9, randomized to 6 active drug, 3 placebo) received doses of 500 mg twice daily of sovaprevir. Preliminary results showed that a mean reduction in viral load of 4.25 log_{10} was achieved in the treatment group, as compared to a mean reduction of 0.29 log_{10} in the placebo group. Safety results from this dosing group were similar to those observed in both the phase Ia segment of the trial and in the first dosing cohort of HCV-infected subjects. Sustained viral suppression was also similar to the first dosing cohort, with patients maintaining a mean reduction of more than 3.0 log_{10} from baseline through day 12, 7 days after dosing was completed, and the last day of viral load measurement in the study. We also completed four additional dose cohorts under the protocol, examining the drug s efficacy at lower doses, without food, and once-daily. We noted similar safety and efficacy results as were found in other cohorts.

Phase IIa Clinical Trials. In September 2010, we initiated dosing in a phase IIa clinical study of sovaprevir in combination with P/R. The trial was comprised of two segments, the first testing three once-daily doses of sovaprevir over 28-days (200 mg, 400 mg or 800 mg). Subjects were randomized and stratified by IL28B genotype, including CC, which indicates a normal or expected level of response to interferon based therapies, CT and TT, which are markers of a patient s diminished response to interferon. Results from the first segment of the trial were announced in March 2011 and demonstrated that sovaprevir reduced mean maximal viral load in patients dosed over 28 days from 4.63 log_{10} to 4.96 log_{10}. Safety measures were the same as those noted in previous clinical trials. In December 2011, we completed a clinical virology analysis of patient samples obtained during this trial segment, examining the resistance mutation profile following treatment. Results indicated that following 28 days of treatment with sovaprevir the presence of highly resistant variants were not detected, particularly those at positions 155, 156 and 168, the mutations commonly seen with treatment with other protease inhibitors.

In June 2011, we initiated a second segment of this ongoing phase IIa trial testing three doses of once-daily sovaprevir (200 mg, 400 mg or 800 mg) in combination with P/R over 12 weeks of therapy in patients with treatment-naïve HCV genotype 1. Subjects were randomized and stratified by IL28B genotype.

In January 2012, we announced that 100% of patients who reached week 12, across all dose groups, reached an undetectable viral load. Further, the compound continued to be safe and well-tolerated with no serious adverse events attributed to the drug.

In April 2012, we announced that sovaprevir was demonstrated to achieve a complete early virologic response, or cEVR, in 94% to 100% of patients. Mean viral load, a measurement of the amount of virus in the blood stream, was reduced in HCV-infected patients by 4.56 log_{10} to 5.08 log_{10}, or reduction of over 99.9% of the virus. Sovaprevir continued to be safe and well-tolerated with no significant drug-related adverse events. Liver enzyme elevations were transient with all patients returning to baseline values while on treatment, and attributable to non-drug-related factors.

In September 2012, we reported sustained virologic response 12 weeks (SVR12) after the completion of 24 weeks of therapy consisting of 12 weeks of sovaprevir and P/R followed by an additional 12 weeks of P/R. In all, 39 patients were assigned to receive 24 weeks of therapy with the remaining 18 patients assigned to receive an additional 36 weeks of P/R. The SVR12 rates were 80%, 77%, and 85% in the 200 mg, 400 mg, and 800 mg dose groups, respectively. Additional SVR data will be presented at a future medical meeting when all patients complete their 4 and 12 week post-treatment visits. Mutations commonly associated with protease inhibitor therapy including mutations at R155, A156 and D168 were not observed with sovaprevir treatment.

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In July 2011, we also initiated a separate pilot study to assess the use of sovaprevir in the treatment of patients with genotype 3 HCV infection. A total of seven patients infected with HCV genotype 3 were enrolled and treated with monotherapy consisting of 400 mg sovaprevir twice daily for 4.5 days. In January 2012, we announced the results of this exploratory study. Sovaprevir was safe and well-tolerated and the maximum HCV genotype 3 RNA viral load reduction achieved was 3.68 $\log_{10}$ among the six out of the seven patients that achieved an antiviral response.

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.

HCV Protease Inhibitor ACH-2684

In another proprietary program against HCV infection, we are developing ACH-2684, also a NS3 protease inhibitor. Our current strategic plan does not include the combination development of ACH-2684 with our other drug candidates in the near-term, but we remain interested in combining ACH-2684 with our other drug candidates in the future, or with other compounds under cooperative study arrangements.

In preclinical studies, ACH-2684 demonstrates excellent potency in the picomolar range, as well as good pharmacokinetic and safety profiles. The compound s profile demonstrates that it very effectively suppresses a broad range of natural variants of the hepatitis C virus, and may be effective in prevention and treatment of emerging resistant variants. Importantly, ACH-2684 retains potent activity against all genotypes in the replicon assay.

The very high potency of ACH-2684 was achieved by designing the compound to optimize the way in which it binds with NS3 protease. We have demonstrated *in vitro* that ACH-2684 can be used in combination with other HCV inhibitors, and that it is synergistic with NS5B nucleoside polymerase inhibitors and NS5A inhibitors. We believe ACH-2684 can have the following advantages:

Potency. Data obtained in the standard laboratory assays used to determine anti-HCV activity against the genotype 1 virus demonstrate that ACH-2684 has potency at inhibitory concentrations less than 100 picomolar and is 3000-fold more potent than telaprevir.

Pan-genotypic potency. Our *in vitro* testing indicates that ACH-2684 is potent against all genotypes of HCV virus. Our clinical testing to date has indicated that ACH-2684 is effective against genotype 1 HCV and, to a lesser degree, genotype 3 HCV. Additional dose-ranging studies are on-going to further explore and optimize the ability of ACH-2684 to address all genotypes.

Pharmacokinetic profile. The means by which ACH-2684 is taken up into the liver by active transport mechanisms may provide a significant advantage in HCV patients with decompensated liver function such as those with cirrhosis.

Resistance profile. The *in vitro* potency and virology profile of ACH-2684 demonstrates that it effectively suppresses a broad range of natural variants of the hepatitis C virus, so it may be effective in prevention and treatment of emerging resistant variants of the HCV virus including mutations R155, A156 and D168.

Clinical Development History

In May 2011, we initiated a phase I clinical study to investigate the safety, tolerability, pharmacokinetic profile and antiviral activity of ACH-2684. We tested healthy volunteers in a single ascending dose (SAD) segment with doses ranging from 10 mg once daily to 300 mg twice daily. ACH-2684 demonstrated good safety and tolerability. The first cohorts of HCV-infected genotype 1 patients were enrolled thereafter and treated with ACH-2684 administered once-daily at 400 mg. HCV-infected patients with genotype 3 HCV were also enrolled and dosed twice-daily with 400mg of ACH-2684.

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In January 2012, we announced proof-of-concept with ACH-2684 in both genotype 1 HCV, where the compound demonstrated a mean maximum 3.73 log_{10} reduction in patient viral load, and in genotype 3 HCV with a maximum HCV RNA viral load reduction of 2.03 log_{10}.

In November 2012, we announced that ACH-2684, in a third phase Ib clinical study of once-daily doses of 400mg administered for three days to HCV patients with cirrhosis achieved a mean maximum 3.67 log_{10} reduction in HCV RNA (range 3.10-4.40 log_{10}) as compared to 0.22 log_{10} reduction for placebo. This result was similar to the antiviral activity achieved in non-cirrhotic genotype 1 HCV patients receiving the same dose of ACH-2684.

Preclinical Development History

In preclinical studies, we have demonstrated that ACH-2684 is efficacious *in vitro* against all genotypes of HCV at very low concentrations of less than 100 picomolar. In 14-day preclinical studies, ACH-2684 demonstrated high safety margins in animals with minimal dose-related side effects in both single ascending dose and multiple dose trials. The compound is metabolically stable and is rapidly and extensively partitioned in the liver, the organ of infection in HCV patients. Therefore, we believe ACH-2684 can be dosed once-daily.

NS5A Inhibitor for Chronic Hepatitis C Infection

In another proprietary program against hepatitis C infection, we have discovered and developed a potent inhibitor of the HCV NS5A protein. The NS5A protein serves multiple functions at various stages of the viral life cycle including involvement in virion production, interacting with host proteins and is implicated in interferon-resistance. Inhibition of NS5A is a clinically validated mechanism of action.

NS5A Inhibitor ACH-3102

In vitro, ACH-3102 demonstrates potency at picomolar concentrations in both genotypes 1a and 1b, the genotypes most prevalent in the United States. Other NS5A inhibitors have been challenged to show continued potency against the difficult-to-treat genotype 1a. The compound is also active against all other known genotypes (2, 3, 4, 5 and 6). ACH-3102 also operates synergistically with both NS3 protease and NS5B polymerase inhibitors.

The following table shows the relative potency of ACH-3102, as measured by the effective concentration required to reduce viral levels by at least 50%, or EC50, compared side by side to a leading compound under clinical development in this class by Bristol-Myers Squibb:

	EC50 (pM) in Replicon Assay	
	Genotype 1b	Genotype 1a
ACH-3102	5.1	26
BMS-0052	2.9	60

Importantly, ACH-3102 has demonstrated ten to one-hundred-fold improvement in efficacy against the common resistance mutations compared to BMS-0052.

Clinical Development History

Phase I Clinical Trials. In March 2012, we filed an Investigational New Drug, or IND, application for ACH-3102 and initiated clinical development in May 2012. In September 2012, we reported both preliminary safety and efficacy results from phase I clinical trials of ACH-3102. In total, 42 healthy volunteers received a single dose of ACH-3102, and 32 healthy volunteers received doses ranging from 25 mg to 1,000 mg, or 14 days of once daily ACH-3102, with dose regimens evaluating day 1 doses of 25 mg to 300 mg and subsequent doses

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on days 2 to 14 ranging from 25 mg to 100 mg. Data from both the single and multiple ascending dose groups demonstrated that ACH-3102 was well tolerated with no serious adverse events and no clinically significant changes in vital signs, electrocardiograms (ECGs), or laboratory evaluations.

Also in September 2012, we announced proof-of-concept efficacy results evaluating a single dose of ACH-3102 in patients with genotype 1a HCV. In all, 12 patients were treated with a single dose of either 50 mg, 150 mg, or 300 mg of ACH-3102, with a mean maximum decline in HCV RNA 3.78, 3.52, and 3.93 $\log_{10}$ achieved, respectively. An assessment of clinical virology, whereby the genetic sequencing of the HCV virus obtained from patient samples was analyzed, revealed that at baseline one patient had a L31M mutation and another had a Y93C mutation. Both of these mutations have been previously reported to convey a high level of resistance to first-generation NS5A inhibitors that was not observed following exposure to ACH-3102. No serious adverse events were reported and there were no patient discontinuations.

Phase II Clinical Trials. In January 2013, we announced preliminary results from an open-label phase II pilot trial evaluating 12 weeks of once-daily ACH-3102 in combination with ribavirin for the treatment of HCV genotype 1b. The study initially enrolled up to 16 treatment-naïve patients with GT 1b HCV who will receive 225 mg of ACH-3102 on day 1 followed by 75 mg of ACH-3102 once daily on subsequent days in combination with twice daily ribavirin. The primary objective of the trial was to determine the safety of this dosing regimen and the sustained virologic response 12 weeks after the completion of 12 weeks treatment (SVR12) with secondary endpoints assessing pharmacokinetics, pharmacodynamics, and other virologic endpoints including undetectable levels of virus at four weeks, or rapid virologic response, (RVR), and undetectable levels of virus at end of treatment, (ETR). Interim results for the initial 8 patients, revealed that 4 out of 5 patients (80%) who had reached four-weeks of dosing achieved RVR, and 3 out of 3 patients (100%) who had reached 12 weeks of dosing achieved ETR. To date, following up to 12 weeks of treatment with ACH-3102 in combination with ribavirin, there have been no reported serious adverse events, no treatment discontinuations and no clinically significant changes in vital signs, electrocardiograms (ECGs), or laboratory evaluations with the exception of one subject with an anemia requiring a ribavirin dose reduction. In February 2013, we announced that no viral breakthrough or viral relapse had been observed to date for any of the eight patients enrolled, including patients currently receiving or having completed 12 weeks of therapy. For the three patients having completed 12 weeks of therapy and continued monitoring through week 16, all achieved a sustained viral response 4 weeks after treatment, or SVR4, and are HCV undetectable.

Preclinical Development History

In preclinical studies, ACH-3102 has demonstrated potent pan-genotypic activity, meaning activity against HCV subtypes referred to as genotypes 1 through 6, including excellent activity against both the 1a genotype and known mutant variants of genotype 1 HCV.

In both 14-day and 3-month preclinical studies, ACH-3102 has demonstrated high safety margins in animals with minimal dose-related side effects in both single ascending dose and multiple dose trials. Long-term 6- and 9-month preclinical studies are on-going.

Drug Discovery Programs and Capabilities

We have successfully advanced seven drug candidates into human clinical trials, with two additional drug candidates in late-stage preclinical studies. We discovered seven of these eight 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.

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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 have 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 tools that enable us to manage our compounds efficiently and advance our programs:

AACP (Achillion Automated Chemistry Platform) is a proprietary software that facilitates synthesis of thousands of small molecules in parallel by automating several cumbersome steps involved.

ACE (Achillion Cheminformatics Engine) is a software interface which provides access to commercially available compound libraries and their physicochemical properties, assists in designing new compound libraries for synthesis, and displays new and database compounds in 3D. ACE is integrated with computational chemistry tools and a database of more than two million compounds.

CART (Compound Acquisition and Repository Tracking) streamlines our scientists ability to select and acquire compounds for lead identification.

CHEM-ACH is a data mining software that allows analysis of Achillion s proprietary compounds and their biological activities. Such analysis helps in studying the structure-activity relationships and designing and synthesizing compounds for lead optimization.

CIDM (Competitive Intelligence & Data Mining) is a web application. It analyzes publicly available information to display competitive information including clinical and preclinical development activities, intellectual property and scientific literature.

HCVWiki is an in-house database of ongoing and completed HCV therapy clinical trial designs and results. It also has an in-house developed, user friendly interface for accessing and analyzing this data.

PSTS (Preclinical Study Tracking System) is a web interface which is used for accessing the details of our preclinical studies. It allows scientists to enter, modify, and query preclinical study documents.

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

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treatment of chronic hepatitis C. The key competitive factors affecting the commercial success of these drugs are likely to be efficacy, safety and tolerability, durability and resistance profile, 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 vaccine, cure or new treatment methods for HCV infection could render our drugs non-competitive or obsolete.

If approved, our NS3 protease inhibitors, sovaprevir and ACH-2684, and our NS5A inhibitor, ACH-3102, would compete with drugs currently approved for the treatment of HCV, i.e., the interferon-alpha-based products from Roche (Pegasys and Roferon-A) or Merck (Intron-A or Peg-Intron), the ribavirin-based products from Merck (Rebetrol), Roche (Copegus) or generic versions sold by various companies, as well as recently-approved protease inhibitors telaprevir by Vertex (Incivek) and boceprevir by Merck (Victrelis). 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.

If approved, our drug candidates may also complete with treatments currently in development to treat HCV infection in multiple classes including protease inhibitors, polymerase inhibitors (nucleoside and non-nucleoside), NS5A inhibitors and cyclophilin inhibitors. Competing drug candidates, or combinations of drug candidates, are being developed by companies such as Abbvie, Astra-Zeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Enanta, Gilead, GlaxoSmithKline, Idenix, Johnson & Johnson, Presidio, Medivir, Merck, Novartis, Pfizer, Roche, Valeant and Vertex.

