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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2014

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 ☐

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

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

Indicate by check mark 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 ☒ No ☐

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

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

Large accelerated filer ☐	Accelerated filer ☒
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 ☒

The aggregate market value of the voting stock held by non-affiliates of the Registrant on June 30, 2014 was approximately $522,706,085 based on the closing price of such stock as reported by the NASDAQ Global Select Market on June 30, 2014.

As of March 1, 2015, the registrant had 117,539,994 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 intend to file with the Securities and Exchange Commission, not later than 120 days after the close of our fiscal year ended December 31, 2014, a definitive proxy statement for our annual meeting of stockholders to be held on June 2, 2015. Such information will appear in our definitive proxy statement and is incorporated by reference into this Annual Report on Form 10-K.

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PART I

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act and Section 21E of the Securities Exchange Act of 1934, as amended, that involve a number of 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.

ITEM 1. BUSINESS

Overview

We are a biopharmaceutical company seeking to transform innovation into novel treatments that address the needs of patients by discovering and developing small molecule therapeutics for the treatment of infectious diseases and immune system disorders. We are currently focusing our efforts on developing commercially competitive, short-duration combination therapies for the treatment of chronic hepatitis C virus, or HCV, infection that are once-daily and ribavirin-free. Specifically, we are advancing combination regimens containing:

- ACH-3102, a NS5A inhibitor, currently in phase II clinical development;
- ACH-3422, a NS5B nucleotide polymerase inhibitor, currently in phase I clinical development; and
- Sovaprevir, a NS3 protease inhibitor, currently in phase II clinical development.

In addition to our work on anti-infectives, we have leveraged our internal discovery capabilities and seek to advance a novel platform for the development of oral inhibitors of complement Factor D. Factor D is an essential protein of the complement pathway, a part of the human innate immune system. Our platform is focused on advancing compounds that inhibit Factor D, can be orally-administered, and potentially can be used in the treatment of immune-related diseases where the complement pathway plays a critical role. We anticipate that our complement inhibitor platform may play a role in addressing needs of patients with paroxysmal nocturnal hemoglobinuria, or PNH, including patients who have suboptimal response to, or who fail to respond to, currently approved treatments for PNH, atypical hemolytic uremic syndrome, or aHUS, myasthenia gravis, and age-related macular degeneration, or AMD. Our compounds in complement Factor D inhibition have demonstrated complete suppression of the complement system with a single oral dose of our inhibitors in non-human primates. We plan to nominate one such compound in early 2015 and advance it to a phase I clinical trial by the end of 2015.

We have established our current drug candidate pipeline entirely through our internal discovery capabilities. Through these efforts, we have identified the following portfolio of drug candidates which we intend to study in combination with each other:

- **ACH-3102, a NS5A Inhibitor.** We are developing combination drug regimens that include ACH-3102, our pan-genotypic, second generation NS5A inhibitor. To date, we have completed three phase IIa clinical trials with ACH-3102 including the -007 trial with sovaprevir, the -005 study, which examined the use of ACH-3102 with ribavirin alone, and the Proxy Doublet study which examined the

use of ACH-3102 in combination with sofosbuvir, a nucleotide NS5B polymerase inhibitor marketed by Gilead Sciences, Inc., or Gilead, under the brand name Sovaldi®. These studies are described below under "Our Proprietary HCV Pipeline – Clinical Development History." In February 2015, we announced updated interim results from our Proxy Doublet study. This ongoing study is a phase II open-label, randomized, controlled partial-crossover study to evaluate the efficacy, safety, and tolerability of eight- and six weeks of 50mg of ACH-3102 and 400mg of sofosbuvir, once daily, in treatment-naïve genotype 1 HCV-infected patients. Initially, eighteen patients were enrolled, including six observational patients, into an eight-week treatment cohort. Following the achievement of 100% SVR12 (12/12) in the eight-week cohort, the six-week treatment cohort was initiated. In all, eighteen patients were enrolled, including twelve active and six observational patients. Mean baseline HCV RNA viral load was 10 million (7 $\log_{10}$) IU/ml, range 2 million (6.23 $\log_{10}$) – 97 million (7.99 $\log_{10}$) IU/ml, including seven patients with baseline HCV RNA viral load exceeding 6 million (6.78 $\log_{10}$) IU/ml. Of the twelve active patients enrolled, seven patients were genotype 1a and five were genotype 1b. Twelve weeks after the completion of therapy, 100% (12/12) achieved SVR12, independent of baseline viral load, gender, and IL28B status, in the six-week treatment arm. Additionally, 100% of patients (12/12) in the eight-week treatment duration arm have achieved SVR24. The combination of ACH-3102 and sofosbuvir was well-tolerated with no serious adverse events, no discontinuations due to adverse events, and no clinically significant laboratory or ECG abnormalities. ACH-3102 has been granted Fast Track status by the U.S. Food and Drug Administration, or FDA.

- **ACH-3422, a NS5B Nucleotide Polymerase Inhibitor.** We are seeking to develop combination drug regimens to address all HCV genotypes based on use of ACH-3422, our nucleotide prodrug inhibitor of HCV NS5B polymerase. ACH-3422 has demonstrated excellent potency and was well-tolerated in a phase Ib proof of concept study in which HCV patients receiving a once-daily 700mg dose of ACH-3422 for fourteen days demonstrated mean maximal viral load reduction of 4.6 $\log_{10}$.
- **Sovaprevir, a NS3 Protease Inhibitor.** We have completed a phase II clinical trial that evaluated 12 weeks of treatment consisting of sovaprevir and our NS5A inhibitor, ACH-3102, with ribavirin for the treatment of genotype 1 HCV (the -007 trial). In this trial, genotype 1b patients achieved 100% SVR24, however, in genotype 1a patients, the combination regimen results were suboptimal. In June 2013, the FDA placed a clinical hold on sovaprevir after elevations in liver enzymes were noted in a phase I healthy subjects drug-drug interaction study evaluating the effects of concomitant administration of sovaprevir with ritonavir-boosted atazanavir. In June 2014, the FDA lifted the full clinical hold, allowing us to advance sovaprevir in clinical trials of HCV-infected patients, but requiring us to seek FDA approval to conduct multi-dose clinical trials in healthy subjects. Following an internal assessment of our protease inhibitor drug candidates, sovaprevir and ACH-2684, we determined to advance sovaprevir in future clinical trials with ACH-3422 and ACH-3102, rather than ACH-2684. We plan to initiate a drug-drug interaction study with sovaprevir plus compounds that potentially impact active transport mechanisms in the liver and intestines in the first half of 2015.

We intend to continue to focus on the discovery and development of new drug candidates through our extensive expertise in biology and medicinal 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.

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 $53.5 million, $46.7 million and $39.0 million in research and development costs for the years ended December 31, 2014, 2013, and 2012, respectively.

Our Strategy

Our objective is to become a leading small-molecule biopharmaceutical company focused on infectious and immunological diseases. In order to advance toward our objective, we are currently focused on developing

commercially competitive, short-duration, once-daily combination therapies for the treatment of HCV. In addition, we are advancing our portfolio of compounds targeting complement Factor D. Specifically, our near-term strategy includes the following efforts:

- ***HCV Doublet Regimen.*** We are developing a short-duration combination drug regimen based on the use of ACH-3422 with ACH-3102. We have completed three clinical trials with ACH-3102 including the -007 study, a phase II study evaluating 12-weeks of once-daily ACH-3102 with sovaprevir and ribavirin, the -005 study, a phase II study evaluating 12-weeks of once-daily ACH-3102 in combination with ribavirin, and most recently, the Proxy Doublet study evaluating ACH-3102 in combination with sofosbuvir for both 6-week and 8-week treatment durations. Based on the results of these phase II studies, we believe ACH-3102 demonstrates best-in-class attributes including the ability to rapidly and robustly inhibit viral replication, minimize the emergence of resistant viral mutations, and achieve cures. We plan to initiate a clinical trial based on ACH-3422 in combination with ACH-3102, which we refer to as the Sparta Doublet trial, in the first half of 2015 for treatment durations of 6, 8 and 12 weeks, and we expect to report data from this trial in the second half of 2015.
- ***HCV Triplet Regimens.*** We believe that nucleotide-based combination regimens, like ACH-3422 regimens, can effectively treat all HCV genotypes over short durations when dosed in combination with other direct-acting antiviral drugs, or DAAs, such as ACH-3102 plus sovaprevir. By the end of 2015, we plan to initiate the pharmacokinetic and virokinetic portion of a triplet regimen study of ACH-3422, ACH-3102 and sovaprevir in HCV patients for treatment durations of 4, 6 and 8 weeks.

  As a proxy for what we might expect to see with a proprietary triple combination of ACH-3422, ACH-3102 and sovaprevir, we are also conducting the Proxy Triplet study examining the use of an approved nucleotide NS5B polymerase inhibitor, sofosbuvir, marketed by Gilead Sciences under the brand name Sovaldi®, in combination with ACH-3102 and sovaprevir. We expect to initiate this four week study in the first half of 2015 and report results by the end of 2015. This study may provide information that will help determine the appropriate dosing and other aspects of our proprietary triplet combination regimen.
- ***Complement Factor D Advancement.*** Our compounds in complement Factor D inhibition have demonstrated complete suppression of the complement system with a single oral dose of our inhibitors in non-human primates. We plan to nominate one such compound in early 2015 and advance it to a phase I clinical trial by the end of 2015.

In addition, we intend to continue to leverage our expertise in structural biology, synthetic chemistry, virology and microbiology to quickly and efficiently discover and develop additional small molecule compounds to meet significant unmet medical needs. Our research team has discovered and advanced all the compounds we currently have under development including in our HCV program, sovaprevir, ACH-3102 and ACH-3422, and all the compounds in our complement Factor D program as well.

Background – Infectious Disease

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 and are currently focused on the development of antivirals for the treatment of chronic HCV infection.

The widespread use of anti-infective drugs has led to a significant reduction in morbidity and mortality associated with infectious diseases. However, for many infectious diseases, current treatment options are associated with suboptimal treatment outcomes, significant drug-related adverse side effects, complex dosing schedules and inconvenient methods of administration, such as 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, shorten treatment durations, improve patient compliance and 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 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 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.

Background – Complement-mediated Disease

Our expertise in structural biology and medicinal chemistry, coupled with our work in antimicrobial discovery research, led us to consider how the immune system plays a part in inhibiting pathogens in the body. This research led us to work in complement system inhibition.

The complement system is a part of the immune system that helps or complements the ability of antibodies and phagocytic cells to clear pathogens from an organism. It is part of the innate immune system, which is not adaptable and does not change over the course of an individual's lifetime. However, it can be recruited and brought into action by the adaptive immune system. Three biochemical pathways activate the complement system: the classical complement pathway, the alternative complement pathway, and the lectin pathway.

The complement system consists of a number of small proteins found in the blood, in general synthesized by the liver, and normally circulating as inactive precursors. When stimulated by one of several triggers, proteases in the system cleave specific proteins to release cytokines and initiate an amplifying cascade of further cleavages. The end-result of this activation cascade is massive amplification of the response and activation of the cell-killing membrane attack complex. Over 30 proteins and protein fragments make up the complement system, including serum proteins, serosal proteins, and cell membrane receptors. They account for about 5% of the globulin portion of blood serum.

Within the alternatives pathway, our compounds focus on inhibition of Factor D, a necessary protein in the formation of membrane attack complex, or MAC. If formation of MAC can be prevented, disease-inducing complement system activation can be stopped.