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 and enforce our patents;
- preserve the confidentiality of our trade secrets; and
- operate without infringing the patents and proprietary rights of third parties.

We hold issued patents and pending patent applications in the United States, and in foreign countries we deem appropriate, covering intellectual property developed as part of our research and development programs.

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Our hepatitis C patent portfolio currently includes the following:

	Issued Patents	Provisional Patent Applications	Pending Non-Provisional Applications	Pending PCT Applications
U.S.	11	1	9	1
Foreign	17		67	

These patents and patent applications, if issued, will expire between 2024 and 2032. The patent applications contain claims directed to classes of compounds, methods of use, mechanism of action, and research assays. Our HCV patents and patent applications are filed in 24 different countries, with the majority of them in Australia, Brazil, Canada, China, Europe, Japan, New Zealand and the United States.

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

Our antibacterial patent portfolio currently includes the following:

	Issued Patents	Provisional Patent Applications	Pending Non-Provisional Applications	Pending PCT Applications
U.S.	6		3	
Foreign	41		15	

These patents and patent applications, if issued, will expire between 2024 and 2032. The patent applications contain claims directed to classes of compounds, methods of use, and processes for synthesis. Our antibacterial patents and patent applications are filed in 42 different countries, with the majority of them in Australia, Canada, Europe, Japan, New Zealand and the United States.

In 2012, we entered into a license and development agreement with ORA, Inc. (Ora) for the worldwide development and commercialization of ACH-702 delivered topically or locally. Under the terms of the agreement, Ora will assume development and regulatory responsibility and associated costs for ACH-702 and we will be eligible to receive development and commercialization milestones and royalties on net sales.

Our HIV patent portfolio currently includes the following:

	Issued Patents	Provisional Patent Applications	Pending Non-Provisional Applications	Pending PCT Applications
U.S.	8			
Foreign	26		3	

We either own or hold exclusive worldwide licenses from Yale University and Emory University to these patents and patent applications. The patents and patent applications, if issued, will expire between 2014 and 2025. The issued U.S. patents contain claims directed to elvucitabine chemical compound, method of use, synthesis, and formulation. Our HIV patents and patent applications are filed in 25 different countries with the majority of them in Australia, China, Mexico, Japan and the United States.

In 2010, we entered into a license agreement for elvucitabine with GCA Therapeutics, Ltd. (GCAT) for the treatment of both Hepatitis B, or HBV, and HIV infection. The exclusive license grants GCAT the right, through its Chinese joint venture with Tianjing Institute of Pharmaceutical Research, or TIPR, to clinically develop and commercialize elvucitabine in mainland China, Hong Kong and Taiwan. Under the terms of the agreement, GCAT, through a sublicense agreement with its Chinese joint venture, T & T Pharma Co., Ltd., formed with

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TIPR, will assume all development and regulatory responsibility and associated costs for elvucitabine, and we will be eligible to receive development milestones and royalties on net sales in those territories.

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.

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 licenses from Yale University and 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.

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 (cGMP), 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 limited number of manufacturers 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 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.

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.

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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 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 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

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 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 investigational new drug to healthy volunteers or patients under the supervision of one or more qualified investigators in accordance with FDA s 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.

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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 requirements, 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 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 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 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.

The FDA has various programs including Fast Track, priority review and accelerated approval that are intended to expedite the development and review of drug candidates, and/or provide for approval on the basis of

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surrogate endpoints. Even if a drug candidate qualifies for one or more of these programs, the FDA may later decide that the drug candidate no longer meets the conditions for qualification or that the time period for FDA review or approval will not be shortened. Generally, drug candidates that may be eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs or those that offer meaningful benefits over existing treatments.

Fast Track is a process designed to facilitate the development, and expedite the review of drug candidates to treat serious diseases and fill an unmet medical need. Priority review is designed to give drug candidates that offer major advances in treatment or provide a treatment where no adequate therapy exists an initial review within six months as compared to a standard review time of ten months. Although Fast Track and priority review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track designated drug candidate and expedite review of the application for a drug candidate designated for priority review. Accelerated approval provides an earlier approval of drugs to treat serious diseases and that fill an unmet medical need based on a surrogate endpoint, which is a laboratory measurement or physical sign used as an indirect or substitute measurement representing a clinically meaningful outcome. As a condition of approval, the FDA may require that a sponsor of a product receiving accelerated approval perform post-marketing clinical trials.

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 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

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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 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 under a 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.

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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 drug therapies for infectious diseases. Accordingly, we have determined that we operate in one operating segment.

Employees

As of February 11, 2013, we had 56 full-time employees and 1 part-time employee, 25 of whom hold doctoral degrees. Approximately 42 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.

Available Information

Our internet address is 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

Name	Age	Position
Michael D. Kishbauch	63	President and Chief Executive Officer
Milind S. Deshpande, Ph.D.	56	President of Research and Development and Chief Scientific Officer
Gautam Shah, Ph.D.	56	Executive Vice President and Chief Compliance Officer
Mary Kay Fenton	48	Senior Vice President and Chief Financial Officer
Joseph Truitt	48	Senior Vice President and Chief Commercial Officer

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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 of OraPharma, Inc., a publicly traded, commercial-stage pharmaceutical company focused on oral health care, from September 1996 to July 2004. OraPharma was acquired by Johnson & Johnson, a pharmaceutical company, in 2003. Prior to OraPharma, Inc., Mr. Kishbauch held senior management positions with MedImmune, Inc., a biotechnology company. 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., President of Research and Development and Chief Scientific Officer. Prior to joining Achillion in September 2001, Dr. Deshpande was Associate Director of Lead Discovery and Early Discovery Chemistry at the Pharmaceutical Research Institute at Bristol-Myers Squibb, a pharmaceutical company, 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., Executive Vice President and Chief Compliance Officer. Prior to joining Achillion in May 2004, Dr. Shah was Senior Director of Regulatory Affairs with Sepracor, a pharmaceutical company, from February 2003 to May 2004. Prior to Sepracor, Dr. Shah was in the Regulatory Affairs Group of Bayer Health Care, a pharmaceutical company. Before Bayer, he held positions of increasing responsibilities at Pfizer Inc., a pharmaceutical company, 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, Senior Vice President and Chief Financial Officer. Prior to joining Achillion in October 2000, Ms. Fenton, a certified public accountant, held various positions within the Technology Industry Group at PricewaterhouseCoopers LLP, an independent registered public accounting firm, from 1991 to 2000, most recently as Senior Manager responsible for the life sciences practice in Connecticut. Prior to 1991, Ms. Fenton was an economic development associate in the nonprofit sector. Ms. Fenton is on the Executive Committee of the Board of Directors of Connecticut Business and Industry Association, a representative business organization. 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.

Joseph Truitt, Senior 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., a biotechnology company, 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, a pharmaceutical company, 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., a pharmaceutical company, 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.

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ITEM 1A. RISK FACTORS

Risks Related to Our Business

We depend on the success of our HCV drug candidates, which are still under development.

We have invested a significant portion of our efforts and financial resources in the development of our candidates for the treatment of HCV, including our protease inhibitors, sovaprevir and ACH-2684, and our NS5A inhibitor, ACH-3102. 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;
- our ability to provide acceptable evidence of the ability of our drug candidates to be dosed safely in combination with other drugs and/or drug candidates, both ours and others;
- our ability to develop drug formulations that will deliver the appropriate drug exposures in longer term clinical trials;
- our ability to obtain patent protection for our drug candidates and freedom to operate under third party intellectual property;
- 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;
- acceptance of the drug in the medical community and with third-party payors; and
- our ability to identify, enter into and maintain collaboration arrangements with appropriate strategic partners for our compounds.

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 the preclinical studies or completed clinical trials for sovaprevir, ACH-3102 or ACH-2684 may not be predictive of the results we may obtain in later stage trials.

We do not expect any of our drug candidates for the treatment of HCV to be commercially available for at least several years, if at all.

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 a segment of the pharmaceutical industry that is 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 generally and HCV in particular. 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 HCV. Additionally, there may be competitive drugs currently under development of which we are not aware.

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If approved, our protease inhibitors, sovaprevir and ACH-2684, and our NS5A inhibitor, ACH-3102, would compete with drugs currently approved for the treatment of HCV, i.e., the interferon-alpha-based products from Roche (Pegasys and Roferon-A) or Merck (Intron-A or Peg-Intron), the ribavirin-based products from Merck (Rebetrol), Roche (Copegus) and generic versions sold by various companies, as well as recently-approved protease inhibitors telaprevir by Vertex (Incivek) and boceprevir by Merck (Victrelis). 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.

If approved, our drug candidates may also complete with treatments currently in development to treat HCV infection in multiple classes including protease inhibitors, polymerase inhibitors (nucleoside and non-nucleoside), NS5A inhibitors and cyclophilin inhibitor. Competing drug candidates for the treatment of HCV, or combinations of drug candidates, are being developed by companies such as Abbvie, Astra-Zeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Enanta, Gilead, GlaxoSmithKline, Idenix, Johnson & Johnson, Presidio, Medivir, Merck, Novartis, Pfizer, Roche, Valeant and Vertex.

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, specific classes of competitive products, or combinations of 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 any of 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.

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, 2012, our accumulated deficit was approximately $323 million. We have not generated any revenue from the sale of drug candidates to date. We expect that our annual operating losses will increase over the next several years as we expand our research, development and commercialization efforts.

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.

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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, cash equivalents and marketable securities will be sufficient to support our current operating plan through at least December 31, 2013. Our operating plan may change as a result of many factors, including:

- the costs involved in the clinical development, manufacturing and formulation of our protease inhibitors, sovaprevir and ACH-2684, and our NS5A inhibitor, ACH-3102;
- the scope of and costs associated with entering cooperative study arrangements, or CSAs, if any, for the collaborative development of our drug candidates with other s drug candidates in combination;
- 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 or equity markets that may impact our ability to obtain capital in the future;
- our acquisition and development of new technologies and drug candidates; and
- competing technological, regulatory 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. We may seek additional financing through a combination of private and public equity offerings, debt financings and collaboration, strategic alliance and licensing arrangements. For example, in November 2012 we entered into an agreement with Cantor Fitzgerald & Co., or Cantor, pursuant to which, from time to time, we may offer and sell up to $50 million of shares of our common stock at the market through Cantor pursuant to a universal shelf registration statement. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interest will be diluted, and the terms may include adverse liquidation or other preferences that adversely affect stockholder s rights. Since August 2008, we have issued an aggregate of 59,713,859 shares of our common stock in two private placements and three registered offerings as well as warrants to purchase an aggregate of 13,279,028 shares of our common stock. As of December 31, 2012, we have 5,358,212 warrants outstanding. These financings substantially diluted our existing stockholders.

Stockholders will be further diluted if, and to the extent, any warrants are exercised. Debt financing, if available, may involve covenants that limit or restrict our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends, or may involve immediate repayment of the debt under certain circumstances. If we raise additional funds through collaborations, strategic alliances and licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies or drug candidates, or grant licenses on terms that are not favorable to us.

If we acquire or license technologies, resources or drug candidates, we will incur a variety of costs and may never realize benefits from the transaction.

If appropriate opportunities become available, we may license or acquire technologies, resources, drugs or drug candidates. We may never realize the anticipated benefits of such a transaction or we may later incur

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impairment charges related to assets acquired in any such transaction. In particular, due to the risks inherent in drug development, we may not successfully develop or obtain marketing approval for the drug candidates we acquire. Future licenses or acquisitions could result in potentially dilutive issuances of equity securities, the incurrence of debt, the creation of contingent liabilities, impairment expenses related to goodwill, and impairment or amortization expenses related to other intangible assets, which could harm our financial condition.

If we 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 president of research and development 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.

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

In late 2011 and early 2012, several acquisitions of smaller biopharmaceutical companies by larger biopharmaceutical companies took place at substantial premiums over the market capitalizations of the target companies, including the acquisitions of Anadys Pharmaceuticals, Pharmasset, Inc. and Inhibitex Pharmaceuticals, by Roche, Gilead and Bristol-Myers Squibb, respectively. If such consolidation continues to take place, we may face competitive pressures to a far greater degree than had those consolidations not occurred, resulting from the greater resources the larger pharmaceutical companies can put toward their development pipelines. Further, if investors who provide capital to our industry continue to seek and advocate for similar acquisitions at similar premiums, we may not be able to satisfy their higher expectations for market value appreciation and our stock price may decline.

Our business has a substantial risk of product liability claims. If we are unable to obtain or maintain appropriate levels of insurance, a product liability claim 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.

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If the estimates we make and the assumptions on which we rely in preparing our financial statements prove inaccurate, our actual results may vary significantly.

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses. Such estimates and judgments include revenue recognition, stock-based compensation expense, accrued expenses and deferred tax assets and liabilities. We base our estimates and judgments on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. However, these estimates and judgments, or the assumptions underlying them, may change over time. Accordingly, our actual financial results may vary significantly from the estimates contained in our financial statements.

For a further discussion of the estimates and judgments that we make and the critical accounting policies that affect these estimates and judgments, see Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Standards and Estimates elsewhere in this Annual Report on Form 10-K.

Our business and operations would suffer in the event of system failures or security breaches.

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liabilities and the further development of our product candidates may be delayed.

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, test and commercialize 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 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 IRBs may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;

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- our preclinical tests or clinical trials for our drug candidates 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 as potential participants have access to commercially launched DAAs, telaprevir (Incivek) or boceprevir (Victrelis), as well as other experimental therapies under development, or participants may not remain adherent to our clinical trial protocols or may drop out of our clinical trials at a higher rate than we currently anticipate, each 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 in our trials, or in third-party trials of similar HCV drug candidates, 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;

- the FDA may require us to carry out more extensive studies, evaluate different treatment combinations or complete comparative effectiveness studies, resulting in significant delays and/or increased costs; and

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

In addition, the current standard of care, telaprevir (Incivek) or boceprivir (Victrelis) in combination with P/R, is subject to change. If change occurs, we could be required to carry out more extensive studies, evaluate different treatment combinations or complete comparative effectiveness studies, resulting in significant delays and/or increased costs.

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.

Expenses associated with clinical trials may cause our earnings to fluctuate, which could adversely affect our stock price.

The clinical trials required for regulatory approval of our products, as well as clinical trials we are required to conduct after approval, are very expensive. It is difficult to accurately predict or control the amount or timing of these expenses from quarter to quarter, and the FDA and/or other regulatory agencies may require more clinical testing than we originally anticipated for our drug candidates. Uneven and unexpected spending on these programs may cause our operating results to fluctuate from quarter to quarter, and our stock price may decline.

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 sovaprevir, ACH-3102, ACH-2684 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;

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- the drug may not prove to be safe;
- the results may not confirm the positive results from earlier preclinical studies or clinical trials;
- the results may not meet the level of statistical significance required by the FDA or other regulatory agencies; and
- the FDA or other regulatory agencies may require us to carry out additional studies.

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 the 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. 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.

Further, we cannot predict whether or how recent program discontinuations by certain of our competitors (such as the recent discontinuation by Bristol-Myers Squibb of BMS-986094, a nucleotide polymerase inhibitor, due to serious cardiac-related adverse events) may increase the level of scrutiny by the FDA on our drug candidates, slowing data review and response times or otherwise creating delays or difficulties in initiating and progressing 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;
- delays in gathering and interpreting clinical data;

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

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the requirement by the FDA, in connection with future HCV development guidelines recently circulated for comment, to carry out additional studies;

delays in completing formulation development of our drug candidates, or delays in planning and executing the bridging studies required to use the new formulations in subsequent clinical trials;

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

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 in third-party clinical trials of similar HCV drug candidates; 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 existence of clinical trials for competing drugs also in clinical development, 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. We currently face competition for subjects to enroll in our clinical trials and may have to expand the number of sites at which the trials are conducted. If we are not successful in doing so, the planned timing for release of data from these trials may not be achieved. 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 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. For example, when we advanced sovaprevir into longer term clinical trials in phase II, we established predetermined stopping rules, as well as a Data Safety Monitoring Board (DSMB) in order to monitor and ensure patient safety. Any interruption of these clinical trials, whether as a result of one of our drug candidates, or of co-administration of a concomitant anti-HCV agent, or of administrative review delays on the part of the DSMB or FDA, could cause delays in our drug development.