Our Drug Candidates

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

Drug Candidate/ Indication	Mechanism	Stage of Development	Current Status of Therapeutic Trials	Current Marketing Rights
ACH-3102 *Chronic Hepatitis C Infection*	HCV NS5A inhibitor	Phase II	Three phase IIa clinical trials completed in combination regimens with ribavirin alone, with sovaprevir and ribavirin, and with sofosbuvir (serving as a proxy for ACH-3422); combination studies with ACH-3422 anticipated to begin in the first half of 2015; combination studies with ACH-3102 and sofosbuvir anticipated to begin in the first half of 2015; combination studies with ACH-3102 and ACH-3422 anticipated to begin before year-end 2015	Achillion
ACH-3422 *Chronic Hepatitis C Infection*	HCV NS5B nucleotide polymerase inhibitor	Phase I	Proof-of-concept studies completed in genotype 1 and remain on-going in genotypes 2 and 3; phase II combination studies with ACH-3102 anticipated to begin in the first half of 2015; combination studies with ACH-3102 and ACH-3422 anticipated to begin before year-end 2015	Achillion
Sovaprevir *Chronic Hepatitis C Infection*	HCV NS3 protease inhibitor	Phase II	Two Phase IIa clinical trials completed in combination regimens with P/R and with ACH-3102 plus ribavirin; combination studies with ACH-3102 and sofosbuvir anticipated to begin in the first half of 2015; combination studies with ACH-3102 and ACH-3422 anticipated to begin before year-end 2015	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, until they experience late-stage disease. Chronic hepatitis can lead to permanent liver damage, which can result in the development of liver cancer, liver failure or death. Estimates by the World Health Organization indicate that approximately 150 million individuals worldwide are chronically infected with HCV.

We believe the lessons learned from the treatment of HIV infection, specifically the improved antiviral response achieved through the use of combination therapies, are relevant for the treatment of HCV due to its rapid replication and high frequency of mutations. One common approach to the discovery of new therapies to treat 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 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.

The HCV market has seen unprecedented change in recent years. 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. Treatment durations range from 6 to 12 months, depending upon viral genotype and level of liver function. Cure rates with P/R range from 40-80%, again depending upon genotype and level of liver function. Further, P/R is complicated by significant adverse side effects, including flu-like symptoms, anemia, depression, fatigue, suicidal tendencies and abnormal fetal development.

In 2011, two DAA protease inhibitors were introduced to the market. These compounds, boceprevir (Victrelis®) and telaprevir (Incivek®), were approved only for the treatment of patients with HCV genotype 1 and remain dosed in combination with P/R. In 2013, another NS3 protease inhibitor, simiprevir (Olysio®), and a NS5B nucleotide polymerase inhibitor, sofosbuvir (Sovaldi®), were also approved for treatment of patients with HCV genotype 1 in combination with P/R. Sofosbuvir was also approved for use with ribavirin alone for use in treatment of patients with HCV genotype 2. In 2014, all-oral combination regimens entered the market including the combination of sofosbuvir and ledipisvir (Harvoni) and the ombitasvir/paritaprevir/ritonavir/dasabuvir/ribavirin combination (Viekira Pak™). These treatment regimens for HCV offer improved SVR rates for patients of the appropriate genotype who can tolerate the combination therapy. Further, the occurrence of side effects, both from P/R and some of 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 poor tolerability by some patients, and inability to combine with certain concomitant medications, sales for newly marketed HCV regimens totaled approximately $15 billion in 2014, including sales of boceprevir (Victrelis®), telaprevir (Incivek®) sofosbuvir (Sovaldi®) and sofosbuvir/ledipisvir (Harvoni™) by Gilead and Viekira Pak™ by Abbvie. It is anticipated that with the introduction of all-oral combination regimens with broad genotypic coverage in 2015 and beyond, the HCV DAA market will grow to over $20 billion by 2020 in the United States, European Union and Japan.

Despite the recent improvements in the treatment landscape for HCV infected patients, there remain important goals for new HCV therapies:

- improve efficacy against the broad spectrum of HCV genotypes 2, 3, 4, 5 and 6;
- shorten treatment durations;
- offer a treatment response in patients who have failed marketed regimens;
- offer therapies to which patients do not develop drug resistance;
- offer therapies to patients with cirrhosis;
- reduce the magnitude of treatment-related adverse side effects; and
- offer a more convenient, orally available, treatment options.

We believe our combination of our NS5A inhibitor in combination with our NS3 protease inhibitor and our NS5B nucleotide polymerase inhibitor for the treatment of HCV patients has the potential to address many of these treatment goals.

Our Proprietary HCV Pipeline

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 NS5A inhibitors, NS5B polymerase inhibitors and NS3 protease inhibitors that are distinct in their efficacy, resistance profile and/or pharmacokinetic profile.

NS5A Inhibitor ACH-3102

In a 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, and interaction with host proteins, and it is also implicated in interferon-resistance. Inhibition of NS5A is a clinically validated mechanism of action.

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 has also demonstrated activity against all other known genotypes (2, 3, 4, 5 and 6). ACH-3102 has also operated synergistically with both NS3 protease and NS5B polymerase inhibitors in *in vitro* studies.

We believe ACH-3102 has the following benefits:

- *Virology*. ACH-3102 is highly specific for inhibition of the NS5A non-structural protein of the hepatitis C virus necessary for viral replication. In clinical studies, the compound has demonstrated robust antiviral activity as a single agent, and in combination with ribavirin, even in the presence of pre-existing resistance mutations, ACH-3102 has demonstrated rapid viral load reduction in HCV patients. To date, in both clinical and laboratory testing, genotype 1b patients treated with ACH-3102 have not generated any resistance mutations in the face of treatment with ACH-3102.
- *Pharmacokinetics and Metabolism*. Pharmacokinetic results and activity in clinical studies indicate that ACH-3102 can be dosed once daily and has a low potential for drug-drug interactions, or DDI, based on multiple DDI studies.
- *Safety*. In animal studies completed in two species for periods up to three months, ACH-3102 demonstrated high safety margins with minimal dose-related effects even at high drug exposures.

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 to data reported for a leading compound in this class by Bristol-Myers Squibb:

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

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

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 preliminary safety results from a phase I clinical trial 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 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. No drug-related serious adverse events were reported and there were no patient discontinuations.

In September 2012, we also 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 of 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 drug-related serious adverse events were reported and there were no patient discontinuations.

Phase II Clinical Trials. We have completed three phase II clinical trials with ACH-3102. In the first, the -005 trial, we studied ACH-3102 in an open-label trial evaluating 12-weeks of once-daily ACH-3102 in combination with ribavirin for the treatment of genotype 1b HCV. The study enrolled 8 treatment-naïve patients with genotype 1b HCV who received 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, referred to as 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). Results from that trial revealed that 75% of patients (6 of 8) achieved RVR and 75% of patients (6 of 8) achieved ETR. Three of 8 patients achieved SVR12. Patients who did not achieve RVR demonstrated multiple viral mutations at baseline, meaning before entering the clinical trial, that would be consistent with prior treatment with an NS5A inhibitor that gave rise to those resistant mutations. No patients experienced viral breakthrough or viral relapse. No drug-related serious adverse events were reported and there were no patient discontinuations.

In a second phase IIa clinical study, the -007 study, a double-blind, placebo-controlled phase II study evaluating the safety, tolerability and efficacy of 12 weeks of sovaprevir, ACH-3102, and ribavirin in treatment-naïve patients with chronic genotype 1a or genotype 1b HCV, each subtypes of genotype 1. Thirty patients were enrolled and randomized to receive a combination of either 200 mg or 400 mg sovaprevir once daily in combination with a 150 mg loading dose followed by a 50 mg daily dose of ACH-3102, and twice daily doses of ribavirin, or matching placebos. The primary endpoints for the trial included safety, tolerability, and sustained viral response both 4 and 12 weeks after the completion of dosing (SVR4 and SVR12). The trial was conducted at sites in the United States, Canada, New Zealand and Australia. Data indicate that all patients achieved a very rapid virologic response (vRVR) meaning undetectable levels of HCV RNA (less than 25 IU (international units)/ml) by week 2. The RVR rate among patients infected with genotype 1a HCV (5 of 8) did not meet our strategic objectives for the regimen; therefore, we are no longer utilizing this combination for treatment of patients with genotype 1a HCV. In January 2014, we announced that 100% of patients infected with genotype 1b HCV achieved both SVR4 and SVR12. There have been no graded increases in liver function tests, including those measurements referred to as ALT or AST, for patients receiving active treatment to date. No drug-related serious adverse events were reported and there were no patient discontinuations. As described below under “Sovaprevir, a NS3 Protease Inhibitor,” sovaprevir is currently on partial clinical hold with the FDA.

In a third phase IIa study, the Proxy Doublet Study, an open label, randomized, controlled, partial crossover study, we examined the use of ACH-3012 in combination with sofosbuvir for both 6-week and 8-week treatment durations. Twelve active and six observational patients per cohort were enrolled and randomized to receive once-daily doses of 50mg of ACH-3012 with 400mg of sofosbuvir or placebo. The primary endpoints for the trial included safety, tolerability and SVR4 and SVR12. In August 2014, we announced that 100% of patients in the 8-week cohort reached SVR4. In December 2014, we announced that 100% of patients in the 6-week duration cohort also attained SVR4. In February 2015, we announced that 100% of patients in the 8-week cohort achieved SVR24 and 100% of the patients in the 6-week cohort achieved SVR12.

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 genotype 1a and known mutant variants of genotype 1 HCV.

In both 14-day and three 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. A long-term six month preclinical study is on-going.

NS5B Nucleotide Polymerase Inhibitor ACH-3422

In another proprietary program against hepatitis C infection, we have discovered and developed a series of prodrugs that, when metabolized to the triphosphate form, serve as defective substrates for a viral protein called polymerase, thereby inhibiting viral RNA synthesis, or preventing the virus from replicating its genetic material.

In vitro, ACH-3422 demonstrates highly potent activity against all HCV genotypes. The following table shows the relative potency of ACH-3422, as measured by the effective concentration required to reduce viral levels by at least 50%, or EC50, compared side by side to a recently approved drug, sofosbuvir (Sovaldi®), developed and marketed by Gilead Sciences:

	EC50 (nM) in Replicon Assay				
	Genotype 1a	Genotype 1b	Genotype 2	Genotype 3	Genotype 4
ACH-3422	74	51	107	14	25
Sofosbuvir	223	66	106	98	78

We believe ACH-3422 has the following benefits:

- *Virology*. Data indicate that ACH-3422 is highly specific for inhibition of HCV polymerase, a protein necessary for viral replication. ACH-3422 is also highly potent, inhibiting HCV genotypes 1b, 1a, 2, 3 and 4 at lower concentrations than sofosbuvir.
- *Pharmacokinetics and Metabolism*. In laboratory and animal studies, ACH-3422 has demonstrated rapid conversion of the prodrug, the form of drug ingested by the subject, to the monophosphate, the active form of the drug in liver cells. Pharmacokinetics studies suggest that ACH-3422 would be dosed once daily.
- *Safety*. In animal studies completed in two species for periods up to 28 days, ACH-3422 demonstrated high safety margins with minimal dose-related effects even at high drug exposures. Further, in laboratory studies, ACH-3422 demonstrated low risk of showing mitochondrial toxicity, a toxicity known to have made other drug candidates unsafe for further clinical development.

In preclinical studies, ACH-3422 has demonstrated potent pan-genotypic activity including excellent activity against both genotype 1a and known mutant variants of genotype 1 HCV.

We conducted three month oral toxicology studies in rats and dogs. The data from these studies support further development of ACH-3422. We are currently conducting a toxicology study in dogs with ACH-3422 in combination with ACH-3102.

Clinical Development History

In June 2014, we initiated a Phase Ib clinical trial evaluating the safety, pharmacokinetics and efficacy of multiple doses of ACH-3422. We evaluated doses of 50mg to 700mg of ACH-3422 administered once daily. In December 2014, we announced results from this trial. HCV patients receiving a once daily 700mg dose of ACH-3422 for fourteen days demonstrated mean maximal viral load reduction of 4.6 $\log_{10}$.

Protease Inhibitor Sovaprevir

We have also discovered and are developing sovaprevir, a NS3 protease inhibitor, originally known as ACH-1625. 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), recently approved HCV protease inhibitors. 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% complete early virologic response, or 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 has the potential to 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 confirmed 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. We plan to initiate a DDI study with ACH-3422 in the first half of 2015.

In August 2014, based on an internal assessment, we determined to advance sovaprevir in future clinical trials rather than ACH-2684, one of our other protease inhibitors. We maintain all rights to ACH-2684 and may seek licensing opportunities for this compound.

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, 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 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 and 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 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. Mutations commonly associated with protease inhibitor therapy including mutations at R155, A156 and D168 were not observed with sovaprevir treatment.

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.

In June 2013, the FDA placed a clinical hold on sovaprevir after elevations in liver enzymes were noted in a phase I healthy subjects drug-drug interaction study evaluating the effects of concomitant administration of sovaprevir with ritonavir-boosted atazanavir. In June 2014, the FDA removed the clinical hold on sovaprevir, allowing us to conduct therapeutic trials of sovaprevir in HCV patients with a maximum dose of 200 mg once daily and in single dose trials in healthy volunteers, but the FDA maintained a partial clinical hold on sovaprevir for multiple dose studies that we may conduct in healthy volunteers.

See "NS5A Inhibitor ACH-3102" for a discussion of the phase IIa clinical study of sovaprevir with ACH-3102 and ribavirin.

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.

Drug Discovery Programs and Capabilities

We have successfully advanced seven drug candidates into human clinical trials, with two additional drug candidates that we advanced into late-stage preclinical studies. We discovered eight of these nine drug candidates in house by applying our expertise in biology and synthetic chemistry. We intend to continue to capitalize on our internal drug discovery and development capabilities to expand our product candidate portfolio.

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

Target Selection and Assay Development

We are focused on addressing unmet medical needs with an emphasis on inhibiting essential proteins or enzymes with small molecule inhibitors. We select targets for our drug discovery programs based upon the relevance of the target to key steps within the viral 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 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. 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;
- CART (Compound Acquisition and Repository Tracking) streamlines our scientists' ability to select and acquire compounds for lead identification and optimization;
- CHEM-ACH is a data mining software that allows analysis of our 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; and
- 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

We are engaged in a segment of the pharmaceutical industry that is highly competitive and rapidly changing. We face potential competition from many different sources pursuing the development of novel drugs that target infectious diseases generally and HCV in particular, including both major and specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research organizations. 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 that have demonstrated potential efficacy for the treatment of HCV 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.

If approved, combinations of our drug candidates that we are advancing, ACH-3102, ACH-3422, and sovaprevir, would compete with drugs currently approved for the treatment of HCV, such as the interferon-alpha-based products from F. Hoffman-La Roche Ltd, or Roche (Pegasys and Roferon-A) or Merck & Co., Inc., 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 protease inhibitors telaprevir by Vertex Pharmaceuticals Incorporated, or Vertex (Incivek®), boceprevir by Merck (Victrelis®), simeprevir by Johnson & Johnson (Olysio®) and the more recently approved nucleotide inhibitor sofosbuvir (Sovaldi®) by Gilead and sofosbuvir/ ledipasvir combination (Harvoni™), also by Gilead, as well as the ombitasvir/paritaprevir/ritonavir/dasabuvir/ribavirin combination (Viekira Pak™) by AbbVie.

If approved, our drug candidates may also compete with all-oral treatments currently in development to treat HCV infection in multiple classes including protease inhibitors, polymerase inhibitors (nucleoside, nucleotide, and non-nucleoside), NS5A inhibitors, cyclophilin inhibitors and others. Competing drug candidates for the treatment of HCV, or combinations of drug candidates, are being developed by companies such as AbbVie, Inc., or AbbVie, AstraZeneca Plc, or AstraZeneca, Bristol-Myers Squibb Company, or Bristol-Myers Squibb, Enanta Pharmaceuticals, Inc., or Enanta, Gilead, GlaxoSmithKline plc, or GlaxoSmithKline, Johnson & Johnson, Medivir AB, or Medivir, Merck, Novartis AG, or Novartis, Regulus Therapeutics Inc., or Regulus, and Roche.

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.

Mergers and acquisitions in the pharmaceutical and biotechnology industry may result in even more resources being concentrated among a smaller number of our competitors. For example, in August 2014, Merck completed its acquisition of Idenix Pharmaceuticals, Inc., or Idenix, a potential competitor of ours. This acquisition follows earlier acquisitions in the HCV therapeutic arena such as Gilead's acquisition of Pharmasset Inc., or Pharmasset and Bristol-Myers Squibb's acquisition of Inhibitex, Inc., or Inhibitex. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. For example, Johnson & Johnson recently acquired Alios Biopharma, Inc., or Alios, a private company which, in addition to assets in respiratory syncytial virus, or RSV, also had assets in HCV.

Competitive products, specific classes of competitive products, or combinations of competitive products may render our drug candidates and products obsolete or noncompetitive before we can recover the expenses of developing and commercializing them. Furthermore, the development of new treatment methods 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.

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, improvements and know-how we consider important to our business;
- defend and enforce our patents;
- preserve the confidentiality of our trade secrets; and
- operate without infringing the valid and enforceable 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.

Our hepatitis C patent portfolio currently includes the following:

	Issued Patents	Pending Applications	Pending PCT Applications
U.S.	11	17	—
Foreign	81	64	7

These patents and patent applications, if issued, will expire on various dates between 2025 and 2034. The patent applications contain claims directed to classes of compounds, methods of use, mechanism of action, and research assays.

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 complement inhibitor patent portfolio currently includes several patent applications directed to classes of compounds, methods of use, mechanism of action, and research assays. Our complement inhibitor patent applications will be filed with the PCT in 2015.

Our antibacterial patent portfolio currently includes the following:

	Issued Patents	Pending Applications	Pending PCT Applications
U.S.	7	—	—
Foreign	37	3	—

These patents and patent applications, if issued, will expire on various dates between 2024 and 2031. The patent applications contain claims directed to classes of compounds, methods of use, and processes for synthesis.

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. We entered into an amendment to the agreement in April 2013. Under the terms of the agreement, as amended, Ora is responsible for development and regulatory activities and associated costs for ACH-702. We are eligible to receive development and commercialization milestones and royalties on net sales, if any, for ACH-702.

Our HIV patent portfolio currently includes the following:

	Issued Patents	Pending Applications	Pending PCT Applications
U.S.	4	—	—
Foreign	2	—	—

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 on various dates between 2016 and 2023. The issued U.S. patents contain claims directed to elvucitabine chemical compound, method of use, synthesis, and formulation.

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 TIPR, assumed all development and regulatory responsibility and associated costs for elvucitabine, and we are eligible to receive development milestones and royalties on net sales, if any, 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 in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

Review and Approval of Drugs in the United States

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice or DOJ or other governmental entities.

An applicant seeking approval to market and distribute a new drug product in the United States must typically undertake the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an IND, which must take effect before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug product for each indication;
- preparation and submission to the FDA of a new drug application, or NDA;
- review of the product by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with current Good Manufacturing Practices, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- payment of user fees and securing FDA approval of the NDA; and
- compliance with any post-approval requirements, including Risk Evaluation and Mitigation Strategies, or REMS, and post-approval studies required by the FDA.

Preclinical Studies

Preclinical studies include laboratory evaluation of the purity and stability of the manufactured drug substance or active pharmaceutical ingredient and the formulated drug or drug product, as well as in vitro and animal studies to assess the safety and activity of the drug for initial testing in humans and to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations. The results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, are submitted to the FDA as part of an IND. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, and long term toxicity studies, may continue after the IND is submitted.

Human Clinical Studies in Support of an NDA

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in

any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to a proposed clinical trial and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin.

In addition, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health for public dissemination on their ClinicalTrials.gov website.

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

Phase I:	The drug is initially introduced into healthy human subjects or patients with the target disease (e.g. cancer) or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine optimal dosage.
Phase II:	The drug is administered to 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:	The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase I, Phase II and Phase III clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

Section 505(b)(2) NDAs

NDAs for most new drug products are based on two full clinical studies which must contain substantial evidence of the safety and efficacy of the proposed new product. These applications are submitted under Section 505(b)(1) of the FDCA. The FDA is, however, authorized to approve an alternative type of NDA under Section 505(b)(2) of the FDCA. This type of application allows the applicant to rely, in part, on the FDA's previous findings of safety and efficacy for a similar product, or published literature. Specifically, Section 505(b)(2) applies to NDAs for a drug for which the investigations made to show whether or not the drug is safe for use and effective in use and relied upon by the applicant for approval of the application "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted."

Thus, Section 505(b)(2) authorizes the FDA to approve an NDA based on safety and effectiveness data that were not developed by the applicant. NDAs filed under Section 505(b)(2) may provide an alternate and potentially more expeditious pathway to FDA approval for new or improved formulations or new uses of previously approved products. If the 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, the applicant may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new drug candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

Submission of an NDA to the FDA

Assuming successful completion of required clinical testing and other requirements, the results of the preclinical and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the drug product for one or more indications. Under federal law, the submission of most NDAs is additionally subject to an application user fee, currently exceeding $2.1 million, and the sponsor of an approved NDA is also subject to annual product and establishment user fees, currently exceeding $104,000 per product and $554,000 per establishment. These fees are typically increased annually.

The FDA conducts a preliminary review of an NDA within 60 days of its receipt and informs the sponsor by the 74th day after the FDA's receipt of the submission to determine whether the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also 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 FDA has agreed to specified performance goals in the review process of NDAs. Most such applications are meant to be reviewed within ten months from the date of filing, and most applications for "priority review" products are meant to be reviewed within six months of filing. The review process may be extended by the FDA for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is or will be manufactured. These pre-approval inspections cover all facilities associated with an NDA submission, including drug component manufacturing (such as Active Pharmaceutical Ingredients), finished drug product manufacturing, and control testing laboratories. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP.

The FDA also may require submission of a REMS plan to mitigate any identified or suspected serious risks. The REMS plan could include medication guides, physician communication plans, assessment plans, and elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools.

The FDA is required to refer an application for a novel drug to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are fast track designation, breakthrough therapy designation and priority review designation.

Specifically, the FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product's NDA before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the NDA is submitted. In addition, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, in 2012, Congress enacted the Food and Drug Administration Safety and Improvement Act. This law established a new regulatory scheme allowing for expedited review of products designated as "breakthrough therapies." A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

Third, the FDA may designate a product for priority review if it is a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed drug represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a drug for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a drug.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of drugs for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

The FDA's Decision on an NDA

On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and

impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Review and Approval of Drug Products in the European Union

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of drug products. Whether or not it obtains FDA approval for a product, the company would need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Pursuant to the European Clinical Trials Directive, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, an applicant must obtain approval from the competent national authority of a European Union member state in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial after a competent ethics committee has issued a favorable opinion. Clinical trial application must be accompanied by an investigational medicinal product dossier with supporting information prescribed by the European Clinical Trials Directive and corresponding national laws of the member states and further detailed in applicable guidance documents.

To obtain marketing approval of a drug under European Union regulatory systems, an applicant must submit a marketing authorization application, or MAA, either under a centralized or decentralized procedure.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union member states. The centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

Under the centralized procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established at the European Medicines Agency, or EMA, is responsible for conducting the initial assessment of a drug. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops, when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. In this circumstance, the EMA ensures that the opinion of the CHMP is given within 150 days.

The decentralized procedure is available to applicants who wish to market a product in various European Union member states where such product has not received marketing approval in any European Union member states before. The decentralized procedure provides for approval by one or more other, or concerned, member states of an assessment of an application performed by one member state designated by the applicant, known as the reference member state. Under this procedure, an applicant submits an application based on identical dossiers and related materials, including a draft summary of product characteristics, and draft labeling and package leaflet, to the reference member state and concerned member states. The reference member state prepares a draft assessment report and drafts of the related materials within 210 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report and related materials, each concerned member state must decide whether to approve the assessment report and related materials.