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.

Fast Track designation does not guarantee approval, or expedited approval, of sovaprevir or ACH-3102 and there is no guarantee that sovaprevir or ACH-3102 will maintain Fast Track designation.

In December 2011 and May 2012, we announced that the FDA granted Fast Track designation to sovaprevir and ACH-3102, respectively, for the treatment of HCV. Under the FDA Modernization Act of 1997, Fast Track designation is designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions. Compounds selected must demonstrate the potential to address an unmet medical need for such a condition. Mechanisms intended to facilitate development include opportunities for frequent dialogue with FDA reviewers and for timely review of submitted protocols. However, the

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designation does not guarantee approval or expedited approval of any application for the product. Furthermore, the FDA may revoke Fast Track designation from a product candidate at any time if it determines that the criteria are no longer met.

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 FDA could allege that our promotional activities misbrand our products. Specifically, the FDA could issue a 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.

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In addition to regulations in the United States, we are and will be subject, either directly or through our distribution partners, to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products, if approved.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in non-U.S. countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a process that requires the submission of a clinical trial application much like an IND prior to the commencement of human clinical trials. In Europe, for example, a clinical trial application, or CTA, must be submitted to the competent national health authority and to independent ethics committees in each country in which a company intends to conduct clinical trials. Once the CTA is approved in accordance with a country s requirements, clinical trial development may proceed in that country.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with good clinical practices, or GCPs, and other applicable regulatory requirements.

To obtain regulatory approval of an investigational drug under European Union, or E.U., regulatory systems, we must submit a marketing authorization application. This application is similar to the NDA in the United States, with the exception of, among other things, country-specific document requirements. Drugs can be authorized in the E.U. by using (i) the centralized authorization procedure, (ii) the mutual recognition procedure, (iii) the decentralized procedure, or (iv) national authorization procedures.

The European Medicines Agency, or EMA, implemented the centralized procedure for the approval of human drugs to facilitate marketing authorizations that are valid throughout the E.U. This procedure results in a single marketing authorization granted by the European Commission that is valid across the European Union, as well as in Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for certain human drugs including those that are: (i) derived from biotechnology processes, such as genetic engineering or (ii) contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases, autoimmune and other immune dysfunctions and viral diseases.

Market exclusivity provisions under the FDCA can delay the submission or the approval of certain applications.

The Federal Food, Drug and Cosmetic Act, or FDCA, provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an approved NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

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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 may consider forming exclusive or non-exclusive alliances with major biotechnology or pharmaceutical companies to jointly develop, and commercialize if approved, our protease inhibitor candidates and/or our NS5A inhibitor candidates. 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 or in a timely manner, if at all. There are a limited number of collaboration partners whose pipeline of HCV clinical candidates are suitable for co-development with ours. There are also a limited number of potential collaboration partners without a robust HCV drug candidate pipeline, but demonstrated commercial interest in HCV therapeutics who may have interest in gaining rights to our HCV drug candidates. Recent consolidation may have reduced the number of potential partners further, making achieving a suitable partnership more difficult, potentially limiting our ability to command a significant premium in any such transaction. Further, if potential collaboration partners enter alliances with other competing HCV companies, our future business prospects may be harmed, as these alliances could reduce the pool of potential partners for our compounds and/or limit the value of such alliance.

Even if we do succeed in securing such alliances, we may not be able to maintain them if development or approval of a drug candidate is delayed or sales of an approved drug are disappointing. For example, a 2004 license and collaboration agreement between us and Gilead for the advancement of certain HCV compounds operating by the mechanism of action known as NS4A antagonism was terminated in February 2012 as neither party was devoting significant time to advancing the compounds under the agreement. 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.

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. 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. We also depend on third parties to assist us in developing appropriate formulations of our 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 depend on third parties to assist us in developing appropriate

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formulations of our drug candidates. 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. Further, if third parties are not successful in formulation development of our drug candidates, our development timelines may be delayed. 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 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.

To date, our third-party formulators and manufacturers have met our formulation and 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 formulators or manufacturers could delay clinical development or regulatory approval of our drug candidates or commercialization of any approved products. If for some reason our current contractors cannot perform as agreed, we may be required to replace them. Although we believe that there are a number of potential replacements given our formulation and manufacturing processes are not contractor 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 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 may 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 may enter into arrangements with other companies for commercialization. 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.

The development of directly acting antivirals to treat HCV, and the potential changes in market dynamics that may result from their introduction for HCV therapy, may present additional risks beyond those inherent in drug development.

We are developing multiple direct-acting antiviral, or DAA, compounds, in two distinct classes, for treatment of HCV. Other companies are also developing DAAs in these classes, as well as other classes. Until the

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recent introduction of DAA therapy, the standard of care for HCV infection included therapy with pegylated interferon and ribavirin. Two DAAs developed by our competitors, telaprevir (Incivek) by Vertex and boceprevir (Victrelis) by Merck, were approved by the FDA for use in combination with P/R, and became a new standard of care for genotype 1 HCV in October 2011. We cannot currently predict when or if additional compounds currently in development may again change the standard of care in the future.

The development plans for our compounds include treatment regimens with our inhibitors in combination with another DAA, or our inhibitors with one or more DAAs with or without concomitant ribavirin therapy. These development programs carry all the risks inherent in drug development activities, including the risk that they will fail to show efficacy or acceptable safety, as well as the risk that a safety issue related to one compound may negatively impact another compound with which it is dosed. In addition, these development programs may also be subject to additional regulatory, commercial and manufacturing risks that may be additional to the risks inherent in drug development activities.

Regulatory guidelines for approval of DAA drugs for the treatment of HCV are evolving in the United States, Europe, and other countries. We anticipate that regulatory guidelines and regulatory agency responses to our and our competitors development programs will continue to change, resulting in the risk that our activities may not meet unanticipated new standards or requirements, which could lead to delay, additional expense, or potential failure of development activities.

Furthermore, even if we or our competitors successfully develop DAAs whose use improves the current standard of care, current HCV-treating physicians, HCV patients, healthcare payers, and others may not readily accept or pay for such improvements or new treatments. In addition, because development of DAAs for HCV infection is an emerging field, the delay or failure of a competitor attempting to develop therapeutics that could have been combined with our product candidates or that are perceived to be similar to our product candidates could have a significant adverse effect on the commercial or regulatory environment for our product candidates or on the price of our stock. Other companies developing DAAs have more advanced development programs than we do. Their success or failure to successfully conclude clinical development and obtain marketing approval could have a material adverse effect on our development and commercialization plans and activities.

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

Even if sovaprevir, ACH-3102, ACH-2684 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;
- the demonstrated clinical safety and efficacy of our product candidates compared to other drugs and other drug candidates;
- the suitability of our drug candidates to be co-administered or combined with other drugs or drug candidates;
- the durability of our drug candidates in their ability to prevent the emergence of drug-resistant viral mutants;
- 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;

the effectiveness of marketing and distribution support;

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the cost-effectiveness of our product candidates; and

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

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 or combinations of 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 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.

In the United States, at both the federal and state levels, the government regularly proposes legislation to reform health care and its cost, and such proposals have received increasing political attention. In 2010, Congress recently passed legislation to reform the U.S. health care system by expanding health insurance coverage, reducing health care costs and making other changes. While health care reform may increase the number of patients who have insurance coverage for the use of any approved drug candidate, it may also include changes that adversely affect reimbursement for approved drug candidates. In addition, there has 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 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.

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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.

Growing availability of orphan pharmaceuticals may lead to increased focus on cost containment.

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

Healthcare reform measures, if implemented, could hinder or prevent our commercial success.

There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

the demand for any drug products for which we may obtain regulatory approval;

our ability to set a price that we believe is fair for our products;

our ability to generate revenues and achieve or maintain profitability;

the ability of government agencies to continue to pay for such care;

the level of taxes that we are required to pay; and

the availability of capital.

Risks Related to Patents and Licenses

If our patent position does not adequately protect our drug candidates, others could compete against us more directly, which would harm our business.

We own or hold exclusive licenses to several issued patents U.S. and pending U.S. provisional and non-provisional patent applications, as well as pending PCT applications and associated non-US patents and patent applications. Our success depends in large part on our ability to obtain and maintain 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. 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

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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. 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 HCV inhibitor space is particularly crowded in terms of intellectual property, and certain competitors such as Merck, Vertex, AstraZeneca, Bayer, Gilead and Bristol-Myers Squibb, have disclosed compounds that may be prior art to our patent applications and prevent issuance or alter the scope of any claims that we may pursue related to our drug candidates.

The claims of the issued patents that are licensed to us, and the claims of any patents which may issue in the future and be owned by or licensed to us, may not confer on us significant commercial protection against competing products. Additionally, our patents may be challenged by third parties, resulting in the patent being deemed invalid, unenforceable or narrowed in scope, or the third party may circumvent any such issued patents. Also, our pending patent applications may not issue, and we may not receive any additional patents. Our patents might not contain claims that are sufficiently broad to prevent others from utilizing our technologies. For instance, the issued patents relating to our drug candidates may be limited to a particular molecule. Consequently, our competitors may independently develop competing products that do not infringe our patents or other intellectual property. To the extent a competitor can develop similar products using a different molecule, our patents may not prevent others from directly competing with us.

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.

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

The Leahy-Smith America Invents Act, or the America Invents Act, was signed into law in September 2011, with many of the substantive changes becoming effective one year or 18 months from its enactment. The America Invents Act reforms United States patent law in part by changing the standard for patent approval from a first to invent standard to a first to file standard and developing a post-grant review system. This legislation changes United States patent law in a way that may weaken our ability to obtain patent protection in the United States.

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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 licenses from Yale University and 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.

Because our research and development of drug candidates incorporates compounds and other information that is the intellectual property of third parties, we depend on continued access to such intellectual property to conduct and complete our preclinical and clinical research and commercialize the drug candidates that result from this research. Some of our existing licenses impose, and we expect that future licenses would impose, numerous obligations on us. For example, under our existing and future license agreements, we may be required to pay minimum annual royalty amounts and/or payments upon the achievement of specified milestones. We may also be required to reimburse patent costs incurred by the licensor, or we may be obligated to pay additional royalties, at specified rates, based on net sales of our product candidates that incorporate the licensed intellectual property rights. We may also be obligated under some of these agreements to pay a percentage of any future sublicensing revenues that we may receive. Future license agreements may also include payment obligations such as milestone payments or minimum expenditures for research and development. In addition to our payment obligations under our current licenses, we are required to comply with reporting, insurance and indemnification requirements under the agreements. We expect that any future licenses would contain similar requirements.

If we fail to comply with these obligations or otherwise breach a license agreement, the licensor may have the right to terminate the license in whole, terminate the exclusive nature of the license or bring a claim against us for damages. Any such termination or claim could prevent or impede our ability to market any drug that is covered by the licensed intellectual property. Even if we contest any such termination or claim and are ultimately successful, our financial results and stock price could suffer. In addition, upon any termination of a license agreement, we may be required to grant to the licensor a license to any related intellectual property that we developed. For example, the licensors have the right to terminate our license of the intellectual property covered by its licenses to us under certain circumstances, including our failure to make payments to the licensor when due and our uncured breach of any other terms of the licenses. If access to such intellectual property is terminated, or becomes more expensive as a result of renegotiation of any of our existing license agreements, our ability to continue development of our product candidates or the successful commercialization of our drug candidates could be severely compromised and our business could be adversely affected.

If we infringe or are alleged to infringe intellectual property rights of third parties, our business could be harmed.

Our research, development and commercialization activities, including any drug candidates resulting from these activities, may infringe or be claimed to infringe patents or other proprietary rights owned by third parties and to which we do not hold licenses or other rights. There may be applications that have been filed but not published that, if issued, could be asserted against us. We are aware that certain third parties, including Bristol-Myers Squibb, Gilead, GlaxoSmithKline plc and Enanta Pharmaceuticals, Inc., have applications that are broadly

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directed to certain classes of HCV inhibitors. If a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the drug or drug candidate that is the subject of the suit.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference proceedings declared by the U. S. Patent and Trademark Office and opposition proceedings in the European Patent Office, regarding intellectual property rights with respect to our product candidates and technology. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

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 Yale University 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. 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 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.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

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Because of the relative weakness of the Chinese legal system in general, and the intellectual property rights in particular, we may not be able to enforce intellectual property rights in China.

The legal regime protecting intellectual property rights in China is weak. Because the Chinese legal system in general, and the intellectual property regime in particular, are relatively weak, it is often difficult to create and enforce intellectual property rights in China. Accordingly, we may not be able to effectively protect our intellectual property rights for our compounds in China.

We rely on our ability to stop others from competing by enforcing our patents, however some jurisdictions may require us to grant licenses to third parties. Such compulsory licenses could be extended to include some of our product candidates, which may limit our potential revenue opportunities.

Many foreign countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, most countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may be limited to monetary relief and may be unable to enjoin infringement, which could materially diminish the value of the patent. Compulsory licensing of life-saving products is also becoming increasingly popular in developing countries, either through direct legislation or international initiatives. Such compulsory licenses could be extended to include some of our product candidates, which may limit our potential revenue opportunities.

The rights we rely upon to protect our unpatented trade secrets may be inadequate.

We rely on unpatented trade secrets, know-how and technology, which are difficult to protect, especially in the pharmaceutical industry, where much of the information about a product must be made public during the regulatory approval process. We seek to protect trade secrets, in part, by entering into confidentiality agreements with employees, consultants and others. These parties may breach or terminate these agreements, or may refuse to enter into such agreements with us, and we may not have adequate remedies for such breaches. Furthermore, these agreements may not provide meaningful protection for our trade secrets or other proprietary information or result in the effective assignment to us of intellectual property, and may not provide an adequate remedy in the event of unauthorized use or disclosure of confidential information or other breaches of the agreements. Despite our efforts to protect our trade secrets, we or our collaboration partners, board members, employees, consultants, contractors or scientific and other advisors may unintentionally or willfully disclose our proprietary information to competitors.

If we fail to maintain trade secret protection, our competitive position may be adversely affected. Competitors may also independently discover our trade secrets. Enforcement of claims that a third party has illegally obtained and is using trade secrets is expensive, time consuming and uncertain. If our competitors independently develop equivalent knowledge, methods and know-how, we would not be able to assert our trade secrets against them and our business could be harmed.

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

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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 Securities

We may dilute our existing stockholders in connection with capital raising activities. Additionally, the market price of our common stock may fall due to the number of freely-tradable shares available in the public market.

In connection with capital raising activities, we may be required to dilute our existing stockholders substantially. For example, since August 2008, we have issued an aggregate of 59,713,859 shares of our common stock in private and registered offerings, as well as warrants to purchase an aggregate of 13,279,028 shares of our common stock. As of December 31, 2012, we have 5,358,212 warrants outstanding. All of the shares of common stock we issued, as well as those shares issuable upon exercise of the warrants, are freely tradable pursuant to effective registration statements, making such shares available for immediate resale in the public market. In November 2012, we filed a universal shelf registration on Form S-3 to register for sale from time to time up to $200,000,000 of common stock, preferred stock, warrants and/or units in one or more offerings. Moreover, in November 2012, we entered into a sales agreement with Cantor pursuant to which, from time to time, we may offer and sell shares of our common stock having an aggregate offering price of up to $50 million through Cantor pursuant to such universal shelf registration statement. Sales of our common stock, if any, under the agreement with Cantor may be made in sales deemed to be at-the-market equity offerings as defined in Rule 415 under the Securities Act of 1933, as amended, or the Securities Act, including sales made directly on or through the NASDAQ Global Select Market, the existing trading market for our common stock, sales made to or through a market maker other than on an exchange or otherwise, in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices, and/or any other method permitted by law, including in privately negotiated transactions. Sales of substantial amounts of shares of our common stock or other securities could lower the market price of our common stock.

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 March 1, 2013, our 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 our clinical trials of our protease inhibitors, sovaprevir and ACH-2684, and our NS5A inhibitor, ACH-3102;
- the results of clinical trials conducted by others on drugs that would compete with our drug candidates;
- the announcements of those data, particularly at high profile medical meetings, and the investment community s perception of and reaction to those data;
- the ability of our drug candidates to be dosed safely in combination with other drugs and/or drug candidates, both ours and others;
- the entry into, modification of, or termination of key agreements, or any new collaboration agreement we may enter;
- market expectations about the timeliness of our entry into, or failure to enter, collaboration arrangements with third parties;

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the entry by a potential third-party collaborator into an alliance with a competitor, or the entry by any other HCV drug developer into an alliance that may be perceived as competitive to us;

the continued industry consolidation of pharmaceutical companies developing HCV drug therapies, or the acquisition of any one of our HCV drug development competitors;

the premiums on other transactions and any significant increases or decreases of those premiums;

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

our failure to obtain patent protection for any of our drug candidates or the issuance of third party patents that cover 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 launch of drugs by others 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 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

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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.

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.

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 Select 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 limited number of 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 or, if our independent auditors are unable to provide us with an attestation and an unqualified report as to the effectiveness of our 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 of the price of our common stock will provide a return to stockholders.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We currently lease approximately 32,000 square feet of laboratory and office space in New Haven, Connecticut, which we occupy under a seven-year lease expiring in 2017. 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

None.

ITEM 4. MINE SAFETY DISCLOSURES

None.

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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 Select 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 Select Market for the period indicated:

	High	Low
2012		
First Quarter	$ 12.95	$ 7.50
Second Quarter	$ 11.08	$ 5.78
Third Quarter	$ 11.01	$ 5.42
Fourth Quarter	$ 11.36	$ 7.11
2011		
First Quarter	$ 7.50	$ 3.57
Second Quarter	$ 8.95	$ 4.55
Third Quarter	$ 8.60	$ 4.50
Fourth Quarter	$ 8.22	$ 3.81

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 February 11, 2013, there were approximately 80 holders of record of our common stock. The number of record holders may not be representative of the number of beneficial owners because many of the shares of our common stock are held by depositories, brokers or other nominees.

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.

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 2012.

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.

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The following graph compares the cumulative total stockholder return on our common stock from January 1, 2008 to December 31, 2012 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 January 1, 2008 in our common stock, the NASDAQ Market Index and the NASDAQ Biotechnology Index, and assumes any dividends are reinvested.

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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, 2012, 2011 and 2010 and balance sheet data as of December 31, 2012 and 2011 set forth below have been derived from our audited financial statements included elsewhere in this Annual Report. The selected statement of comprehensive loss data for the years ended December 31, 2009 and 2008 and balance sheet data as of December 31, 2010, 2009 and 2008 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.

	Years Ended December 31,				
	2012	2011	2010	2009	2008
	(in thousands, except per share amounts)				
Statement of Comprehensive Loss Data:					
Total revenue	$ 2,607	$ 247	$ 2,436	$ (294)	$ (234)
Research and development	38,999	35,441	20,529	18,419	21,018
General and administrative	10,901	9,153	7,205	6,553	6,546
Restructuring charges				274	
Total operating expenses	49,900	44,594	27,734	25,246	27,564
Loss from operations	(47,293)	(44,347)	(25,298)	(25,540)	(27,798)
Interest income (expense), net	166	141	(183)	(392)	(353)
Net loss	(47,127)	(44,206)	(25,481)	(25,932)	(28,151)
Net loss per share basic and diluted	$ (0.64)	$ (0.69)	$ (0.57)	$ (0.98)	$ (1.42)
Weighted average number of shares outstanding basic and diluted	73,965	64,248	45,079	26,537	19,812

	2012	2011	2010	2009	2008
Balance Sheet Data:					
Cash and cash equivalents	$ 18,526	$ 16,110	$ 25,373	$ 9,712	$ 11,060
Short-term marketable securities	46,884	37,456	29,827		24,297
Long-term marketable securities	12,008	26,377			
Working capital	58,731	46,148	52,296	2,803	24,359
Total assets	81,530	82,630	58,235	11,670	38,561
Long-term liabilities	347	2,718	2,489	2,906	1,361
Total liabilities	9,483	11,662	7,691	10,648	13,540
Total stockholders equity	72,047	70,968	50,544	1,022	25,021

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

Overview

We are a biopharmaceutical company that was established to discover, develop and commercialize 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 viral infection, or HCV. We are currently focusing our efforts on developing the following three clinical-stage drug candidates which we intend to study in combination with each other and/or potentially in combination with compounds owned by others, each combination being investigated for the treatment of HCV:

- Sovaprevir, a NS3 protease inhibitor being investigated for the treatment of HCV, currently in phase II clinical development;
- ACH-3102, a NS5A inhibitor being investigated for the treatment of HCV, currently in phase II clinical development;
- ACH-2684, a NS3 protease inhibitor being investigated for the treatment of HCV, which recently completed phase I clinical development.

In addition, we have established a pipeline of certain antibacterial product candidates for which we are currently seeking appropriate collaborative partners, but to which we are not devoting significant resources at this time. These product candidates include ACH-702 for the treatment of dermatologic and ophthalmic infections, and ACH-2881 for the treatment of serious resistant bacterial infections, including methicillin resistant staphylococcus aureus. We have also developed and out licensed certain development and commercialization rights to elvucitabine, for the treatment of both Hepatitis B, or HBV, and human immunodeficiency virus, or HIV.

We have devoted and are continuing to devote substantially all of our efforts toward product research and development. We have incurred losses of $309 million from inception through December 31, 2012 and had an accumulated deficit of $323 million at December 31, 2012, which includes preferred stock dividends recognized until our initial public offering in 2006. Our net losses were $47.1 million, $44.2 million and $25.5 million for the years ended December 31, 2012, 2011, and 2010, respectively.

We have funded our operations primarily through proceeds from the sale of equity securities, including our initial public offering in October 2006, private placements of our common stock in August 2008 and August 2010 and registered offerings of our common stock in January 2010, June 2011 and August 2012.

In August 2012, we issued 6,367,853 shares of our common stock in a registered direct offering with funds managed by QVT Financial LP. We received net proceeds of $41.7 million.

In June 2011, we issued 11,040,000 shares of our common stock in an underwritten public offering, including the underwriters exercise of an over-allotment option. We received net proceeds of $60.9 million.

In August 2010, we issued 19,775,101 shares of our common stock and warrants to purchase 6,921,286 shares of common stock in a private placement to institutional and other accredited investors. We received net proceeds of $49.9 million.

In January 2010, we issued 10,275,000 shares of our common stock in an underwritten public offering. In February 2010, we issued an additional 1,541,250 shares of common stock in connection with the underwriters exercise of an over-allotment option. We received net proceeds of $22.6 million.

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

- continue clinical testing of sovaprevir, ACH-2684 and ACH-3102; and

identify and progress additional drug candidates.

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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 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, find and maintain appropriate collaboration partners 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.

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 former collaboration with Gilead to develop compounds for use in treating HCV. During the years ended December 31, 2012, 2011, and 2010 we recognized $2.5 million, $247,000, and $180,000, respectively, under this collaboration agreement.

Upon initiating the collaboration with Gilead in 2004, 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, as well as a $2.0 million milestone achieved during the period prior to proof-of-concept, was accounted for under the proportionate performance model. Revenue under the proportionate performance model was recognized as effort under the collaboration was incurred. Payments made by us to Gilead in connection with this collaboration were recognized as a reduction of revenue.

In February 2012, our collaboration with Gilead was terminated. We retain the right to develop ACH-1095, a compound discovered and developed under the collaboration, although we do not have current plans to do so.

We did not recognize any revenue related to the amortization of deferred revenue during the years ended December 31, 2011 and 2010, as we were unable to accurately estimate our total performance obligations under the Gilead collaboration. Effective with the February 2012 termination of the collaboration, we recognized the remaining $2.5 million of deferred revenue.

In October 2012, we entered into a license and development agreement with Ora, Inc. (Ora) for the worldwide development and commercialization of ACH-702 delivered topically or locally. During the year ended December 31, 2012, we recognized $100,000 of revenue upon the initiation of the Ora agreement related to the one time nonrefundable license fee and an additional $18,000 upon the sublicensing by Ora of ACH-702 to Taejoon Pharmaceutical Co., Ltd in December 2012.

We have also recognized revenue under a Small Business Innovation Research, or SBIR, grant by the National Institutes of Health, or NIH, for the further study of a back-up series of compounds related to ACH-702 for the treatment of tuberculosis infection. During the year ended December 31, 2010, we recognized revenue of $300,000 under this grant.

Additionally, we recognized revenue related to the Qualifying Therapeutic Discovery Project program, or QTDP. The QTDP program was created by the United States Congress as part of the Patient Protection and Affordable Care Act and provided for reimbursement of certain costs paid or incurred during 2009 and 2010 directly related to the conduct of a Qualifying Therapeutic Discovery Project, as defined. The Department of Health and Human Services designated such projects based on the potential for them to result in new therapies to treat areas of unmet medical need, the potential to create and sustain jobs in the U.S. and to advance U.S. competitiveness. During the year ended December 31, 2010, we recognized revenue of $2.0 million related to this program.

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Research and Development

Our research and development expenses reflect costs incurred for our proprietary research and development projects which 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 and operating supplies.

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 patents for our candidates are expensed as incurred as indirect costs. Our research and development expenses for the years ended December 31, 2012, 2011 and 2010 were as follows:

	For the Years Ended December 31,		
	2012	2011	2010
	(in thousands)		
Direct external costs:			
Sovaprevir (and related compounds)	$ 10,893	$ 12,210	$ 5,679
ACH-3102 (and related compounds)	10,554	2,795	
ACH-2684 (and related compounds)	3,166	5,764	2,115
ACH-2928 (and related compounds)	525	3,265	1,378
Other	1,205	657	861
	26,343	24,691	10,033
Direct internal personnel costs	9,824	7,664	6,755
Sub-total direct costs	36,167	32,355	16,788
Indirect costs and overhead	3,386	3,504	3,871
Connecticut research and development tax credit	(554)	(418)	(130)
Total research and development	$ 38,999	$ 35,441	$ 20,529

We are currently conducting phase II clinical trials of sovaprevir, phase II clinical trials of ACH-3102, and phase I clinical trials of ACH-2684.

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. This benefit is recorded as a reduction of research and development expenditures.

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 any of our compounds. 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;
- the potential benefits of our drug candidates over other therapies;
- 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;

results of future clinical trials that we may conduct;

results of clinical trials conducted by our competitors;

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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 to increase over time. 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.

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.

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 Accounting Standards Codification 605, or ASC 605, *Revenue Recognition*. Revenue-generating research and development collaborations are often multiple element arrangements, providing for a license as well as research and development services. In order to account for these arrangements, we must identify the deliverable included within the arrangement and evaluate which deliverables represent separate units of

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accounting based on if certain criteria are met, including whether the delivered element has stand-alone value to the collaborator. The consideration received is allocated among the separate units of accounting and the applicable revenue recognition criteria are applied to each of the separate units.

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 FTEs incurred and include research and development activities performed by internal scientists. Total expected effort is generally based upon the total projected direct labor hours. 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. 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. 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.

Substantive milestone payments are recognized upon achievement of the milestone. Determining whether a milestone is substantive requires judgment that should be made at the inception of the arrangement. To meet the definition of a substantive milestone, the consideration earned by achieving the milestone (1) would have to be commensurate with either the level of effort required to achieve the milestone or the enhancement in the value of the item delivered, (2) would have to relate solely to past performance, and (3) should be reasonable relative to all deliverables and payment terms in the arrangement. No bifurcation of an individual milestone is allowed and there can be more than one milestone in an arrangement.

Stock-Based Compensation Employee Stock-Based Awards

We apply ASC 718, *Stock Compensation,* 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.

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, stock-based compensation cost is based on the value of the portion of stock-based awards that is ultimately expected to vest.

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.

We utilize the simplified method in developing an estimate of the expected term of plain vanilla share options. This method is considered appropriate given our limited exercise history. Further, we do not believe the

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exercise patterns associated with these option grants are predictive of future exercise patterns. Additionally, we calculate volatility based on actual volatility from the end of our initial public offering lock-up period to the end of the reporting period. For periods before we had sufficient actual volatility data, we used a weighted average rate of historical and peer group volatility. We are also required to estimate forfeitures at the grant date and recognize compensation costs for only those awards that are expected to vest.

If factors change and we employ different assumptions in future periods, or if we experience significant fluctuations in our stock price, the compensation expense that we record 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. There is risk that our estimates of the fair values of our 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 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 using an option pricing model, that value may not be indicative of the fair value observed in a willing buyer/willing seller market transaction.

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. 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.

We apply the provisions of ASC 740, *Income Taxes,* which 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. Our financial statements reflect expected future tax consequences of such positions presuming the taxing authorities full knowledge of the position and all relevant facts.

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We do not have any unrecognized tax benefits as of December 31, 2012. 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 progress of our research and development projects, technological advances and determinations as to the commercial potential of proposed products, the timing of payments received under existing or future strategic alliances, joint ventures or financings, if any.

Revenues:

Our sources of revenue during the years ended December 31, 2012, 2011, and 2010 consisted of the following:

	For the Years Ended			Change			
				(in thousands)			
	2012	2011	2010	2012 vs. 2011		2011 vs. 2010	
Gilead collaboration revenue	$ 2,489	$ 247	$ 180	$ 2,242	908%	$ 67	37%
Other collaboration revenue	118			118			
QTDP revenue			1,956			(1,956)	
SBIR revenue			300			(300)	
Total revenue	$ 2,607	$ 247	$ 2,436	$ 2,360	955%	$ (2,189)	(90)%

Effective with the February 2012 termination of the Gilead collaboration, we recognized the remaining $2.5 million of deferred revenue under the collaboration. We did not recognize any revenue related to the amortization of deferred revenue during the years ended December 31, 2011 and 2010 as we were unable to accurately estimate our total performance obligations under the Gilead collaboration.

During the year ended December 31, 2012, we also recognized $100,000 of revenue related to the upfront license payment received upon initiation of the Ora Agreement and $18,000 upon the subsequent sublicensing of ACH-702 entered into by Ora with Taejoon Pharmaceuticals.

During the year ended December 31, 2010, in addition to revenue under our Gilead collaboration, we recognized revenue under a SBIR grant and the QTDP program.

Comparison of the Years Ended December 31, 2012 and 2011

The increase in collaboration revenue in 2012 is primarily related to the recognition of $2.5 million of deferred revenue related to our former collaboration with Gilead which was terminated in February 2012.

Comparison of the Years Ended December 31, 2011 and 2010

The increase in collaboration revenue in 2011 was due to increased intellectual property costs related to our NS4A antagonist. These costs were incurred by us and were shared with Gilead. Reimbursement of costs under our collaboration with Gilead were recorded as revenue.