If a member state cannot approve the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points are subject to a dispute resolution mechanism and may eventually be referred to the European Commission, whose decision is binding on all member states.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Sales of products will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Third-party reimbursement may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular drug candidate to currently available therapies. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Healthcare Law and Regulation

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with third-party payors and customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations. Such restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal healthcare Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;
- the federal False Claims Act imposes civil penalties, and provides for civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the Health Care Reform Law will require manufacturers of drugs, devices, drugs and medical supplies to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Segment Reporting

We are engaged solely in the discovery and development of innovative drug therapies for infectious diseases and immune system disorders. Accordingly, we have determined that we operate in one operating segment.

Employees

As of March 1, 2015, we had 67 full-time employees and two part-time employees, 28 of whom hold doctoral degrees. Approximately 51 of our employees are engaged in research and development, with the remainder engaged in administration, finance and business development functions. None of our employees is represented by a labor union or covered by collective bargaining agreements. We believe our relations with our employees are good.

Information Available on the Internet

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, or the SEC. We also make available on our website our corporate governance guidelines, the charters for our audit committee, nominating and corporate governance committee and compensation committee and audit committee, and our code of business conduct and ethics, which applies to our directors, officers and employees, and such information is available in print and free of charge to any of our stockholders who requests it. In addition, we intend to disclose on our website any amendments to, or waivers from, our code of business conduct and ethics that are required to be publicly disclosed pursuant to rules of the SEC.

Executive Officers of the Registrant

Name	Age	Position
Milind S. Deshpande, Ph.D.	58	President and Chief Executive Officer, Director
Mary Kay Fenton	51	Executive Vice President and Chief Financial Officer
David Apelian, M.D., Ph.D.	49	Executive Vice President and Chief Medical Officer
Gautam Shah, Ph.D.	58	Executive Vice President and Chief Compliance Officer
Joseph Truitt	50	Executive Vice President and Chief Commercial Officer

Milind S. Deshpande, Ph.D., President and Chief Executive Officer. Dr. Deshpande was appointed our President and Chief Executive Officer in May 2013, at which time he was also elected to our board of directors. Prior to that, he was our 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 is on the board of directors of Spero Therapeutics, a biotechnology company. Dr. Deshpande received his Ph.D. in Organic Chemistry from Ohio University, following his undergraduate education in India.

Mary Kay Fenton, Executive 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.

David Apelian, M.D, Ph.D., Executive Vice President and Chief Medical Officer. Prior to Joining Achillion in May 2013, Dr. Apelian was Senior Vice President and Chief Medical Officer at GlobeImmune, a biopharmaceutical company, from 2005 to 2013, where he was responsible for clinical development, regulatory affairs, clinical immunology, development of companion diagnostics, as well as target discovery and preclinical research. Prior to GlobeImmune, Dr. Apelian was Clinical Director in the Infectious Diseases Group at Bristol-Myers Squibb, a pharmaceutical company, serving as medical co-lead for the clinical development and NDA submission of entecavir for chronic hepatitis B viral infection. Prior to BMS, Dr. Apelian served as Clinical Director in the Department of Hepatology/Gastroenterology at Schering Plough, a pharmaceutical company, coordinating a supplemental NDA filing for interferon alpha-2b and ribavirin for the treatment of pediatric patients with chronic hepatitis C viral infection. Dr. Apelian completed his residency training in Pediatrics at New York Hospital, Cornell Medical Center. He received his M.D. from the University of Medicine and Dentistry of New Jersey, and his Ph.D. in Biochemistry and B.A. from Rutgers University. He also holds an M.B.A. from Quinnipiac University.

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.

Joseph Truitt, Executive 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.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below before buying our common stock. If any of the following risks actually occurs, our business, financial condition, results of operations and cash flows could be materially adversely affected, the trading price of our common stock could decline materially and you could lose all or part of your investment.

Risks Related to Our Business

We depend on the success of our 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 NS5A inhibitor, ACH-3102, our nucleotide polymerase inhibitor, ACH-3422, our protease inhibitor, sovaprevir, and more recently, our complement Factor D inhibitors. 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 our drugs, whether alone or in collaboration with others, particularly in a market in which competing therapeutics have very high efficacy rates;
- acceptance of our drugs 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 drug candidates.

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 ACH-3102, ACH-3422, or sovaprevir 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 or complement-mediated diseases to be commercially available for 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. We face potential competition from many different sources pursuing the development of novel drugs that target infectious diseases generally and HCV in particular, including both major and specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and

private research organizations. 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 that have demonstrated potential efficacy for the treatment of HCV 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.

If approved, combinations of our drug candidates that we are advancing, ACH-3102, ACH-3422, and sovaprevir, would compete with drugs currently approved for the treatment of HCV, such as the interferon-alpha-based products from F. Hoffman-La Roche Ltd, or Roche (Pegasys and Roferon-A) or Merck & Co., Inc., 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 protease inhibitors telaprevir by Vertex Pharmaceuticals Incorporated, or Vertex (Incivek®), boceprevir by Merck (Victrelis®), -simeprevir by Johnson & Johnson (Olysio®) and the more recently approved nucleotide inhibitor sofosbuvir (Sovaldi®) by Gilead and sofosbuvir/ ledipasvir combination (Harvoni™), also by Gilead, as well as the ombitasvir/paritaprevir/ritonavir/dasabuvir/ribavirin combination (Viekira Pak™) by AbbVie.

If approved, our drug candidates may also compete with all-oral treatments currently in development to treat HCV infection in multiple classes including protease inhibitors, polymerase inhibitors (nucleoside, nucleotide, and non-nucleoside), NS5A inhibitors, cyclophilin inhibitors and others. Competing drug candidates for the treatment of HCV, or combinations of drug candidates, are being developed by companies such as AbbVie, Inc., or AbbVie, AstraZeneca Plc, or AstraZeneca, Bristol-Myers Squibb Company, or Bristol-Myers Squibb, Enanta Pharmaceuticals, Inc., or Enanta, Gilead, GlaxoSmithKline plc, or GlaxoSmithKline, Johnson & Johnson, Medivir AB, or Medivir, Merck, Novartis AG, or Novartis, Regulus Therapeutics Inc., or Regulus, and Roche.

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.

Mergers and acquisitions in the pharmaceutical and biotechnology industry may result in even more resources being concentrated among a smaller number of our competitors. For example, in August 2014, Merck completed its acquisition of Idenix Pharmaceuticals, Inc., or Idenix, a potential competitor of ours. This acquisition follows earlier acquisitions in the HCV therapeutic arena such as Gilead's acquisition of Pharmasset Inc., or Pharmasset and Bristol-Myers Squibb's acquisition of Inhibitex, Inc., or Inhibitex. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. For example, Johnson & Johnson recently acquired Alios Biopharma, Inc., or Alios, a private company which, in addition to assets in respiratory syncytial virus, or RSV, also had assets in HCV.

Competitive products, specific classes of competitive products, or combinations of competitive products may render our drug candidates and products obsolete or noncompetitive before we can recover the expenses of developing and commercializing them. Furthermore, the development of new treatment methods 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.

As a result of elevations in liver enzymes noted in a phase I drug-drug interaction study for healthy volunteers evaluating the effects of concomitant administration of sovaprevir with ritonavir-boosted atazanavir, the FDA previously placed a clinical hold on sovaprevir. While the FDA removed its clinical hold on sovaprevir for patient studies and single dose studies in healthy volunteers in June 2014, the FDA maintained a partial clinical hold on sovaprevir for certain multiple dose studies in healthy volunteers. Our business may be adversely affected if such regulatory concerns lead to delays in developing sovaprevir or if elevated liver enzyme levels or other adverse drug-drug interactions are observed in subsequent studies.

One of our most advanced compounds under development is sovaprevir, a NS3 protease inhibitor in phase II clinical development. In June 2013, the FDA placed a clinical hold on sovaprevir after elevations in liver enzymes were noted in a phase I healthy subjects drug-drug interaction study evaluating the effects of concomitant administration of sovaprevir with ritonavir-boosted atazanavir. In June 2014, the FDA removed the clinical hold on sovaprevir, allowing us to conduct therapeutic trials of sovaprevir in HCV patients with a maximum dose of 200 mg once daily and in single dose studies in healthy volunteers, but the FDA maintained a partial clinical hold on sovaprevir for multiple dose studies that we may conduct in healthy volunteers.

The FDA may not remove the partial clinical hold on sovaprevir and may not allow us to conduct additional multiple dose studies in healthy volunteers without their prior permission. Moreover, elevated liver enzymes or other adverse drug-drug interactions could be observed in our ongoing clinical trials or any other subsequent preclinical studies or clinical trials that we may conduct. If the FDA does not remove the partial clinical hold or if elevated liver enzymes or other adverse drug-drug interactions are observed, our development of sovaprevir may be delayed, and the associated costs may be significantly increased, adversely affecting our business. If the FDA places sovaprevir on clinical hold again, we may terminate the development of sovaprevir, which may adversely affect our business.

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

We have incurred significant losses since our inception in August 1998. As of December 31, 2014, our accumulated deficit was $450.7 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.

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.

Based on our current clinical plan, and after giving effect to our underwritten public offering of shares of our common stock in February 2015, which resulted in aggregate net proceeds to us of $132.6 million, after deducting underwriting discounts and commissions and offering expenses, we believe that our existing cash, cash equivalents and marketable securities will be sufficient to meet our current projected operating requirements for at least the next 12 months. However, our future capital 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 ACH-3102, ACH-3422, and sovaprevir;
- the costs involved in the preclinical and clinical development of certain complement inhibitors;

- the scope of and costs associated with entering into cooperative study arrangements, or CSAs, or licensing arrangements, if any, for the collaborative development of our drug candidates in combination with others' drug candidates;
- 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;
- the costs associated with, and the outcome of, lawsuits against us, if any;
- our acquisition and development of new technologies and drug candidates; and
- competing technological, regulatory and market developments currently unknown to us.

We intend to augment our cash balance through financing transactions, including through a combination of private and public equity offerings, debt financings and collaboration, strategic alliance and licensing arrangements. In connection with capital raising activities, we may be required to dilute our existing stockholders substantially.

As of December 31, 2014, we have 2,843,980 warrants outstanding at a weighted average exercise price of $3.13. 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.

There can be no assurance that we will be able to obtain adequate levels of additional funding on 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.

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. 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 stockholders' rights.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a company undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change taxable income or taxes may be limited. Changes in our stock ownership, some of which are outside of our control, may have resulted or could in

the future result in an ownership change. For example, we completed a review of our changes in ownership through December 31, 2011, and determined that we had three ownership changes since inception. The changes of ownership will result in net operating loss and research and development credit carryforwards that we expect to expire unutilized. If additional limitations were to apply, utilization of a portion of our net operating loss and tax credit carryforwards could be further limited in future periods and a portion of the carryforwards could expire before being available to reduce future income tax liabilities.

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. 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, material 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. 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 in our industry may increase and our business may be harmed.

In recent years, 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, Inc., Pharmasset and Inhibitex by Roche, Gilead and Bristol-Myers Squibb, respectively. Most recently, in August 2014, Merck completed its acquisition of Idenix. As 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 biopharmaceutical 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. In addition, such acquisitions at significant premiums to market price tend to increase volatility of stock prices in our industry, potentially making investors wary of making incremental investment in us.

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 $20.0 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.

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.