During 2010, we recognized $300,000 in grant revenue under a SBIR grant for the further study of a back-up series of compounds related to ACH-702 for the treatment of tuberculosis infection. We also recognized $2.0 million in grant revenue related to the QTDP program which provided for reimbursement of certain costs paid or incurred during 2009 and 2010 directly related to the conduct of a Qualifying Therapeutic Discovery Project.

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Research and Development Expenses:

Our research and development expenses 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			
	2012	2011	2010	2012 vs. 2011		2011 vs. 2010	
	(in thousands)						
Personnel costs	$ 8,493	$ 6,511	$ 5,970	$ 1,982	30%	$ 541	9%
Stock based compensation	1,333	1,153	785	180	16%	368	47%
Outsourced research and supplies	25,108	24,039	10,033	1,069	4%	14,006	140%
Professional and consulting fees	2,340	2,164	1,588	176	8%	576	36%
Facilities costs	2,044	1,856	2,075	188	10%	(219)	(11)%
Travel and other costs	235	136	208	99	73%	(72)	(35)%
Research and development tax credit	(554)	(418)	(130)	(136)	33%	(288)	222%
Total	$ 38,999	$ 35,441	$ 20,529	$ 3,558	10%	$ 14,912	73%

Comparison of the Years Ended December 31, 2012 and 2011

The increase in research and development expenses from 2011 to 2012 was primarily the result of increased personnel costs due to the addition of personnel in our development group. Expenses related to clinical testing and manufacturing of ACH-3102 also increased and were partially offset by decreased clinical trial expenses for ACH-2928 and decreased manufacturing expenses for ACH-2684.

We expect research and development expenses will increase fairly significantly over the next year as we initiate combination studies and continue clinical testing of ACH-1625 and ACH-3102.

Comparison of the Years Ended December 31, 2011 and 2010

The increase in research and development expenses from 2010 to 2011 was primarily the result of increased expenses related to clinical testing and manufacturing of sovaprevir, ACH-2684 and ACH-2928, combined with increased preclinical costs primarily related to ACH-3102.

General and Administrative Expenses:

General and administrative expenses consist primarily of salaries and benefits for management and administrative personnel, professional and consulting fees for legal, business development, 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			
	2012	2011	2010	2012 vs. 2011		2011 vs. 2010	
	(in thousands)						
Personnel costs	$ 3,415	$ 3,110	$ 2,650	$ 305	10%	$ 460	17%
Stock based compensation	2,599	1,836	1,478	763	42%	358	24%
Professional and consulting fees	2,809	2,219	1,429	590	27%	790	55%
Facilities costs	1,000	975	988	25	3%	(13)	(1)%
Travel and other costs	1,078	1,013	660	65	6%	353	53%
Total	$ 10,901	$ 9,153	$ 7,205	$ 1,748	19%	$ 1,948	27%

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Comparison of the Years Ended December 31, 2012 and 2011

The increase in general and administrative expenses from 2011 to 2012 was primarily due to an increase in non-cash stock compensation combined with increased professional and consulting fees including corporate legal fees, director s compensation and business development consulting fees.

Comparison of the Years Ended December 31, 2011 and 2010

The increase in general and administrative expenses from 2010 to 2011 was primarily due to an increase in professional and consulting fees including business development consulting fees and directors compensation. Additionally, corporate legal fees, salaries, non-cash charges related to stock based compensation, corporate taxes and general corporate fees also increased.

Other Income and Expense:

Comparison of the Years Ended December 31, 2012 and 2011

Interest income was $234,000 and $186,000 for the years ended December 31, 2012 and 2011, respectively. The $48,000, or 26%, increase from 2011 to 2012 was primarily due to increased average cash balances.

Interest expense was $68,000 and $45,000 for the years ended December 31, 2012 and 2011, respectively. The increase of $23,000, or 51%, was primarily due to higher average debt balances outstanding in 2012.

Comparison of the Years Ended December 31, 2011 and 2010

Interest income was $186,000 and $101,000 for the years ended December 31, 2011 and 2010, respectively. The $85,000, or 84%, increase from 2010 to 2011 was primarily due to increased average cash balances.

Interest expense was $45,000 and $284,000 for the years ended December 31, 2011 and 2010, respectively. The decrease of $239,000, or (84) %, was primarily due to lower average debt balances outstanding in 2011.

Liquidity and Capital Resources

Since our inception in August 1998, we have financed our operations primarily through proceeds from the sale of equity securities. Through December 31, 2012, we have received approximately $374.0 million in aggregate gross proceeds from stock issuances, including convertible preferred stock, our initial public offering in 2006, private placements of our common stock in 2008 and 2010 and registered offerings of our common stock in 2010, 2011 and 2012.

As of December 31, 2012, our debt balance due to borrowings was $697,000 with a weighted average interest rate of 6.56%. As of December 31, 2012, the following amounts remain outstanding under the following debt facilities:

Lender	Date	Interest Rate (per annum)	Principal Amount	Outstanding Balance	Maturity Date
Webster Bank	June 2011	6.79%	$ 437,959	$ 229,172	June 2014
Webster Bank	February 2012	6.44%	$ 608,769	$ 467,663	March 2015

We had $77.4 million, $79.9 million, and $55.2 million in aggregate cash, cash equivalents and marketable securities as of December 31, 2012, 2011, and 2010, respectively.

In August 2012, we issued 6,367,853 shares of our common stock in a registered direct offering with funds managed by QVT Financial LP. We received net proceeds of $41.7 million.

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In June 2011, we issued 11,040,000 shares of our common stock at a price of $5.90 per share in an underwritten public offering, including the exercise of the underwriter s exercise of an over-allotment option. We received net proceeds of $60.9 million, after deducting offering related expenses and underwriting discounts from this offering.

In August 2010, we issued 19,775,101 shares of our common stock at a price of $2.49 per share, as well as common stock warrants which represent the right to acquire an aggregate of 6,921,286 shares of common stock in a private placement to institutional and other accredited investors. The warrants have a seven-year term and are exercisable at a price of $3.1125 per share. The warrants allow for a net share settlement. We received net proceeds of $49.9 million from this private placement.

In January 2010, we issued 10,275,000 shares of our common stock at a price of $2.08 per share in an underwritten public offering. In February 2010, we issued an additional 1,541,250 shares of common stock in connection with the underwriter s exercise of an over-allotment option. We received net proceeds of $22.6 million from these share issuances.

In November 2012, we filed a universal shelf registration on Form S-3 to register for sale from time to time up to $200 million of common stock, preferred stock, warrants and/or units in one or more offerings. Further, in November 2012, we entered into a sales agreement with Cantor Fitzgerald & Co. pursuant to which, from time to time, we may offer and sell shares of our common stock having an aggregate offering price of up to $50 million through Cantor pursuant to such universal shelf registration statement.

Cash used in operating activities was $46.5 million for the year ended December 31, 2012 and was primarily attributable to our $47.1 million net loss combined with a $2.5 million decrease in deferred revenue, $0.8 million in premiums paid for the purchase of marketable securities, a $0.8 million increase in prepaid expenses and a $0.5 million decrease in accounts payable. These amounts were primarily offset by $4.3 million in non-cash charges related to depreciation, amortization and stock based compensation, and a $0.5 million increase in accrued expenses. Cash used in operating activities was $36.1 million for the year ended December 31, 2011 and was primarily attributable to our $44.2 million net loss and $0.6 million in premiums paid on marketable securities, primarily offset by $3.8 million in non-cash charges related to depreciation, amortization and non-cash interest and stock based compensation, a $2.1 million increase in accounts payable and a $1.9 million increase in accrued expenses. Cash used in operating activities was $24.3 million for the year ended December 31, 2010 and was primarily attributable to our $25.5 million net loss, a $1.3 million increase in prepaid expenses, $0.4 million in premiums paid on the purchase of marketable securities and a $500,000 decrease in accrued expenses, partially offset by $2.9 million in non-cash charges related to depreciation, amortization and non-cash interest and stock based compensation.

Cash provided by investing activities was $4.6 million for the year ended December 31, 2012 and was primarily attributable to maturities of marketable securities partially offset by purchases of marketable securities. Cash used in investing activities was $34.6 million for the year ended December 31, 2011 and was primarily attributable to purchases of marketable securities partially offset by maturities of marketable securities. Cash used in investing activities was $29.9 million for the year ended December 31, 2010 and was primarily attributable to purchases of marketable securities partially offset by maturities of marketable securities.

Cash provided by financing activities was $44.3 million for the year ended December 31, 2012 and was primarily attributable to $41.7 million in net proceeds from our registered direct offering in August 2012 combined with $2.4 million in proceeds from the exercise of stock options, partially offset by $0.5 million used for repayments of debt and the payment of deferred financing costs. Cash provided by financing activities was $61.5 million for the year ended December 31, 2011 and was primarily attributable to $60.9 million in net proceeds from our public offering in June 2011, partially offset by $0.5 million used for repayments of debt. Cash provided by financing activities was $69.9 million for the year ended December 31, 2010 and was primarily attributable to $72.6 million in net proceeds from our public and private offerings, partially offset by $2.9 million used for repayments of debt.

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

- continue clinical testing of sovaprevir, ACH-3102 and ACH-2684; and
- identify and progress additional drug candidates.

We do not expect our existing capital resources 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, among other things, being able to market any drug candidates, to 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) other sources of financing.

We believe that our existing cash and cash equivalents will be sufficient to meet our projected operating requirements through at least December 31, 2013. However, our funding resources and requirements may change and will depend upon numerous factors, including but not limited to:

- the costs involved in the clinical development, manufacturing and formulation of sovaprevir, ACH-3102 and ACH-2684;
- the scope of and costs associated with entering cooperative study arrangements, or CSAs, if any, for the collaborative development of our drug candidates with other s drug candidates in combination;
- 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 or equity markets that may impact our ability to obtain capital in the future;
- 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 through financing transactions, including the issuance of debt or equity securities, and/or further corporate alliances. 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, we will be required to:

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

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.

Any future equity funding may dilute the ownership of our equity investors.

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Contractual Obligations and Commitments

The following table sets forth a summary of our commitments as of December 31, 2012:

	Payment Due by Period				
	Total	Less Than 1 Year	1-3 Years	3-5 Years	More than 5 Years
			(in thousands)		
Debt, including interest	$ 746	$ 386	$ 360	$	$
Operating lease obligations	2,704	606	1,268	830	
Clinical research obligations	14,624	12,758	1,845	21	
Research obligations and licenses	575	115	230	230	
Other professional obligations	321	321			
Other license and research development agreements	1,250		100		1,150
Total	$ 20,220	$ 14,186	$ 3,803	$ 1,081	$ 1,150

Other professional obligations consist mainly of general and administrative consulting obligations. Other license and research development agreements consists of potential payments due to Yale University and Emory University upon the achievement of specified development milestones for elvucitabine. We are also required to pay Yale University and Emory University royalties on net sales of elvucitabine and a specified share of sublicensing fees that we receive under any sublicenses that we grant. The timing and achievement of such milestones is uncertain and may differ from current assumptions.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements as of December 31, 2012.

Recently Issued Accounting Standards

We review new accounting standards to determine the expected financial impact, if any, that the adoption of each such standard will have. As of the filing of this report, there were no new accounting standards issued that we expect to have a material impact on our consolidated financial position, results of operations or liquidity.

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. We invest in high-quality financial instruments, primarily money market funds, government sponsored bond obligations and government-backed corporate debt securities, with the effective duration of the portfolio less than twelve months and no security with an effective duration in excess of twenty four 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 debt or 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.

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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, 2012. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial 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, 2012, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management s Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in 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 our 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 our internal control over financial reporting as of December 31, 2012. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control Integrated Framework*.

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Based on this assessment, management concluded that, as of December 31, 2012, our internal control over financial reporting is effective based on the criteria set forth in *Internal Control Integrated Framework* issued by the COSO.

The effectiveness of our internal control over financial reporting as of December 31, 2012 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included herein.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting occurred during the fiscal quarter ended December 31, 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

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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, 2012. The information required by this item is incorporated herein by reference to the information contained under the sections captioned Election of 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 20 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 code of ethics is available on our website at www.achillion.com. We did not waive any provisions of the code of business ethics during the year ended December 31, 2012. 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.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated herein by reference to the information contained under the sections captioned Information About Executive and Director Compensation .

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.

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PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements

The following documents are included on pages F-1 through F-25 attached hereto and are filed as part of this annual report on Form 10-K.

(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.

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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 February 20, 2013.

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.

Signature	Title	Date
/s/ MICHAEL D. KISHBAUCH **Michael D. Kishbauch**	President and Chief Executive Officer and Director (Principal executive officer)	February 20, 2013
/s/ MARY KAY FENTON **Mary Kay Fenton**	Senior Vice President and Chief Financial Officer (Principal financial and accounting officer)	February 20, 2013
/s/ JASON FISHERMAN, M.D. **Jason Fisherman, M.D.**	Director	February 20, 2013
/s/ GARY E. FRASHIER **Gary E. Frashier**	Director	February 20, 2013
/s/ KURT GRAVES **Kurt Graves**	Director	February 20, 2013
/s/ DENNIS LIOTTA **Dennis Liotta**	Director	February 20, 2013
/s/ DAVID SCHEER **David Scheer**	Chairman of the Board	February 20, 2013
/s/ ROBERT VAN NOSTRAND **Robert Van Nostrand**	Director	February 20, 2013
/s/ NICOLE VITULLO **Nicole Vitullo**	Director	February 20, 2013

/s/ David Wright	Director	February 20, 2013

David Wright

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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 comprehensive loss, of stockholders equity and of cash flows present fairly, in all material respects, the financial position of Achillion Pharmaceuticals, Inc. at December 31, 2012 and December 31, 2011, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2012 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company s management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management s Annual Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company s internal control over financial reporting based on our audits (which were integrated audits in 2012 and 2011). We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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

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

/s/ PricewaterhouseCoopers LLP

Hartford, Connecticut

February 20, 2013

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Achillion Pharmaceuticals, Inc.

Balance Sheets

(in thousands, except per share amounts)

	As of December 31, 2012	2011
Assets		
Current assets:		
Cash and cash equivalents	$ 18,526	$ 16,110
Marketable securities	46,884	37,456
Accounts and other receivables	277	103
Prepaid expenses and other current assets	2,180	1,423
Total current assets	67,867	55,092
Marketable securities	12,008	26,377
Fixed assets, net	1,247	994
Deferred financing costs	256	15
Restricted cash	152	152
Total assets	$ 81,530	$ 82,630
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 4,276	$ 4,795
Accrued expenses	4,510	4,008
Current portion of long-term debt	350	141
Total current liabilities	9,136	8,944
Long-term debt	347	229
Deferred revenue		2,489
Total liabilities	9,483	11,662
Commitments (Notes 13 and 14)		
Stockholders Equity:		
Preferred Stock, undesignated, $.01 par value; 5,000 shares authorized at December 31, 2012 and 2011; no shares issued or outstanding		
Common Stock, $.001 par value; 200,000 shares authorized at December 31, 2012 and 2011; 79,626 and 69,788 shares issued and outstanding at December 31, 2012 and 2011, respectively	80	70
Additional paid-in capital	394,675	346,518
Accumulated deficit	(322,727)	(275,600)
Accumulated other comprehensive income (loss)	19	(20)
Total stockholders equity	72,047	70,968
Total liabilities and stockholders equity	$ 81,530	$ 82,630

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

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Achillion Pharmaceuticals, Inc.