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 Institutional Review Boards, or IRBs, may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- 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;
- 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, such as the FDA's recent decision to place a clinical hold on sovaprevir, or noncompliance with regulatory requirements;
- due to the high SVR rates demonstrated by newly approved, competitive therapies like nucleotide polymerase inhibitors sofosbuvir (Sovaldi®) and the sofosbuvir and ledipasvir combination (Harvoni™), the FDA may require us to carry out more extensive studies, evaluate different treatment combinations or complete comparative effectiveness studies and analysis, resulting in significant delays and/or increased costs;
- enrollment in our clinical trials may be slower than we currently anticipate as potential participants have access to commercially launched DAAs, such as telaprevir (Incivek®), boceprevir (Victrelis®), simeprevir (Olysio®) or sofosbuvir (Sovaldi®), the sofosbuvir/ledipasvir combination (Harvoni™), and the ombitasvir/paritaprevir/ritonavir/dasabuvir/rivavirin combination (Viekira Pak™) 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; 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 for the treatment of HCV has recently changed from a protease inhibitor such as telaprevir (Incivek®), boceprevir (Victrelis®) or simeprevir (Olysio®) in combination with P/R to new classes of compounds that provide better safety and efficacy such as nucleotide polymerase inhibitors sofosbuvir (Sovaldi®) and the sofosbuvir and ledipasvir combination (Harvoni™). 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 if the treatment landscape and standard of care continues to change as new therapies are developed.

We, and a number of other companies in the pharmaceutical and biotechnology industries, have suffered significant setbacks in later stage clinical trials even after achieving promising results in early-stage development. For example, in June 2013, the FDA placed a full clinical hold on sovaprevir that was not released until June 2014, during which time we suffered a significant decline in share price.

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 and analysis than we originally anticipated for our drug candidates. Further, we may be required to purchase expensive competitor drugs as comparators to our drug combinations. 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 combinations of ACH-3102, ACH-3422, sovaprevir, and any other drug candidate we may seek to develop in the future, we face risks that:

- the drug candidate may not prove to be efficacious;
- the drug candidate 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 maintain required approvals could materially adversely affect our ability to progress the development of a drug candidate and to generate revenues from that drug candidate. For example, in June 2013, the FDA placed a full clinical hold on sovaprevir that was not released until June 2014.

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 program discontinuations by competitors (such as the discontinuation in 2012 by Bristol-Myers Squibb of BMS-986094, a nucleotide polymerase inhibitor, due to serious cardiac-related adverse events, or the discontinuation in 2013 of Vertex of VX-135, a nucleotide polymerase inhibitor, due to elevations in liver enzymes) 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. We also cannot predict the degree to which new therapies from competitors, like nucleotide polymerase inhibitor sofosbuvir (Sovaldi®), will increase the rigor the FDA applies in its review of subsequent therapies. In addition, in October 2013, the FDA's Center for Drug Evaluation and Research, or CDER, issued for comment new guidelines on the development of DAAs for the treatment of chronic HCV entitled "Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Drugs for Treatment." The guidelines indicate that there is less certainty around the FDA's expectations for clinical development of DAAs for the treatment of HCV and the extent of preclinical and clinical trials, including required clinical comparators that are necessary for registration and approval of a drug candidate.

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;
- the placement by the FDA of a clinical hold or partial clinical hold on a trial, such as the clinical hold placed on sovaprevir from June 2013 until June 2014 and the partial clinical hold currently on sovaprevir for multiple dose studies in healthy volunteers;
- 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; or
- 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.

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, in June 2013, the FDA placed a full clinical hold on sovaprevir after elevations in liver enzymes were noted in a phase I healthy subject drug-drug interaction study evaluating the effects of concomitant administration of sovaprevir with ritonavir-boosted atazanavir. Such hold was lifted in June 2014, allowing us to continue dosing sovaprevir in HCV-infected subjects. Additionally, 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, or 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 ACH-3102 or sovaprevir and there is no guarantee that ACH-3102 or sovaprevir 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 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 FDA, 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.

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 investigational new drug application 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 must be 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 Federal Food, Drug and Cosmetic Act, or FDCA, can delay the submission or the approval of certain applications.

The 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.

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 NS5A inhibitor candidates, our nucleotide polymerase inhibitor candidates and/or our protease 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 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 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 DAA compounds, in three distinct classes, for combination treatment of HCV. Other companies are also developing DAAs in these classes, as well as other classes. Until the recent introduction of DAA therapy, the standard of care for HCV infection included therapy with pegylated interferon and ribavirin. DAAs developed by our competitors, telaprevir (Incivek®) by Vertex, boceprevir (Victrelis®) by Merck, simeprevir (Olysio®) by Johnson & Johnson and sofosbuvir (Sovaldi®) by Gilead, were approved by the FDA for use in combination with P/R, and became a new standard of care for genotype 1 HCV (in the case of telaprevir, boceprevir and simeprevir) and for genotype 2/3 in the case of sofosbuvir. In addition, in October 2014, the first all oral DAA combination therapy for genotype 1 HCV, Gilead's combination therapy of sofosbuvir/ledipasvir (Harvoni™), was approved for commercialization by the FDA, followed in December 2014 by AbbVie's ombitasvir/paritaprevir/ritonavir/ dasabuvir/ribavirin combination (Viekira Pak™.) 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 our future drugs do not achieve market acceptance, we may be unable to generate significant revenue, if any.

Even if combinations of ACH-3102, ACH-3422, sovaprevir, 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;
- 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.

Further, we may face future challenges from payors as new HCV drug approvals such as sofosbuvir (Sovaldi®) have relatively high cost per course of treatment. For example, Sovaldi® is currently priced at approximately $84,000 per 12 week treatment course, or $1,000 per daily dose, and Harvoni™ is currently priced at approximately $94,500 per 12 week treatment course. As a result, pharmacy benefit managers, or PBMs, such as Express Scripts, Inc. and CVS Caremark Corporation have negotiated and announced discounted pricing for participants in contracted health plans, and patients may not have access to all regimens. For example, Gilead Sciences recently announced that they expect aggregate discounts and rebates from list price to total approximately 46% for 2015. Market reaction to announcements about these types of discounts and market expectations about future price pressure may negatively impact our market value and place downward pressure on our stock price.

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.

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 specialty and orphan pharmaceuticals may lead to increased focus on cost containment.

Specialty pharmaceuticals refer to drugs that are generally complex to manufacture, can be difficult to administer, and may require specialty distribution and special patient monitoring. Orphan pharmaceuticals refer

to medicines that treat rare or life-threatening conditions that have smaller patient populations, such as certain types of cancer. The growing availability and use of specialty and 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 specialty and 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.

Even if we are able to commercialize any product candidates, the products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, thereby harming our business.

The regulations that govern marketing approvals, pricing and reimbursement for new therapeutic and diagnostic products vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain regulatory approval.

Our ability to commercialize any products successfully also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with products administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

There may be significant delays in obtaining reimbursement for approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or regulatory authorities in other countries. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government funded and private payors for new products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

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 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 lags 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. 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 AstraZeneca, Bayer AG, or Bayer, Boehringer Ingelheim GmbH, Bristol-Myers Squibb, Enanta, Gilead (including Pharmasset), GlaxoSmithKline, the Janssen Pharmaceuticals companies of Johnson & Johnson (including Alios), Merck (including Idenix), Novartis and Vertex 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 Leahy-Smith America Invents Act, or the America Invents Act, was signed into law in September 2011, and many of the substantive changes became effective in March 2013. 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 for those applications filed after March 2013.

Further, the America Invents Act created for the first time new procedures to challenge issued patents in the United States, including post-grant review and inter partes review proceedings, which some third parties have been using to cause the cancellation of selected or all claims of issued patents of competitors. For a patent with a priority date of March 16, 2013 or later, a petition for post-grant review can be filed by a third party in a nine month window from issuance of the patent. A petition for inter partes review can be filed immediately following the issuance of a patent if the patent was filed prior to March 16, 2013. A petition for inter partes review can be filed after the nine month period for filing a post-grant review petition has expired for a patent with a priority date of March 16, 2013 or later. Post-grant review proceedings can be brought on any ground of challenge, whereas inter partes review proceedings can only be brought to raise a challenge based on published prior art. These adversarial actions at the U.S. Patent Office review patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts, and use a lower burden of proof than used in litigation in U.S. federal courts. Therefore, it is generally considered easier for a competitor or third party to have a U.S. patent cancelled in a Patent Office post-grant review or inter partes review proceeding than invalidated in a litigation in a U.S. federal court. If any of our patents are challenged by a third party in such a U.S. patent office proceeding, there is no guarantee that we or our licensors will be successful in defending the patent, which would result in a loss of the challenged patent right to 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 FDCA or trade secret protection.

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 AstraZeneca, Bayer, Bristol-Myers Squibb, Enanta, Gilead, (including Pharmasset), GlaxoSmithKline, the Janssen Pharmaceuticals companies of Johnson & Johnson (including Alios), Merck (including Idenix), Novartis and Vertex have applications that are directed to certain classes of HCV inhibitors, including synthetic nucleotides. 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. Further, if we are found to have infringed a third-party patent, we could be obligated to pay royalties and/or other payments to the third party for the sale of our product, which may be substantial, or we could be enjoined from selling our product.

For example, we are aware that litigation has been instituted between Merck and Gilead, as well as Idenix and Gilead, wherein Merck (including Idenix) has asserted that Gilead's commercialization of Sovaldi® (sofosbuvir), a nucleotide analog polymerase inhibitor, for the treatment of chronic hepatitis C would infringe certain patents owned by Merck and certain patents co-owned by Idenix. Given the heightened litigation environment around Sovaldi®, it follows that the commercialization of ACH-3422, which is also a uridine nucleotide prodrug, may be subject to similar infringement challenges by Merck, Gilead and/or other companies.

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 post-grant review proceedings, inter partes review proceedings or interference proceedings declared by the U. S. Patent and Trademark Office and/or 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, intellectual property, 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 against us 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.

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

The legal regime protecting intellectual property rights in China and India is weak. Because the Chinese and Indian legal systems 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 and India. Accordingly, we may not be able to effectively protect our intellectual property rights for our compounds in China and India.

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 Asia, 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 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 Related to Our Securities

Our executive officers, directors and principal stockholders have the ability to control or significantly influence all matters submitted to our stockholders for approval, which could have the effect of delaying, deferring or preventing a change in control if us and entrenching our management or board of directors.

As of December 31, 2014, our directors, executive officers and stockholders who own more than 5% of our outstanding common stock, together with their affiliates and related persons, beneficially own, in the aggregate, greater than approximately 40% of our outstanding common stock. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation, sale of

all or substantially all of our assets or similar transaction, as well as our management and affairs. The interests of this group of stockholders may not always coincide with our corporate interests or the interest of other stockholders, and they may act in a manner with which you may not agree or that may not be in the best interests of other stockholders. This concentration of voting power may have the effect of delaying, deferring or preventing a change in control of our company on terms that other stockholders may desire and entrenching our management or board or directors.

Our stock price has been and may in the future 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, 2009 to December 31, 2014, our stock price has ranged from a low of $0.70 to a high of $16.87. 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 clinical trials of our NS5A inhibitor, ACH-3102, our nucleotide polymerase inhibitor, ACH-3422, and our protease inhibitor, sovaprevir;
- further developments relating to the FDA's partial clinical hold on sovaprevir for multiple dose studies in healthy volunteers;
- 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;
- market expectations about and response to the level of sales achieved by, or the prices for, competitive, recently approved drugs such as sofosbuvir (Sovaldi®);
- 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 and actions 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;
- failure of any of our drug candidates, if approved, to achieve commercial success;
- general and industry-specific economic conditions that may affect our business, financial condition and operations, including without limitation 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;
- low trading volume of our common stock; and
- the other factors described in this "Risk Factors" section.