Statements of Comprehensive Loss

(in thousands, except per share amounts)

	Years Ended December 31,		
	2012	2011	2010
Revenue	$ 2,607	$ 247	$ 2,436
Operating expenses			
Research and development	38,999	35,441	20,529
General and administrative	10,901	9,153	7,205
Total operating expenses	49,900	44,594	27,734
Loss from operations	(47,293)	(44,347)	(25,298)
Other income (expense)			
Interest income	234	186	101
Interest expense	(68)	(45)	(284)
Net loss	$ (47,127)	$ (44,206)	$ (25,481)
Unrealized gain (loss) on marketable securities	39	(22)	2
Total other comprehensive income	39	(22)	2
Total comprehensive loss	$ (47,088)	$ (44,228)	$ (25,479)
Basic and diluted net loss per share attributable to common stockholders (Note 4)	$ (0.64)	$ (0.69)	$ (0.57)
Weighted average shares used in computing basic and diluted net loss per share attributable to common stockholders	73,965	64,248	45,079

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

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Achillion Pharmaceuticals, Inc.

Statements of Stockholders Equity for the Years Ended December 31, 2010, 2011 and 2012

(in thousands)

	Common Stock					
	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders Equity
Balances at December 31, 2009	26,706	$ 27	$ 206,908	$ (205,913)	$	$ 1,022
Net loss				(25,481)		(25,481)
Other comprehensive income (loss)					2	2
Comprehensive loss						(25,479)
Stock compensation			2,263			2,263
Issuance of common stock upon exercise stock options	26		77			77
Issuance of common stock under the Employee Stock Purchase Plan	53		99			99
Issuance of common stock and warrants in connection with the public offering and private placement, net of issuance costs	31,591	31	72,531			72,562
Balances at December 31, 2010	58,376	$ 58	$ 281,878	$ (231,394)	$ 2	$ 50,544
Net loss				(44,206)		(44,206)
Other comprehensive income (loss)					(22)	(22)
Comprehensive loss						(44,228)
Stock compensation			2,989			2,989
Issuance of common stock upon exercise of warrants	8					
Issuance of common stock upon exercise of stock options	320	1	569			570
Issuance of common stock under the Employee Stock Purchase Plan	44		146			146
Issuance of common stock in connection with the public offering, net of issuance costs	11,040	11	60,936			60,947
Balances at December 31, 2011	69,788	$ 70	$ 346,518	$ (275,600)	$ (20)	$ 70,968
Net loss				(47,127)		(47,127)
Other comprehensive income (loss)					39	39
Comprehensive loss						(47,088)
Stock compensation			3,932			3,932
Issuance of common stock upon exercise of warrants	2,549	3	(3)			
Issuance of common stock upon exercise of stock options	888	1	2,378			2,379
Issuance of common stock under the Employee Stock Purchase Plan	33		196			196
Issuance of common stock in connection with the public offering, net of issuance costs	6,368	6	41,654			41,660
Balances at December 31, 2012	79,626	$ 80	$ 394,675	$ (322,727)	$ 19	$ 72,047

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

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Achillion Pharmaceuticals, Inc.

Statements of Cash Flows

(in thousands)

	Years Ended December 31,		
	2012	**2011**	**2010**
Cash flows from operating activities			
Net loss	$ (47,127)	$ (44,206)	$ (25,481)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	408	327	615
Noncash stock-based compensation	3,932	2,989	2,263
Noncash interest expense		9	52
(Gain) loss on disposal/trade-in of equipment	1	(111)	6
Premium on purchases of marketable securities	(755)	(574)	(406)
Amortization of premium (accretion of discount) on marketable securities	444	478	325
Changes in operating assets and liabilities:			
Accounts and other receivables	(174)	143	(181)
Prepaid expenses and other current assets	(757)	739	(1,348)
Accounts payable	(519)	2,123	395
Accrued expenses	502	1,947	(537)
Deferred revenue	(2,489)		
Net cash used in operating activities	(46,534)	(36,136)	(24,297)
Cash flows from investing activities			
Purchase of fixed assets	(656)	(732)	(169)
Purchase of marketable securities	(79,759)	(79,706)	(39,294)
Maturities of marketable securities	85,050	45,774	9,550
Net cash provided by (used in) investing activities	4,635	(34,664)	(29,913)
Cash flows from financing activities			
Proceeds from issuance of common stock and warrants in connection with the public offering and private placement, net of issuance costs	41,660	60,947	72,562
Proceeds from exercise of stock options	2,378	570	77
Proceeds from sale of stock under the Employee Stock Purchase Plan	197	146	99
Borrowings of debt	609	438	
Repayments of debt	(282)	(546)	(2,867)
Payment of deferred financing costs	(247)	(18)	
Net cash provided by financing activities	44,315	61,537	69,871
Net increase (decrease) in cash and cash equivalents	2,416	(9,263)	15,661
Cash and cash equivalents, beginning of period	16,110	25,373	9,712
Cash and cash equivalents, end of period	$ 18,526	$ 16,110	$ 25,373
Supplemental disclosure of cash flow information			
Cash paid for interest	$ 60	$ 33	$ 207
Supplemental disclosure of noncash financing activities			
Cashless exercise of warrants	$ 14,106	$ 43	$

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

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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 $308,865 from inception through December 31, 2012 and had an accumulated deficit of $322,727 at December 31, 2012, which includes preferred stock dividends recognized until the Company s initial public offering in 2006. The Company has funded its operations primarily through the sale of equity securities.

The Company believes that its existing cash, cash equivalents and marketable securities will be sufficient to support its current operating plan through at least December 31, 2013. However, the Company s operating plan may change as a result of many factors, including but not limited to:

- the costs involved in the clinical development, manufacturing and formulation of sovaprevir, ACH-3102 and ACH-2684;
- the scope of and costs associated with entering cooperative study arrangements, or CSAs, if any, for the collaborative development of our drug candidates with other s drug candidates in combination;
- the costs involved in obtaining regulatory approvals for the Company s drug candidates;
- the scope, prioritization and number of programs the Company pursues;
- the costs involved in preparing, filing, prosecuting, maintaining, enforcing and defending patent and other intellectual property claims;
- the Company s ability to raise incremental debt or equity capital, including any changes in the credit or equity markets that may impact its ability to obtain capital in the future;
- the Company s acquisition and development of new technologies and drug candidates; and
- competing technological and market developments currently unknown to the Company.

Certain prior period amounts have been reclassified to conform to the current year s presentation. The premiums paid on the purchase of marketable securities were reclassified from investing activities to operating activities on the Statement of Cash Flows for the years ended December 31, 2011 and 2010.

Upon adoption of the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2011-05 Comprehensive Income: Presentation of Comprehensive Income as of January 1, 2012, the Company has elected the single continuous statement option. As this

guidance relates to presentation only, the adoption of this guidance did not have any other effect on the Company s financial statements.

2. 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.

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Revenue Recognition

The Company recognizes revenue from contract research and development and research progress payments in accordance with ASC 605, *Revenue Recognition*. Revenue-generating research and development collaborations are often multiple element arrangements, providing for a license as well as research and development services. In order to account for these arrangements, the Company must identify the deliverable included within the arrangement and evaluate which deliverables represent separate units of accounting based on if certain criteria are met, including whether the delivered element has stand-alone value to the collaborator. The consideration received is allocated among the separate units of accounting and the applicable revenue recognition criteria are applied to each of the separate units.

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 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 its performance obligations under the arrangement. Actual effort is generally determined based upon actual direct labor hours or full-time equivalents (FTE) incurred and include research and development activities performed by internal scientists. Total expected effort is generally based upon the total direct labor hours of FTEs 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 the Company expects to complete the related performance obligations. 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, including negative revenue in some periods. 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.

Substantive milestone payments are recognized upon achievement of the milestone. Determining whether a milestone is substantive requires judgment that should be made at the inception of the arrangement. To meet the definition of a substantive milestone, the consideration earned by achieving the milestone (1) would have to be commensurate with either the level of effort required to achieve the milestone or the enhancement in the value of the item delivered, (2) would have to relate solely to past performance, and (3) should be reasonable relative to all deliverables and payment terms in the arrangement. No bifurcation of an individual milestone is allowed and there can be more than one milestone in an arrangement.

Effective with the February 2012 termination of the Gilead collaboration, the Company recognized the remaining $2,489 of deferred revenue. The Company did not recognize any revenue related to the amortization of deferred revenue during the years ended December 31, 2011 and 2010 as the Company was unable to accurately estimate its total performance obligations under the Gilead collaboration.

During the year ended December 31, 2012, the Company recognized $100 of revenue related to the upfront license payments received upon initiation of the Ora agreement and $18 upon the subsequent sublicensing agreement entered into by Ora with Taejoon Pharmaceutical. The Company does not believe that the milestones specified under the agreement are substantive as achievement of the milestones is based solely on the performance of Ora and their sub licensee(s) and does not relate to any past or future performance by the Company. Because the Company has no performance obligations under the agreement, it intends to recognize milestone revenues upon achievement of the milestones by Ora.

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The Company recognizes grant revenue when the following criteria are met: persuasive evidence of an arrangement exists, services have been rendered, the price is fixed or determinable, and collectability is reasonably assured. For the year ended December 31, 2010, the Company s grant revenue consisted of amounts related to a Small Business Innovation Research, or SBIR, grant by the National Institutes of Health and revenue related to the Qualifying Therapeutic Discovery Project program, or QTDP. The SBIR grant was for the further study of a back-up series of compounds related to ACH-702 for the treatment of tuberculosis infection. The QTDP program was created by the United States Congress as part of the Patient Protection and Affordable Care Act and provided for reimbursement of certain costs paid or incurred during 2009 and 2010 directly related to the conduct of a Qualifying Therapeutic Discovery Project, as defined. The Department of Health and Human Services designated such projects based on the potential for them to result in new therapies to treat areas of unmet medical need, the potential to create and sustain jobs in the U.S. and to advance U.S. competitiveness. No grant revenue was recognized during the years ended December 31, 2012 or 2011.

Stock-Based Compensation Employee Stock-Based Awards

The Company applies the provisions of ASC 718, *Stock Compensation,* 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.

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, stock-based compensation cost is based on the fair value of the portion of stock-based awards that is ultimately expected to vest.

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.

The Company utilizes the simplified method in developing an estimate of the expected term of plain vanilla share options. This method is considered appropriate given the Company s limited exercise history. Further, the Company does not believe the exercise patterns associated with these option grants are predictive of future exercise patterns. Additionally, the Company calculates volatility based on actual volatility from the end of its initial public offering lock-up period to the end of the reporting period. For periods before we had sufficient actual volatility data, we used a weighted average rate of historical and peer group volatility. The Company estimates forfeitures at the grant date and recognizes compensation costs for only those awards that are expected to vest.

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

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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 fair value, 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 in 2017. At December 31, 2012, the Company had $14,726 of cash and $3,800 of cash equivalents.

Marketable Securities and Equity Investments

The Company applies the provisions of ASC 820, *Fair Value Measurements and Disclosures,* for financial assets and liabilities measured on a recurring basis which requires disclosure that establishes a framework for measuring fair value. The guidance requires that fair value measurements be classified and disclosed in one of 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 marketable securities of $58,892 as of December 31, 2012 was valued based on level 2 inputs. The Company s investments consist mainly of U.S. government and agency securities, government sponsored bond obligations and certain other corporate debt securities. Fair value is determined by taking into consideration valuations obtained from third-party pricing services. The third-party pricing services utilize industry standard valuation models, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; and other observable inputs. The Company classifies its entire investment portfolio as available for sale as defined in ASC 320, *Debt and Equity Securities*. Securities are carried at fair value with the unrealized gains (losses) reported as a separate component of stockholders equity within accumulated other comprehensive income.

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.

The Company believes that the carrying value of its debt balance outstanding approximates fair value. Fair value is determined using a discounted cash flow model based on current interest rates.

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.

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For the years ended December 31, 2012, 2011 and 2010, 95%, 100% and 7%, respectively, of the Company s revenue was generated from an agreement with one former collaboration partner. At December 31, 2012, 2011 and 2010, 0%, 60% and 7%, respectively, 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	Lesser of life of improvement or lease term

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) from operations.

Long-lived Assets

ASC 360, *Property, Plant and Equipment,* 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 and indirect 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.

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.

The Company applies the provisions of ASC 740, *Income Taxe*s, which 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). 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 did not have any unrecognized tax benefits as of December 31, 2012. 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.

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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.

Accounting Standards Updates

In June 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2011-05 Comprehensive Income: Presentation of Comprehensive Income. Under the amendment, an entity has the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. This amendment, therefore, eliminated the option to present the components of other comprehensive income as part of the statement of changes in stockholders equity. The amendment did not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. In December 2011, the FASB issued ASU No. 2011-12, Comprehensive Income: Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in ASU No. 2011-05 (ASU 2011-12). ASU 2011-12 deferred changes in Update 2011-05 that relate to the presentation of reclassification adjustments. ASU 2011-12 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. The Company adopted this guidance as of January 1, 2012 and elected the single continuous statement option. As this guidance relates to presentation only, the adoption of this guidance did not have any other effect on the Company s financial statements.

In May 2011, the FASB issued ASU 2011-04, Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and International Financial Reporting Standards (IFRS). ASU 2011-04 represents converged guidance between generally accepted accounting principles in the United States (U.S. GAAP) and IFRS resulting in common requirements for measuring fair value and for disclosing information about fair value measurements. This new guidance is effective for interim and annual periods beginning after December 15, 2011. The Company adopted this guidance as of January 1, 2012. The adoption of ASU 2011-04 did not have a material impact on the Company s condensed consolidated financial statements.

3. Financing Activities

Public Offerings

In August 2012, the Company issued 6,368 shares of the Company s common stock, par value $0.001 per share, at a price per share of $6.57, in a registered direct offering to funds managed by QVT Financial LP. The shares were offered and sold pursuant to a registration statement on Form S-3 and a related prospectus supplement filed with the SEC on August 30, 2012. The offering resulted in net proceeds to the Company of $41,660.

In June 2011, the Company entered into an underwriting agreement (the Underwriting Agreement) with Merrill Lynch, Pierce, Fenner & Smith Incorporated and Leerink Swann LLC, as underwriters (the Underwriters) related to a public offering of shares of the Company s common stock, par value $.001 per share, at a price of $5.90 per share less underwriting discounts and commissions (the Offering). The Company issued and sold an aggregate of 11,040 shares of common stock in connection with the Offering and the exercise of the over-allotment option that was granted to the underwriters in the Underwriting Agreement. The Offering resulted in net proceeds to the Company of $60,947.

In January 2010, the Company entered into an underwriting agreement (the Underwriting Agreement) with Roth Capital Partners, LLC, Noble Financial Capital Markets and National Securities Corporation, as underwriters (the Underwriters), related to a public offering of shares of the Company s common stock, par

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value $.001 per share, at a price of $2.08 per share less underwriting discounts and commissions (the Offering). The Company issued and sold 10,275 shares of common stock in connection with the Offering in January 2010. In February 2010, the Company issued and sold an additional 1,541 shares of common stock in connection with the exercise of the over-allotment option that was granted to the underwriters in the Underwriting Agreement. The Offering resulted in net proceeds to the Company of $22,628.

Private Placements

In August 2010, the Company issued 19,775 shares of the Company s common stock at a price of $2.49 per share, as well as warrants to purchase 0.35 shares of common stock for each share issued (the Common Warrants) of common stock underlying each Common Warrant in a private placement to institutional and other accredited investors (the Private Placement). The Common Warrants, which represent the right to acquire an aggregate of 6,921 shares of common stock, expire on August 20, 2017, and are exercisable at a price of $3.1125 per share. The warrants allow for a net share settlement. The Private Placement resulted in net proceeds to the Company of $49,934.