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. For example, we, and certain of our current and former officers, were named as defendants in a consolidated class action lawsuit following our announcements regarding the FDA's clinical hold related to sovaprevir, our clinical-stage drug candidate for the treatment of chronic hepatitis C viral infection. On May 5, 2014, without any settlement payment by us, any individual defendant or any third party on their behalf, the lead plaintiffs in the consolidated class action lawsuit voluntarily dismissed all of their claims without prejudice.

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

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

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.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be stockholders' sole source of gain.

We have never declared or paid cash dividends on our capital stock. 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 March 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.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock trades on the NASDAQ Global Select Market under the symbol "ACHN". The following table sets forth the high and low sale prices per share for our common stock, as reported on the NASDAQ Global Select Market for the periods indicated:

	High	Low
2013		
First Quarter	$10.17	$7.78
Second Quarter	$ 8.80	$6.70
Third Quarter	$ 8.49	$2.87
Fourth Quarter	$ 3.65	$2.26
2014		
First Quarter	$ 4.36	$2.98
Second Quarter	$ 8.61	$2.45
Third Quarter	$13.80	$6.61
Fourth Quarter	$16.87	$9.32

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 the close of business on March 1, 2015, there were approximately 73 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.

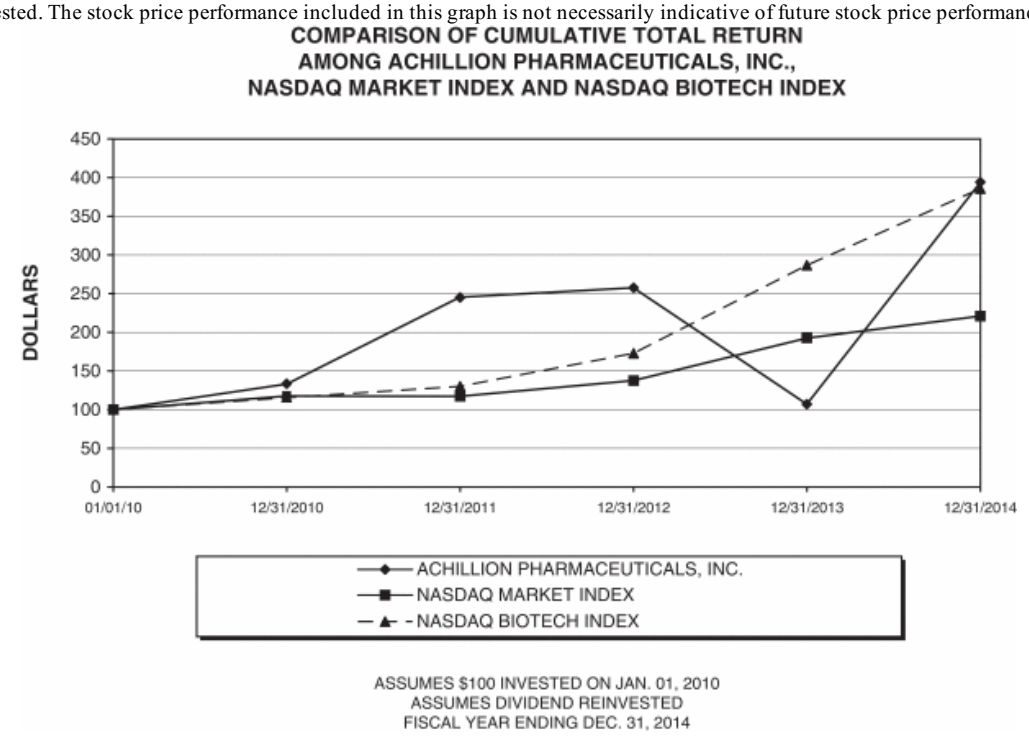
Issuer Purchases of Equity Securities

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 2014.

Comparative Stock Performance

The following graph and related information should not be deemed "soliciting material" or to be "filed" with the SEC for purposes of Section 18 of the Exchange Act, nor shall such information be incorporated by reference into any future filing under the Securities Act or Exchange Act, except to the extent that we specifically incorporate it by reference into such filing.

The following graph compares the cumulative total stockholder return on our common stock from December 31, 2009 to December 31, 2014 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 after the market closed on December 31, 2009 in our common stock, and in the NASDAQ Market Index and the NASDAQ Biotechnology Index, and it assumes any dividends are reinvested. The stock price performance included in this graph is not necessarily indicative of future stock price performance.



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 statement of comprehensive loss data for the years ended December 31, 2014, 2013 and 2012 and balance sheet data as of December 31, 2014 and 2013 set forth below have been derived from our audited financial statements included elsewhere in this Annual Report on Form 10-K. The selected statement of comprehensive loss data for the years ended December 31, 2011 and 2010 and balance sheet data as of December 31, 2012, 2011 and 2010 set forth below have been derived from the audited financial statements for such years not included in this Annual Report on Form 10-K. The historical results presented here are not necessarily indicative of future results.

	Years Ended December 31,				
	2014	2013	2012	2011	2010
	(in thousands, except per share amounts)				
Statement of Comprehensive Loss Data:					
Total revenue	$ —	$ —	$ 2,607	$ 247	$ 2,436
Research and development	53,515	46,736	38,999	35,441	20,529
General and administrative	15,911	12,741	10,901	9,153	7,205
Total operating expenses	69,426	59,477	49,900	44,594	27,734
Loss from operations	(69,426)	(59,477)	(47,293)	(44,347)	(25,298)
Interest income (expense), net	418	530	166	141	(183)
Net loss	(69,008)	(58,947)	(47,127)	(44,206)	(25,481)
Net loss per share—basic and diluted	$ (0.70)	$ (0.63)	$ (0.64)	$ (0.69)	$ (0.57)
Weighted average number of shares outstanding—basic and diluted	98,367	93,983	73,965	64,248	45,079

	2014	2013	2012	2011	2010
Balance Sheet Data:					
Cash and cash equivalents	$ 73,664	$ 33,457	$ 18,526	$ 16,110	$ 25,373
Short-term marketable securities	79,215	88,393	46,884	37,456	29,827
Long-term marketable securities	—	36,139	12,008	26,377	—
Working capital	141,816	115,379	58,731	46,148	52,296
Total assets	156,807	162,417	81,530	82,630	58,235
Long-term liabilities	279	56	347	2,718	2,489
Total liabilities	13,338	9,459	9,483	11,662	7,691
Total stockholders' equity	143,469	152,958	72,047	70,968	50,544

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

The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and the notes to those financial statements appearing elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many important factors, such as those set forth in Part I, Item 1A. "Risk Factors" of this Annual Report on Form 10-K, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

We are a biopharmaceutical company seeking to transform innovation into novel treatments that address the needs of patients by discovering and developing small molecule therapeutics for the treatment of infectious diseases and immune system disorders. We are currently focusing our efforts on developing commercially competitive, short-duration combination therapies for the treatment of chronic hepatitis C virus, or HCV, infection that are once-daily and ribavirin-free. Specifically, we are advancing combination regimens containing:

- ACH-3102, a NS5A inhibitor, currently in phase II clinical development;
- ACH-3422, a NS5B nucleotide polymerase inhibitor, currently in phase I clinical development; and
- Sovaprevir, a NS3 protease inhibitor, currently in phase II clinical development.

In addition to our work on anti-infectives, we have leveraged our internal discovery capabilities and seek to advance a novel platform for the development of oral inhibitors of complement Factor D. Factor D is an essential protein of the complement pathway, a part of the human innate immune system. Our platform is focused on advancing compounds that inhibit Factor D, can be orally-administered, and potentially can be used in the treatment of immune-related diseases where the complement pathway plays a critical role. We anticipate that our complement inhibitor platform may play a role in addressing needs of patients with paroxysmal nocturnal hemoglobinuria, or PNH, including patients who have suboptimal response to, or who fail to respond to, currently approved treatments for PNH, atypical hemolytic uremic syndrome, or aHUS, myasthenia gravis, and age-related macular degeneration, or AMD. Our compounds in complement Factor D inhibition have demonstrated complete suppression of the complement system with a single oral dose of our inhibitors in non-human primates. We plan to nominate one such compound in early 2015 and advance it to a phase I clinical trial by the end of 2015.

We have devoted and are continuing to devote substantially all of our efforts toward product research and development. We have incurred losses of $436.8 million from inception through December 31, 2014 and had an accumulated deficit of $450.7 million at December 31, 2014, which includes preferred stock dividends recognized until our initial public offering in 2006. Our net losses were $69.0 million, $58.9 million and $47.1 million for the years ended December 31, 2014, 2013, and 2012, respectively.

We have funded our operations primarily through proceeds from the sale of equity securities. Through December 31, 2014, we have received approximately $565.9 million in aggregate gross proceeds from stock issuances, including convertible preferred stock, our initial public offering, private placements of our common stock and registered offerings of our common stock. This amount includes proceeds from our sale of 3,236,497 shares of our common stock between December 22, 2014 and December 31, 2014 pursuant to the Sales Agreement, dated November 8, 2012, between us and Cantor Fitzgerald & Co., which we refer to as the Cantor Sales Agreement. In addition, as of December 31, 2014, we had $5.7 million in subscriptions receivable, as a portion of the sales under the Cantor Sales Agreement closed in early January 2015. In February 2015, we sold an aggregate of 13,800,000 shares of our common stock at a price to the public of $10.25 per share in a follow-on underwritten public offering and received approximately $132.6 million in net proceeds, after deducting underwriting discounts and commissions and offering expenses.

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

- continue clinical development of ACH-3102, ACH-3422 and sovaprevir;
- continue preclinical and initiate clinical development of certain complement inhibitors; and
- identify and progress additional drug candidates.

We will need substantial additional financing to obtain regulatory approvals, fund operating losses, and, if deemed appropriate, establish manufacturing and sales and marketing capabilities, which we will seek to raise through public or private equity or debt financings, collaborative or other arrangements with third parties or through other sources of financing. There can be no assurance that such funds will be available on terms favorable to us, if at all.

In addition to the risks associated with being an early-stage drug development company, there can be no assurance that we will successfully advance or complete our research and development programs, 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, which was terminated in February 2012. During the year ended December 31, 2012, we recognized $2.5 million in revenue under the collaboration agreement with Gilead. As a result of the termination of that agreement in February 2012, we did not recognize any revenue under the collaboration agreement in the years ended December 31, 2014 or 2013.

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. Effective with the February 2012 termination of the collaboration, we recognized $2.5 million of deferred revenue relating to the collaboration.

In October 2012, we entered into a license and development agreement with Ora, Inc. for the worldwide development and commercialization of ACH-702, an antibacterial drug candidate, delivered topically or locally, which was amended in April 2013. During the year ended December 31, 2012, we recognized $100,000 of revenue upon the initiation of the 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.

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, 2014, 2013 and 2012 were as follows:

	For the Years Ended December 31,		
	2014	2013	2012
	(in thousands)		
Direct external costs:			
ACH-3102 (and related compounds)	$ 4,415	$ 9,061	$10,554
ACH-3422 (and related compounds)	18,539	2,972	—
Sovaprevir (and related compounds)	1,301	7,725	10,893
Sovaprevir/ACH-3102 combination trials	848	10,471	—
ACH-3102/ACH-2684 combination trial	2,074	49	—
ACH-3102/sofosbuvir combination trial	3,317	—	—
ACH-2684 (and related compounds)	1,465	1,037	3,166
Complement and other	2,881	387	1,730
	34,840	31,701	26,343
Direct internal personnel costs	14,607	11,489	9,824
Sub-total direct costs	49,447	43,190	36,167
Indirect costs and overhead	4,746	3,729	3,386
Connecticut research and development tax credit	(678)	(183)	(554)
Total research and development	$53,515	$46,736	$38,999

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 credit at a rate of 65% of the annual research and development credit, as defined. The benefit for such exchange is recorded as a reduction of research and development expenditures.

We expect research and development expenses associated with the completion of these programs to be substantial and to increase over time. There are numerous existing 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.

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;

- 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.