The Common Warrants issued in the Private Placement meet the conditions necessary for equity classification pursuant to ASC 815, *Derivatives and Hedging.*

Pursuant to the Company s obligations, in September 2010, the Company filed a registration statement with the Securities and Exchange Commission covering the resale of the 19,775 shares of common stock issued in the Private Placement and the 6,921 shares of common stock issuable upon the exercise of the Common Warrants. This registration statement was declared effective by the Securities and Exchange Commission on September 30, 2010.

4. Earnings (Loss) Per Share (EPS)

Basic EPS is calculated in accordance with ASC 260, *Earnings Per Share*, by dividing net income or loss attributable to common stockholders by the weighted average common stock outstanding. Diluted EPS is calculated by adjusting weighted average common shares outstanding for the dilutive effect of common stock options and warrants. In periods in which a net loss is recorded, no effect is given to potentially dilutive securities, since the effect would be antidilutive. The calculation of basic and diluted net loss per share are as follows:

	Years Ended December 31,		
	2012	2011	2010
Net loss (numerator)	$ (47,127)	$ (44,206)	$ (25,481)
Weighted-average shares, in thousands (denominator)	73,965	64,248	45,079
Total potentially dilutive securities outstanding	$ (0.64)	$ (0.69)	$ (0.57)

Securities that could potentially dilute basic EPS in the future were not included in the computation of diluted EPS because to do so would have been antidilutive. Potentially dilutive securities were as follows during the years ended December 31, 2012, 2011 and 2010:

	Years Ended December 31,		
	2012	2011	2010
Stock Options:			
Weighted average number, in thousands	6,038	5,804	3,449
Weighted average exercise price	$ 5.56	$ 4.40	$ 3.67
Warrants:			
Weighted average number, in thousands	7,168	9,665	5,321
Weighted average exercise price	$ 3.21	$ 3.25	$ 3.27

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5. Collaboration Arrangements

Gilead Sciences, Inc.

In November 2004, the Company entered into a research collaboration and license agreement with Gilead Sciences, Inc. (Gilead) pursuant to which the Company agreed to collaborate exclusively with Gilead to develop and commercialize compounds for the treatment of chronic hepatitis C which inhibit HCV replication through a novel mechanism of action targeting the HCV NS4A protein. In February 2012, the Company s collaboration with Gilead was terminated. The Company retains the right to develop ACH-1095, an NS5A antagonist, although it does not have current plans to do so.

The Company received $10,000 from Gilead upon the execution of the license agreement, of which $2,000 was allocated to the fair value of the preferred stock purchased. The remaining $8,000 of the non-refundable up-front license fee, as well as a $2,000 milestone achieved during the period prior to achievement of proof-of-concept, were accounted for under the proportionate performance model.

During the year ended December 31, 2012, effective with the termination of the collaboration, the Company recognized the remaining $2,489 of deferred revenue as it no longer has any future obligations under the collaboration. During the years ended December 31, 2011 and 2010, the Company did not recognize revenue from upfront, milestone and FTE fees previously received under the collaboration as it was unable to estimate its total performance obligations under the collaboration.

During the years ended December 31, 2012, 2011 and 2010, the Company recognized cost-sharing revenue of $0, $247 and $180, respectively, of external costs billed by the Company to Gilead. Payments to Gilead under this collaboration were recognized as a reduction in revenue.

Included in the accompanying balance sheets as of December 31, 2012 and 2011 are $0 and $62, of accounts receivable resulting from this collaboration agreement and $0 and $2,489, respectively, of deferred revenue resulting from the up-front fee, the milestone payment and FTE costs.

GCA Therapeutics, Ltd.

In February 2010, the Company entered into a license agreement (the Agreement) with GCA Therapeutics, Ltd. (GCAT) for elvucitabine, the Company s nucleoside reverse transcriptase inhibitor for the treatment of both hepatitis B virus (HBV) infection and human immunodeficiency virus (HIV) infection. The Agreement was amended and restated in March 2010. The exclusive license grants GCAT the right, through a Chinese joint venture with Tianjing Institute of Pharmaceutical Research, to clinically develop and commercialize elvucitabine in mainland China, Hong Kong and Taiwan.

Under the terms of the Agreement, GCAT, through a sublicense agreement with a Chinese joint venture, T&T Pharma Co., Ltd., will assume all development and regulatory responsibility and associated costs for elvucitabine. There was no financial impact upon the signing of the agreement. Upon the first commercial sale of a licensed product GCAT is obligated to pay $100 to the Company. Further, the Company will be eligible to receive royalties up to 15% of net sales in those territories.

The Company does not believe that the milestone specified under the Agreement is substantive as achievement of the milestone is based solely on the performance of GCAT and does not relate to any past or future performance by the Company. Because the Company has no performance obligations under the Agreement, it intends to recognize revenue related to the milestone payment upon achievement of the milestone by GCAT. However, there can be no assurance that GCAT will achieve the milestone or that the Company will receive the related revenue. This Agreement shall be effective, unless earlier terminated, until the expiration of the last to expire royalty term.

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Ora, Inc.

In October 2012, the Company entered into a license and development agreement (the Ora Agreement) with Ora, Inc. (Ora) for the worldwide development and commercialization of ACH-702 delivered topically or locally. Under the terms of the Ora Agreement, Ora will assume development and regulatory responsibility and associated costs for ACH-702. Upon initiation of the agreement, the Company received a one-time license fee of $100, which was recognized as revenue upon the completion of the technology transfer by the Company. The Company is eligible to receive up to $4,000 in development milestones and up to $7,000 in commercialization milestones as well as royalties up to 3.5% of net sales. The Company has no further obligations under the Ora Agreement.

The Ora Agreement includes the right to sublicense any or all of the licensed rights, subject to the Company s approval. Ora shall pay the Company15% of all up-front licensing payments and any other payment allocated to or received by Ora pursuant to any sublicense agreement granted by Ora under this agreement; provided that such payment is not a royalty on net sales and not a development or commercial milestone already due to Achillion. In December 2012, Ora entered into a sublicense agreement with Taejoon Pharmaceutical Co. for the development of ACH-702.

The Company does not believe that the milestones specified under the Ora Agreement are substantive as achievement of the milestones is based solely on the performance of Ora and its sub licensee(s) and does not relate to any past or future performance by the Company. Because the Company has no performance obligations under the Ora Agreement, it intends to recognize revenue related to the milestone payments upon achievement of the milestone by Ora or its sub licensee(s). The Ora Agreement shall be effective and, unless earlier terminated, will continue until the last sale of each and every licensed product to an unrelated third party by Ora, its affiliate or sublicensee.

6. Marketable Securities

The fair value of the Company s marketable securities of $58,892 and $63,833 as of December 31, 2012 and 2011, respectively, is valued based on level 2 inputs. The Company s investments consist mainly of U.S. government and agency securities, government sponsored bond obligations and certain other corporate debt securities. Fair value is determined by taking into consideration valuations obtained from third-party pricing services. The third-party pricing services utilize industry standard valuation models, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; and other observable inputs. There were no transfers between levels within the hierarchy during the year ended December 31, 2012. The Company classifies its entire investment portfolio as available for sale as defined in ASC 320, *Debt and Equity Securities*. Securities are carried at fair value with the unrealized gains (losses) reported in other comprehensive income.

As of December 31, 2012, none of the Company s investments were determined to be other than temporarily impaired.

The following table summarizes the Company s investments:

	As of December 31,					
	2012			2011		
	Amortized Cost	Unrealized Gain (Loss)	Estimated Fair Value	Amortized Cost	Unrealized Gain (Loss)	Estimated Fair Value
Commercial Paper	$ 30,462	$ 29	$ 30,491	$ 19,488	$ 11	$ 19,499
Corporate Debt Securities	26,912	(11)	26,901	12,866	(18)	12,848
Government and Agency Securities	1,499	1	1,500	28,499	(13)	28,486
Certificate of Deposit				3,000		3,000
Total	$ 58,873	$ 19	$ 58,892	$ 63,853	$ (20)	$ 63,833

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The following additional table summarizes, by industry, the fair value of investments:

	As of December 31, 2012	2011
Government	$ 1,500	$ 34,989
Banking	21,703	21,070
Industrial	35,689	7,774
Total	$ 58,892	$ 63,833

7. Prepaid Expenses and Other Current Assets

A summary of prepaid expenses and other current assets is as follows:

	As of December 31, 2012	2011
Prepaid research and development costs	$ 1,126	$ 343
Tax credit receivable	552	420
Maintenance agreements	219	159
Interest receivable	241	260
Other prepaid expenses	42	241
Total	$ 2,180	$ 1,423

8. Fixed Assets, net

A summary of property and equipment is as follows:

	As of December 31, 2012	2011
Laboratory equipment	$ 2,880	$ 2,907
Office equipment	736	658
Leasehold improvements	2,963	2,919
	6,579	6,484
Less accumulated depreciation and amortization	(5,332)	(5,490)
Total	$ 1,247	$ 994

Depreciation expense was $402, $317 and $571for the years ended December 31, 2012, 2011 and 2010, respectively.

9. Accrued Expenses

Accrued expenses consist of the following:

	As of December 31,

	2012	2011
Accrued compensation	$ 507	$ 1,169
Accrued research and development expenses	3,280	2,341
Accrued professional expenses	426	281
Other accrued expenses	297	217
Total	$ 4,510	$ 4,008

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Accrued research and development 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, 2012	2011
2011 Credit Facility, payable in equal monthly installments through March 2015, with fixed interest of 6.44% to 6.79% per annum	$ 697	$ 370
Total long-term debt	697	370
Less: current portion	(350)	(141)
Total long-term debt, net of current portion	$ 347	$ 229

In March 2011, the Company entered into a Master Security Agreement for a $2,000 Capital Expenditure Line of Credit, (the 2011 Credit Facility) with Webster Bank. Under the 2011 Credit Facility, the Company can draw down equipment loan advances for the purchase of new laboratory equipment through March 2013. The purchased equipment serves as collateral for the 2011 Credit Facility. Through December 31, 2012, the Company had drawn down $1,047 under the 2011 Credit Facility.

The fair value for this debt would be classified as a level 2 measurement. Fair value is computed using a discounted cash flow model based on current interest rates. At this time, the carrying value approximates fair value.

11. Capital Structure

Preferred Stock

At December 31, 2012, the Company had 5,000 authorized shares of undesignated preferred stock of which no shares were issued and outstanding.

Common Stock

At December 31, 2012, the Company had 200,000 authorized shares of $0.001 par value common stock of which 79,626 shares were issued and outstanding and 24,589 shares were reserved for future issuance.

Warrants

At December 31, 2012, there were 5,358 warrants outstanding with a weighted average exercise price of $3.21 and a weighted average remaining contractual life of 4.33 years.

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.

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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 the Company s initial public offering. The Company originally reserved for issuance 750 shares of common stock under the 2006 Plan. In addition, the Plan contained an evergreen provision, which allowed 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. Under the evergreen provision, the Company registered an additional 2,673 shares of common stock to be issued under the 2006 Plan.

On June 10, 2010, stockholders of the Company approved an amendment to the 2006 Plan to increase by 3,000 shares the number of shares of common stock reserved for issuance under the 2006 Plan from 3,423 shares to 6,423 shares.

On June 5, 2012, stockholders of the Company approved an amendment to the 2006 Plan to increase by 7,000 shares the number of shares of common stock reserved for issuance under the 2006 Plan from 6,423 shares to 13,423 shares.

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;
- 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 Incentive 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.

As of December 31, 2012, there were 5,689 shares available to be granted under the 2006 Plan.

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A summary of the status of the Company s stock option activity for the year ended December 31, 2012 is presented in the table and narrative below:

	2012	
	Options	Weighted Average Exercise Price
Outstanding at January 1, 2012	6,610	$ 4.40
Granted	1,754	8.40
Exercised	(888)	2.68
Forfeited	(335)	5.33
Cancelled	(29)	3.30
Outstanding at December 31, 2012	7,112	$ 5.56
Options exercisable at December 31, 2012	3,595	$ 4.69
Options vested and expected to vest at December 31, 2012	6,762	$ 5.51

The following table summarizes information about stock options outstanding at December 31, 2012:

	Options Outstanding			Options Vested	
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Vested	Weighted Average Exercise Price
$0.00 $2.00	605	5.8	$ 1.05	597	$ 1.05
$2.01 $4.00	2,905	7.6	3.14	1,703	3.16
$4.01 $6.00	601	5.1	5.08	569	5.04
$6.01 $8.00	1,126	8.9	7.36	337	7.37
$8.01 $10.00	1,485	10.0	8.64	40	8.64
$10.01 $12.00	41	9.4	10.63		
$12.01 $14.00	2	3.8	14.00	2	14.00
$14.01 $16.00	343	4.0	14.75	343	14.75
$16.01 $20.00	4	4.1	19.00	4	19.00
	7,112	7.8	$ 5.56	3,595	$ 4.69

As of December 31, 2012, the intrinsic value of the options outstanding and options vested was $20,845 and $14,324, respectively. 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.

The total intrinsic value of stock options exercised for the years ended December 31, 2012, 2011 and 2010 was $6,206, $1,721 and $2, respectively.

The weighted-average grant-date fair value of options granted during the years ended December 31, 2012, 2011 and 2010 was $6.15, $5.40 and $2.25, respectively. The weighted-average grant-date fair value of options vested at December 31, 2012 and 2011 was $3.31 and $3.35, respectively.

The weighted average remaining contractual life is 6.6 years for options exercisable and 7.7 years for options vested and expected to vest.

Stock Based Compensation

Under the provisions of ASC 718, stock-based compensation cost is based on the fair value of the portion of stock-based awards that is ultimately expected to vest during the period. The Company utilizes the Black-Scholes

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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. The Company is also 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. In addition, due to the Company s limited exercise history, the Company utilizes the simplified method in developing an estimate of expected term of plain vanilla options.

The assumptions used to value options granted are as follows:

	For the Years Ended December 31,		
	2012	2011	2010
Expected term of option	5.0 - 6.1 years	5.0 - 6.1 years	5.0 - 6.1 years
Expected volatility	88% - 90%	87% - 88%	86% - 87%
Risk free interest rate	0.83 1.33%	1.09 - 2.57%	1.59 - 2.92%
Expected dividend yield	0%	0%	0%

Total compensation expense recorded in the accompanying statements of comprehensive loss associated with option grants made to employees for the years ended December 31, 2012, 2011 and 2010 was $3,643, $2,747 and $2,163, respectively. Total compensation expense recorded in the accompanying statements of comprehensive loss associated with option grants made to consultants for the years ended December 31, 2012, 2011 and 2010 was $197, $175 and $61, respectively. The Company recorded no tax benefit related to these options as the Company is currently in a net operating loss position and maintains a full valuation allowance.

As of December 31, 2012, the total compensation cost related to options not yet recognized in the financial statements is approximately $14,519, net of estimated forfeitures, and the weighted average period over which it is expected to be recognized is 1.7 years.

2006 Employee Stock Purchase Plan

The Company established an Employee Stock Purchase Plan effective December 1, 2006 (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 originally reserved for issuance 250 shares of common stock under the 2006 ESPP Plan. On June 10, 2010, stockholders of the Company approved an amendment to the 2006 ESPP Plan to increase by 250 shares the number of shares of common stock reserved for issuance under the 2006 ESPP Plan from 250 shares to 500 shares.

The Company measures the fair value of issuances under the 2006 ESPP 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 Company recorded compensation cost related to 2006 ESPP Plan of $92, $67 and $39 for the years ended December 31, 2012, 2011 and 2010, respectively. As of December 31, 2012, there were 188 shares available for future issuance under the 2006 ESPP Plan.