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 accounting based on whether 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 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.

For the year ended December 31, 2014, we based our estimate of the expected term of historical data for similar stock option grants. We utilized the simplified method in developing an estimate of the expected term of "plain vanilla" share options for the years ended December 31, 2013 and 2012. This method was considered appropriate given our limited exercise history. For the years ended December 31, 2014 and 2013, we calculated volatility based on actual volatility for the expected term of the option. For the year ended December 31, 2012, we calculated volatility from the end of our initial public offering lock-up period to the end of the reporting period. 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 stock-based compensation. There is risk that our estimates of the fair values of our stock-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 stock-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.

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.

We do not have any unrecognized tax benefits as of December 31, 2014 and 2013. 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, determinations as to the commercial potential of proposed products, and 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, 2014, 2013, and 2012 consisted of the following:

	For the Years Ended			Change			
				(in thousands)			
	2014	2013	2012	2014 vs. 2013		2013 vs. 2012	
Gilead collaboration revenue	$—	$—	$2,489	$—	—	$(2,489)	(100)%
Other collaboration revenue	—	—	118	—	—	(118)	(100)%
Total revenue	$—	$—	$2,607	$—	—	$(2,607)	(100)%

Effective with the February 2012 termination of the Gilead collaboration, we recognized the remaining $2.5 million of deferred revenue under the 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.

Comparison of the Years Ended December 31, 2014 and 2013

We did not recognize any revenue during the years ended December 31, 2014 and 2013.

Comparison of the Years Ended December 31, 2013 and 2012

The decrease in collaboration revenue in 2013 is primarily related to the loss of revenue related to our former collaboration with Gilead, which was terminated in February 2012.

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			
	2014	2013	2012	2014 vs. 2013		2013 vs. 2012	
	(in thousands)						
Personnel costs	$11,894	$ 9,342	$ 8,493	$2,552	27%	$ 849	10%
Stock based compensation	2,713	2,146	1,333	567	26%	813	61%
Outsourced research and supplies	31,706	30,326	25,108	1,380	5%	5,218	21%
Professional and consulting fees	5,263	2,720	2,376	2,543	93%	344	14%
Facilities costs	2,083	2,028	2,008	55	3%	20	1%
Travel and other costs	534	357	235	177	50%	122	52%
Research and development tax credit	(678)	(183)	(554)	(495)	270%	371	(67%)
Total	$53,515	$46,736	$38,999	$6,779	15%	$7,737	20%

Comparison of the Years Ended December 31, 2014 and 2013

The increase in research and development expenses from 2013 to 2014 was primarily due to increased clinical and manufacturing costs related to ACH-3422, and increased costs related to our ACH-3102 and sofosbuvir combination trial, as well as increased costs related to our complement inhibitor program. Consulting,

intellectual property and medical affairs related costs also increased. Additionally, personnel costs and non-cash stock-based compensation increased due to the addition of personnel in our development group and increased incentive compensation as the result of exceeding achievement of corporate goals. These amounts were primarily offset by decreased costs related to combination and drug interaction studies of sovaprevir and ACH-3102.

We expect research and development expenses will increase significantly over the next year as we initiate additional Phase II clinical trials for our combinations regimens.

Comparison of the Years Ended December 31, 2013 and 2012

The increase in research and development expenses from 2012 to 2013 was primarily the result of increased costs related to combination trials and drug interaction studies of sovaprevir and ACH-3102, increased costs related to ACH-3422 preclinical studies, and increased scientific consulting fees. Personnel costs and non-cash stock-based compensation also increased due to the addition of personnel in our development group. These costs were partially offset by decreased clinical trial expenses related to ACH-2684.

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			
	2014	2013	2012	2014 vs. 2013		2013 vs. 2012	
	(in thousands)						
Personnel costs	$ 4,339	$ 3,533	$ 3,415	$ 806	23%	$ 118	3%
Stock based compensation	4,560	3,774	2,599	786	21%	1,175	45%
Professional and consulting fees	4,983	3,681	3,208	1,302	35%	473	15%
Facilities costs	729	655	601	74	11%	54	9%
Travel and other costs	1,300	1,098	1,078	202	18%	20	2%
Total	$15,911	$12,741	$10,901	$3,170	25%	$1,840	17%

Comparison of the Years Ended December 31, 2014 and 2013

The increase in general and administrative expenses from 2013 to 2014 was primarily due to increased professional consulting and corporate legal fees as well as insurance costs. Personnel costs and non-cash stock-based compensation also increased primarily due to increased incentive compensation as a result of exceeding achievement of corporate goals.

We expect general and administrative costs to increase during the next year as we continue to support our portfolio development.

Comparison of the Years Ended December 31, 2013 and 2012

The increase in general and administrative expenses from 2012 to 2013 was primarily due to an increase in non-cash stock compensation charges as a result of annual incentive stock option grants made at 2012 year end, combined with increased business development consulting fees and insurance costs.

Other Income and Expense:

Comparison of the Years Ended December 31, 2014 and 2013

Interest income was $455,000 and $582,000 for the years ended December 31, 2014 and 2013, respectively. The $127,000, or 22%, decrease from 2013 to 2014 was primarily due to decreased average cash balances.

Interest expense was $37,000 and $52,000 for the years ended December 31, 2014 and 2013, respectively. The decrease of $15,000, or 29%, was primarily due to lower average debt balances outstanding in 2014.

Comparison of the Years Ended December 31, 2013 and 2012

Interest income was $582,000 and $234,000 for the years ended December 31, 2013 and 2012, respectively. The $348,000, or 149%, increase from 2012 to 2013 was primarily due to increased average cash balances.

Interest expense was $52,000 and $68,000 for the years ended December 31, 2013 and 2012, respectively. The decrease of $16,000, or 24%, was primarily due to lower average debt balances outstanding in 2013.

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through proceeds from the sale of equity securities. Through December 31, 2014, we have received approximately $565.9 million in aggregate gross proceeds from stock issuances, including convertible preferred stock, our initial public offering, private placements of our common stock and registered offerings of our common stock, including the following:

- Between December 22, 2014 and December 31, 2014, we issued 3,236,497 shares of our common stock pursuant to the Cantor Sales Agreement and received net proceeds of $48.3 million;
- In February 2013, we issued 16,894,410 shares of our common stock in an underwritten public offering and received net proceeds of $133.2 million;
- In August 2012, we issued 6,367,853 shares of our common stock in a registered direct offering and 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 and 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 and received net proceeds of $49.9 million; and
- In January and February 2010, we issued 10,275,000 shares of our common stock in an underwritten public offering and received net proceeds of $22.6 million.

In addition, as of December 31, 2014, we had $5.7 million in subscriptions receivable, as a portion of the sales under the Cantor Sales Agreement closed in early January 2015. In February 2015, we sold an aggregate of 13,800,000 shares of our common stock at a price to the public of $10.25 per share in a follow-on underwritten public offering and received $132.6 million in net proceeds, after deducting underwriting discounts and commissions and offering expenses.

In October 2014, we entered into a Master Security Agreement for a $1,000 Capital Expenditure Line of Credit, or 2014 Credit Facility, with Webster Bank, National Association, or Webster. Under the 2014 Credit Facility, we can draw down equipment loan advances for the purchase of new laboratory equipment through October 3, 2015. Each advance under the 2014 Credit Facility will be payable over a three year term and bear interest at a fixed rate, determined at the time of each advance, equal to the three year Federal Home Loan Bank of Boston Classic Advance rate plus 4.75%. On October 3, 2014, Webster advanced $0.4 million to us under the 2014 Credit Facility.

As of December 31, 2014, our debt balance due to borrowings was $474,000 with a weighted average interest rate of 6.32%. As of December 31, 2014, the following amounts remain outstanding under the following debt facilities:

Lender	Date	Interest Rate (per annum)	Principal Amount	Outstanding Balance	Maturity Date
Webster Bank	February 2012	6.44%	$608,769	$ 55,990	March 2015
Webster Bank	October 2014	6.30%	$440,000	$ 417,563	October 2017

We had $152.9 million, $158.0 million and $77.4 million in aggregate cash, cash equivalents and marketable securities as of December 31, 2014, 2013, and 2012, respectively.

Cash used in operating activities was $55.5 million for the year ended December 31, 2014 and was primarily attributable to our $69.0 million net loss primarily offset by $9.7 million non-cash charges related to depreciation, amortization of premiums on marketable securities and stock -based compensation combined with a $3.8 million increase in accounts payable and accrued expenses. Cash used in operating activities was $53.6 million for the year ended December 31, 2013 and was primarily attributable to our $58.9 million net loss combined with $3.4 million in premiums paid on the purchase of marketable securities, primarily offset by $8.7 million in non-cash charges related to depreciation, amortization of premiums on marketable securities and stock -based compensation. 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 provided by investing activities was $43.3 million for the year ended December 31, 2014 and was primarily attributable to maturities of marketable securities partially offset by purchases of marketable securities. Cash used in investing activities was $65.0 million for the year ended December 31, 2013 and was primarily attributable to purchases of marketable securities partially offset by maturities of marketable securities. 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 provided by financing activities was $52.4 million for the year ended December 31, 2014 and was primarily attributable to $42.6 million in net proceeds from the sale of 3,236,497 shares of our common stock pursuant to the Cantor Sales Agreement, combined with $9.4 million in proceeds from the exercise of stock options and warrants. Cash provided by financing activities was $133.6 million for the year ended December 31, 2013 and was primarily attributable to $133.2 million in net proceeds from our public offering in February 2013. 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.

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

- continue clinical development of ACH-3102, ACH-3422, and sovaprevir;
- continue preclinical and initiate clinical development of certain complement inhibitors; 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.

Based on our current clinical plan, and after giving effect to our underwritten public offering of shares of our common stock in February 2015, which resulted in aggregate net proceeds to us of $132.6 million, after deducting underwriting discounts and commissions and offering expenses, we believe that our existing cash, cash

equivalents and marketable securities will be sufficient to meet our current projected operating requirements for at least the next 12 months. However, our future capital 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 ACH-3102, ACH-3422, and sovaprevir;
- the costs involved in the preclinical and clinical development of certain complement inhibitors;
- the scope of and costs associated with entering into CSAs or licensing arrangements, if any, for the collaborative development of our drug candidates in combination with third-party drug candidates;
- 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;
- the costs associated with, and the outcome of, lawsuits against us, if any;
- 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 through a combination of public and private equity offerings, debt financings and collaboration, strategic alliance and licensing arrangements. In connection with capital raising activities, we may be required to dilute our existing stockholders substantially. 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 that may be 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.

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. 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 stockholders' rights.

Contractual Obligations and Commitments

The following table sets forth a summary of our commitments as of December 31, 2014:

	Payment Due by Period				
	Total	Less Than 1 Year	1-3 Years	3-5 Years	More than 5 Years
	(in thousands)				
Debt, including interest	$ 514	$ 218	$ 296	$ —	$ —
Operating lease obligations	1,636	638	830	168	—
Clinical research obligations	16,387	16,063	308	16	—
Research obligations and licenses	575	115	230	230	—
Other professional obligations	488	488	—	—	—
Total	$19,600	$17,522	$1,664	$ 414	$ —

Other professional obligations consist mainly of general and administrative consulting obligations. Upon the achievement of specified development milestones for elvucitabine we will be required to make milestone payments to Yale University and Emory University. We will also be 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 potential payments under these agreements have been excluded from the above amounts.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements as of December 31, 2014.

Recently Issued Accounting Standards

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-09, "Revenue from Contracts with Customers (Topic 606)," which supersedes all existing revenue recognition requirements, including most industry-specific guidance. ASU No. 2014-09 requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. ASU No. 2014-09 will be effective for us on January 1, 2017. We do not believe ASU No. 2014-09 will have a material effect on our financial position and results of operations.