13. Other License and Research and Development Agreements

The Company has entered into certain non-exclusive HCV 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 non-exclusive licenses to use the licensed compounds or

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technologies. Included in the accompanying 2012, 2011 and 2010 statements of operations is $153, $145 and $140, respectively, of research and development expense resulting from these arrangements. In order to maintain its rights under these agreements, provided that the Company does not terminate such agreements, the Company will also be required to pay an additional $575 of aggregate minimum payments over the next five years.

In February 2000, the Company entered into a license agreement with Vion Pharmaceuticals, (Vion), pursuant to which it 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 University, (Yale). Upon the dissolution of Vion in a 2011 bankruptcy, the Company became a direct licensee of Yale. 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. Through December 31, 2012, the Company has made aggregate payments of $35 to Yale under this agreement, including a $10 initial license fee and a $25 development milestone payment. Under the terms of the agreement, the Company may be required to make additional milestone payments to Yale of up to an aggregate of $850 for each licensed product based on the achievement of specified development and regulatory approval milestones. The Company is also required to pay Yale specified royalties on net product sales and a specified share of sublicensing fees that it receives under any sublicenses that it grants. No other payments are included in the Company s financial statements as these payments are contingent on the achievement of certain milestones that have not yet been reached.

In July 2002, the Company entered into a license agreement with Emory University (Emory), pursuant to which it 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, 2012, the Company has made aggregate payments of $150 to Emory under this agreement, including an initial license fee of $100 and a development milestone payment of $50. The Company may also be required to make additional payments of up to an aggregate of $400 based on the achievement of specified development and regulatory approval milestones. Under this agreement, the Company is also required to pay Emory specified royalties on net product sales and a specified share of sublicensing fees that it receives under any sublicenses that it grants. As these payments are contingent on the achievement of certain milestones that have not yet been reached, the related amounts are not recognized as expense in the accompanying financial statements.

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 $203, $177 and $165 for the years ended December 31, 2012, 2011 and 2010.

Operating Leases

The Company leases its operating facility located in New Haven, Connecticut. The lease agreements require monthly lease payments through March 2017. The Company is recording the expense associated with the lease on a straight-line basis over the expected seven-year term of the lease and, as a result, has accrued $89 and $72 at December 31, 2012 and 2011, respectively.

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The future minimum annual lease payments under these operating leases at December 31, 2012 are as follows:

Year Ended December 31,	
2013	$ 606
2014	$ 630
2015	$ 638
2016	$ 662
2017	$ 168
Total	$ 2,704

Rent expense under operating leases was approximately $617, $616 and $693 for the years ended December 31, 2012, 2011 and 2010, 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.

The Company applies the provisions of ASC 740, *Income Taxes,* which 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). The Company s 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:

	As of December 31,		
	2012	2011	2010
Deferred:			
Federal and state	$ 3,293	$ (19,855)	$ (10,882)
Valuation allowance	(3,293)	19,855	10,882
Total deferred	$	$	$

A reconciliation of the statutory tax rates to the effective tax rates is as follows:

	Years Ended December 31,		
	2012	2011	2010
Federal statutory rate	(34.0)%	(34.0)%	(34.0)%
State tax, net of federal benefit	(5.0)	(5.0)	(5.0)
Other	0.05	0.1	0.1
Share-based compensation	(2.51)	1.3	4.2
Valuation allowance	41.46	37.6	34.7

0%	0%	0%

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Future tax benefits (deferred tax assets) related to temporary differences are as follows:

	As of December 31, 2012	2011
Gross deferred tax assets:		
Net operating losses	$ 103,017	$ 102,022
Tax credits (federal and state)	6,388	10,132
Deferred revenue		1,033
Share-based compensation	3,217	2,781
Other	954	902
	$ 113,576	$ 116,870
Less valuation allowance	(113,576)	(116,870)
Net deferred tax asset	$	$

At December 31, 2012 and 2011, the Company had gross deferred income tax assets of approximately $113,576 and $116,870, respectively, which result primarily from net operating loss and tax credit carryforwards. ASC 740 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, 2012 and 2011, the Company had available the following net operating loss and credit carryforwards:

	As of December 31, 2012	2011
Federal net operating loss carryforwards	$ 237,749	$ 245,266
State net operating loss carryforwards	295,768	248,420
Federal research and development credit carryforwards	2,629	6,695
State research and development credit carryforwards	3,759	3,437

The Company s federal net operating loss carryforwards expire commencing in 2018 through 2032 and state net operating loss carryforwards which expire commencing in 2020 through 2032. The Company s federal research and development credit carryforwards expire commencing in 2028 through 2031. The Connecticut research and development carryforwards have no expiration period.

Deferred tax assets relating to tax benefits of employee stock options have been reduced to reflect exercises. Some exercises resulted in tax deductions in excess of previously recorded benefits based on the option value at the time of grant (windfalls). Although these windfalls are reflected in net operating loss carryforwards, the additional tax benefit associated with the windfall is not recognized until the deduction reduces taxes payable. Accordingly, approximately $5,418 of the net operating loss carryforwards available, if realized, would be credited to additional paid-in capital.

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 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

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public groups in the stock of a corporation by more than 50 percentage points over a three-year period. In 2012, we completed our review of our changes in ownership through a testing date of December 31, 2011, and determined that we had three ownership changes since inception. The changes of ownership will result in approximately $55,429 of net operating loss carryforwards that we expect to expire unutilized and approximately $4,066 of research and development credit carryforwards that we expect to expire unutilized. The Company had historically recorded a valuation allowance against the net operating losses and research and development carryforwards. This resulted in no change to the income statement, with a change to footnote disclosure only. We will continue to update our analysis of ownership changes and the potential limitations on our deferred tax assets.

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 2001 through 2012 in federal and the State of Connecticut jurisdictions.

The Company did not have any unrecognized tax benefits as of December 31, 2012.

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, 2012, 2011 and 2010, the Company had recorded a benefit of approximately $554, $418 and $130, respectively, for the estimated proceeds from this exchange. This benefit is recorded as a reduction of research and development expenditures.

16. Related Party Transactions

Nicholas Simon

In connection with Clarus Ventures, LLC s (Clarus) agreement to invest in Achillion, the Board of Directors of the Company elected Nicholas Simon as a Class I member of the Board of Directors to serve until his successor is duly elected and qualified. Mr. Simon is a managing director of Clarus.

In August 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 million. Additionally, in August 2010, Clarus purchased 4,875 shares of common stock and warrants to purchase 1,706 shares of common stock for an aggregate purchase price of $12.4 million.

In June 2012, Nicholas Simon resigned from the Board of Directors of the Company and Clarus effected a full distribution of its holdings.

Nicole Vitullo

In connection with Domain Associates, LLC s (Domain) agreement to in invest in Achillion, the Board of Directors of the Company elected Nicole Vitullo of Domain as a Class II member of the Board of Directors on September 30, 2010 to serve until her successor is duly elected and qualified. Ms. Vitullo is a partner at Domain.

In August 2010, Domain purchased 8,032 shares of common stock and warrants to purchase 2,811 shares of common stock for an aggregate purchase price of $20.4 million.

As of December 31, 2012, Domain was the beneficial owner of approximately 11% of the Company s total issued and outstanding shares of common stock.

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17. Unaudited Quarterly Results

The following tables summarize unaudited quarterly financial data for the years ended December 31, 2012 and 2011. This data has been derived from unaudited financial statements that, in the Company s opinion, include all adjustments necessary for a fair statement of such information. The operating results for any quarter are not necessarily indicative of results for any future period.

	2012 Quarters			
	First	Second	Third	Fourth
Total operating revenue	$ 2,489	$	$	$ 118
Total operating expenses	11,681	11,559	15,288	11,372
Net loss	(9,141)	(11,527)	(15,255)	(11,204)
Net loss per share basic and diluted	$ (0.13)	$ (0.16)	$ (0.20)	$ (0.14)
Weighted average number of shares outstanding basic and diluted	70,411	71,211	74,647	79,523

	2011 Quarters			
	First	Second	Third	Fourth
Total operating revenue	$ 65	$ 56	$ 64	$ 62
Total operating expenses	10,216	11,332	10,537	12,509
Net loss	(10,133)	(11,250)	(10,438)	(12,385)
Net loss per share basic and diluted	$ (0.17)	$ (0.19)	$ (0.15)	$ (0.18)
Weighted average number of shares outstanding basic and diluted	58,389	58,938	69,725	69,755

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EXHIBIT INDEX

		Incorporated by Reference			
Exhibit No.	Description	Form	SEC Filing date	Exhibit Number	Filed with this 10-K
3.1	Amended and Restated Certificate of Incorporation of the Registrant, as amended to date.	10-K	03/08/12	3.1	
3.2	Amended and Restated Bylaws.	10-K	03/29/07	3.2	
4.1	Specimen Certificate evidencing shares of common stock.	S-1/A	09/22/06	4.1	
10.1	License Agreement, dated as of February 3, 2000, by and between Vion Pharmaceuticals, Inc. and the Registrant, as amended on January 28, 2002.	S-1	03/31/06	10.2	
10.2	Letter Agreement, dated as of September 22, 2006, by and between the Registrant and Yale University.	S-1	10/10/06	10.2.1	
10.3	License Agreement, dated as of July 19, 2002 by and between the Registrant and Emory University.	S-1	03/31/06	10.3	
10.4	Third Amended and Restated Investor Rights Agreement, dated as of August 11, 2008, by and among the Registrant and the Holders named therein.	S-3	10/06/08	10.5	
10.5	Amendment No. 1 to the Third Amended and Restated Investor Rights Agreement, dated as of August 20, 2010.	S-3	09/17/10	10.4	
10.6	Securities Purchase Agreement, dated as of August 5, 2008, by and among the Registrant and the Purchasers named therein.	S-3	10/06/08	10.1	
10.7	Form of Common Warrant pursuant to the Securities Purchase Agreement dated as of August 5, 2008.	S-3	10/06/08	10.3	
10.8	Registration Rights Agreement, dated as of August 11, 2008, by and among the Registrant and the Purchasers named therein.	S-3	10/06/08	10.4	
10.9	Securities Purchase Agreement, dated as of August 18, 2010, by and among the Registrant and the Holders named therein.	S-3	09/17/10	10.1	
10.10	Form of Common Warrant pursuant to the Securities Purchase Agreement dated as of August 18, 2010.	S-3	09/17/10	10.2	
10.11	Registration Rights Agreement, dated as of August 18, 2010, by and among the Registrant and the Purchasers named therein.	S-3	09/17/10	10.3	
10.12	Subscription Agreement, dated as of August 30, 2012 by and among the Registrant and the Investors named therein.	8-K	08/31/12	10.1	
10.13	Sales Agreement, dated as of November 8, 2012 by and between the Registrant and Cantor Fitzgerald & Co.	10-Q	11/8/12	10.2	
10.14	Lease Agreement by and between the Registrant and WE George Street LLC for Suite 202, dated as of March 6, 2002.	S-1	03/31/06	10.14	
10.15	Amendment No. 2 to Lease, dated as of March 31, 2010, by and between Achillion Pharmaceuticals, Inc. and WE George Street, LLC.	8-K	04/06/10	10.1	

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			Incorporated by Reference			
	Exhibit No.	Description	Form	SEC Filing date	Exhibit Number	Filed with this 10-K
#	10.16	1998 Stock Option Plan, as amended, dated as of March 30, 2001.	S-1	03/31/06	10.17	
#	10.17	Form of Incentive Stock Option Agreement under the 1998 Stock Option Plan.	S-1	03/31/06	10.19	
#	10.18	Form of Incentive Stock Option Agreement for Non-Executives under the 1998 Stock Option Plan.	S-1	03/31/06	10.2	
#	10.19	Form of Nonstatutory Stock Option Agreement under the 1998 Stock Option Plan.	S-1/A	03/31/06	10.21	
#	10.20	2006 Stock Incentive Plan as amended September 18, 2006, March 9, 2010 and June 5, 2012.	8-K	06/11/12	99.3	
#	10.21	Form of Nonstatutory Stock Option Agreement under the 2006 Stock Incentive Plan.	8-K	12/22/10	99.1	
#	10.22	Form of Incentive Stock Option Agreement under the 2006 Stock Incentive Plan.	8-K	12/22/10	99.2	
#	10.23	2006 Employee Stock Purchase Plan as amended September 18, 2006, March 9, 2010, and June 10, 2010.	10-K	03/11/10	10.32	X
#	10.24	Employment Agreement entered into by the Company and Michael D. Kishbauch, dated April 5, 2011.	8-K	04/08/11	10.3	
#	10.25	Second Amended and Restated Employment Agreement and Supplemental Severance Agreement, dated as of March 9, 2010, and Supplemental Terms of Compensation, dated as of April 5, 2011, entered into by the Company and Milind S. Deshpande, Ph.D.	8-K	04/08/11	10.1	
#	10.26	Employment Agreement entered into by the Company and Gautam Shah, Ph.D., dated April 5, 2011.	8-K	04/08/11	10.5	
#	10.27	Second Amended and restated Employment Agreement and Supplemental Severance Agreement, dated as of March 9, 2010, and Supplemental Terms of Compensation, dated as of April 5, 2011, entered into by the Company and Mary Kay Fenton.	8-K	04/08/11	10.2	
#	10.28	Employment Agreement entered into by the Company and Joseph Truitt, dated April 5, 2011.	8-K	04/08/11	10.6	
#	10.29	Letter Agreement by and between Dr. Elizabeth A. Olek and the Company, dated as of June 5, 2012.	8-K	06/28/12	99.1	
	10.30	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-K	03/05/08	10.13	
	10.31	Form of Common Stock Warrant under Loan and Security Agreement of GE Capital Corporation and Oxford Finance Corporation.	10-K	03/05/08	10.14	
	10.32	Master Security Agreement between the Registrant and Webster Bank, National Association, dated as of March 21, 2011.	8-K	03/25/11	10.1	

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Exhibit No.	Description	Incorporated by Reference			Filed with this 10-K
		Form	SEC Filing date	Exhibit Number	
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.				X
31.1	Certification of Chief Executive Officer pursuant to Rule 13a- 14(a)/Rule 15d-14(a) of the Securities Exchange Act of 1934				X
31.2	Certification of Chief Financial Officer pursuant to Rule 13a- 14(a)/Rule 15d-14(a) of the Securities Exchange Act of 1934				X
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.				X
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.				X
101.CAL	XBRL Taxonomy Calculation Linkbase Document				*
101.INS	XBRL Instance Document				*
101.SCH	XBRL Taxonomy Extension Schema Document				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	XBRL Taxonomy Label Linkbase Document				*
101.PRE	XBRL Taxonomy Presentation Linkbase Document				*

Management contracts or compensatory plans or arrangement

* Submitted electronically herewith

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.

Attached as Exhibit 101 to this report are the following formatted in XBRL (Extensible Business Reporting Language): (i) Balance Sheets at December 31, 2012 and December 31, 2011, (ii) Statements of Operations for the years ended December 31, 2012, 2011 and 2010, (iii) Statements of Stockholders Equity and Comprehensive Loss for the years ended December 31, 2010, 2011 and 2012, (iv) Statements of Cash Flows for the years ended December 31, 2012, 2011 and 2010 and (v) Notes to Financial Statements.

In accordance with Rule 406T of Regulation S-T, the XBRL-related information in Exhibit 101 to this Annual Report on Form 10-K is deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act, is deemed not filed for purposes of section 18 of the Exchange Act, and otherwise is not subject to liability under these sections.