In August 2014, FASB issued ASU No. 2014-15, "Presentation of Financial Statements – Going Concern." ASU No. 2014-15 provides guidance regarding management's responsibility to evaluate whether there exists substantial doubt about a company's ability to continue as a going concern and to provide related footnote disclosures in certain circumstances. ASU No. 2014-15 is effective for annual reporting periods beginning after December 15, 2016, and interim periods thereafter. We do not believe ASU No. 2014-15 will have a material effect on our financial position and results of operations.

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 duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. 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, among other things, capital market forces affecting our stock price.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2014. 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, 2014, 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, 2014. 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 (2013)*.

Based on its assessment, management concluded that, as of December 31, 2014, our internal control over financial reporting is effective based on those criteria.

The effectiveness of our internal control over financial reporting as of December 31, 2014 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, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

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, 2014. 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 26 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, 2014. 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" of the Proxy Statement.

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

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

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

The information required by this item is incorporated herein by reference to the information contained under the sections captioned "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.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements

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

(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.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 5, 2015.

ACHILLION PHARMACEUTICALS, INC.

By: /s/ MILIND S. DESHPANDE
Milind S. Deshpande
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 and on the dates indicated.

Signature	Title	Date
/s/ MILIND S. DESHPANDE **Milind S. Deshpande**	President and Chief Executive Officer and Director (Principal executive officer)	March 5, 2015
/s/ MARY KAY FENTON **Mary Kay Fenton**	Executive Vice President and Chief Financial Officer (Principal financial and accounting officer)	March 5, 2015
/s/ JASON FISHERMAN, M.D. **Jason Fisherman, M.D.**	Director	March 5, 2015
/s/ GARY E. FRASHIER **Gary E. Frashier**	Director	March 5, 2015
/s/ KURT GRAVES **Kurt Graves**	Director	March 5, 2015
/s/ MICHAEL D. KISHBAUCH **Michael D. Kishbauch**	Director	March 5, 2015
/s/ DENNIS LIOTTA **Dennis Liotta**	Director	March 5, 2015
/s/ DAVID SCHEER **David Scheer**	Chairman of the Board	March 5, 2015
/s/ ROBERT VAN NOSTRAND **Robert Van Nostrand**	Director	March 5, 2015
/s/ NICOLE VITULLO **Nicole Vitullo**	Director	March 5, 2015

INDEX TO FINANCIAL STATEMENTS

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, 2014 and December 31, 2013, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2014 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, 2014, based on criteria established in *Internal Control—Integrated Framework (2013)* 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. Our responsibility is to express opinions on these financial statements, and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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

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

/s/ PricewaterhouseCoopers LLP

Hartford, Connecticut
March 5, 2015

Achillion Pharmaceuticals, Inc.

Balance Sheets
(in thousands, except per share amounts)

	As of December 31,	
	2014	2013
Assets		
Current assets:		
Cash and cash equivalents	$ 73,664	$ 33,457
Marketable securities	79,215	88,393
Accounts and other receivables	95	480
Prepaid expenses and other current assets	1,901	2,452
Total current assets	154,875	124,782
Marketable securities	—	36,139
Fixed assets, net	1,726	1,265
Deferred financing costs	54	79
Restricted cash	152	152
Total assets	$ 156,807	$ 162,417
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 6,418	$ 4,591
Accrued expenses	6,446	4,521
Current portion of long-term debt	195	291
Total current liabilities	13,059	9,403
Long-term debt	279	56
Total liabilities	13,338	9,459
Commitments (Notes 13 and 14)		
Stockholders' Equity:		
Common Stock, $.001 par value; 200,000 shares authorized at December 31, 2014 and 2013; 103,594 and 96,792 shares issued and outstanding at December 31, 2014 and 2013, respectively	104	97
Additional paid-in capital	599,796	534,529
Stock subscription receivable	(5,737)	—
Accumulated deficit	(450,682)	(381,674)
Accumulated other comprehensive income (loss)	(12)	6
Total stockholders' equity	143,469	152,958
Total liabilities and stockholders' equity	$ 156,807	$ 162,417

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

Achillion Pharmaceuticals, Inc.

Statements of Comprehensive Loss
(in thousands, except per share amounts)

	Years Ended December 31,		
	2014	2013	2012
Revenue	$ —	$ —	$ 2,607
Operating expenses			
Research and development	53,515	46,736	38,999
General and administrative	15,911	12,741	10,901
Total operating expenses	69,426	59,477	49,900
Loss from operations	(69,426)	(59,477)	(47,293)
Other income (expense)			
Interest income	455	582	234
Interest expense	(37)	(52)	(68)
Net loss	$(69,008)	$(58,947)	$(47,127)
Unrealized (loss) gain on marketable securities	(18)	(13)	39
Total other comprehensive (loss) income	(18)	(13)	39
Total comprehensive loss	$(69,026)	$(58,960)	$(47,088)
Basic and diluted net loss per share attributable to common stockholders (Note 4)	$ (0.70)	$ (0.63)	$ (0.64)
Weighted average shares used in computing basic and diluted net loss per share attributable to common stockholders	98,367	93,983	73,965

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

Achillion Pharmaceuticals, Inc.

Statements of Stockholders' Equity for the Years Ended December 31, 2012, 2013 and 2014
(in thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Stock Subscription Receivable	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount					
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
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
Net loss	—	—	—	(58,947)	—	—	(58,947)
Other comprehensive income (loss)	—	—	—	—	—	(13)	(13)
Stock compensation	—	—	5,920	—	—	—	5,920
Issuance of common stock upon exercise of warrants	4	—	—	—	—	—	—
Issuance of common stock upon exercise of stock options	224	—	555	—	—	—	555
Issuance of common stock under the Employee Stock Purchase Plan	44	—	185	—	—	—	185
Issuance of common stock in connection with the public offering, net of issuance costs	16,894	17	133,194	—	—	—	133,211
Balances at December 31, 2013	96,792	$ 97	$534,529	$(381,674)	—	$ 6	$ 152,958
Net loss	—	—	—	(69,008)	—	—	(69,008)
Other comprehensive income (loss)	—	—	—	—	—	(18)	(18)
Stock compensation	—	—	7,273	—	—	—	7,273
Issuance of common stock upon exercise of warrants	2,099	2	5,249	—	—	—	5,251
Issuance of common stock upon exercise of stock options	1,364	1	4,192	—	(126)	—	4,067
Issuance of common stock under the Employee Stock Purchase Plan	102	1	240	—	—	—	241
Issuance of common stock in connection with the public offering, net of issuance costs	3,237	3	48,313	—	(5,611)	—	42,705
Balances at December 31, 2014	103,594	$ 104	$599,796	$(450,682)	(5,737)	$ (12)	$ 143,469

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

Achillion Pharmaceuticals, Inc.

Statements of Cash Flows
(in thousands)

	Years Ended December 31,		
	2014	2013	2012
Cash flows from operating activities			
Net loss	$ (69,008)	$ (58,947)	$(47,127)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	489	399	408
Noncash stock-based compensation	7,273	5,920	3,932
(Gain)/loss on disposal/trade-in of equipment	(2)	—	1
Premium on purchases of marketable securities	(947)	(3,387)	(755)
Amortization of premium on marketable securities	1,959	2,360	444
Changes in operating assets and liabilities:			
Accounts and other receivables	385	(203)	(174)
Prepaid expenses and other current assets	575	(104)	(757)
Accounts payable	1,827	315	(519)
Accrued expenses	1,925	11	502
Deferred revenue	—	—	(2,489)
Net cash used in operating activities	(55,524)	(53,636)	(46,534)
Cash flows from investing activities			
Purchase of fixed assets	(947)	(408)	(656)
Purchase of marketable securities	(79,338)	(168,117)	(79,759)
Maturities of marketable securities	123,625	103,491	85,050
Net cash provided by (used in) investing activities	43,340	(65,034)	4,635
Cash flows from financing activities			
Proceeds from issuance of common stock in connection with the public offerings and the private placement, net of issuance costs	42,705	133,211	41,660
Proceeds from exercise of stock options	4,067	555	2,378
Proceeds from exercise of warrants	5,251	—	—
Proceeds from sale of stock under the Employee Stock Purchase Plan	241	185	197
Borrowings of debt	440	—	609
Repayments of debt	(313)	(350)	(282)
Payment of deferred financing costs	—	—	(247)
Net cash provided by financing activities	52,391	133,601	44,315
Net increase in cash and cash equivalents	40,207	14,931	2,416
Cash and cash equivalents, beginning of period	33,457	18,526	16,110
Cash and cash equivalents, end of period	$ 73,664	$ 33,457	$ 18,526
Supplemental disclosure of cash flow information			
Cash paid for interest	$ 35	$ 46	$ 60
Supplemental disclosure of noncash financing activities			
Cashless exercise of warrants	$ 2,848	$ 47	$ 14,106

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

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 is seeking to transform innovation into novel treatments that address the needs of patients by discovering and developing small molecule therapeutics for the treatment of infectious diseases and immune system disorders. The Company is devoting substantially all of its efforts towards product research and development.

The Company incurred losses of $436,819 from inception through December 31, 2014 and had an accumulated deficit of $450,682 at December 31, 2014, 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.

Based on the Company's current clinical plan, and after giving effect to its underwritten public offering of shares of its common stock in February 2015, which resulted in aggregate net proceeds to the Company of $132.6 million, after deducting underwriting discounts and commissions and offering expenses, the Company believes that its existing cash, cash equivalents and marketable securities will be sufficient to meet its current projected operating requirements for at least the next 12 months. However, the Company's future capital 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 ACH-3102, ACH-3422 and sovaprevir;
- the costs involved in the preclinical and clinical development of certain complement inhibitors;
- the scope of and costs associated with entering into cooperative study arrangements or licensing arrangements, if any, for the collaborative development of its drug candidates in combination with others' drug candidates;
- 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 costs associated with, and the outcome of, lawsuits against the Company, if any;
- the Company's acquisition and development of new technologies and drug candidates; and
- competing technological and market developments currently unknown to the Company.

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.

Achillion Pharmaceuticals, Inc.

Notes to Financial Statements—(Continued)
(in thousands, except per share amounts)

Revenue Recognition

The Company recognizes revenue from contract research and development and research progress payments in accordance with Accounting Standards Codification ("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.

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.

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.

For the year ended December 31, 2014, the Company based its estimate of the expected term on historical data for similar stock option grants. The Company utilized the simplified method in developing an estimate of the expected term of "plain vanilla" share options for the years ended December 31, 2012 and 2013. This method was considered appropriate given the Company's limited exercise history. For the years ended December 31, 2014 and 2013, the Company calculated volatility based on actual volatility for the expected term of the option. For the year ended December 31, 2012, the Company calculated volatility from the end of its initial public offering lock-up period to the end of the reporting period. 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 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.

Achillion Pharmaceuticals, Inc.

Notes to Financial Statements—(Continued)
(in thousands, except per share amounts)

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, 2014, the Company had $73,664 of cash and 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 in active markets, that are observable either directly or indirectly, such as quoted prices for similar assets or liabilities, quoted in markets that are not active, or other inputs that are observable; or

Level 3: Unobservable inputs.

The fair value of the Company's marketable securities of $79,215 as of December 31, 2014 was valued based on level 2 inputs. The Company's investments consist mainly of corporate debt securities and government sponsored bond obligations. 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 has assessed these as level 2 within the fair value hierarchy of ASC 820. 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 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.

Achillion Pharmaceuticals, Inc.

Notes to Financial Statements—(Continued)
(in thousands, except per share amounts)

For the years ended December 31, 2014, 2013, and 2012, 0%, 0% and 95%, respectively, of the Company's revenue was generated from an agreement with one former collaboration partner. At December 31, 2014, 96% of the Company's accounts receivable was from one contract research organization.

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 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 financial statements reflect expected future tax consequences of such positions presuming the taxing authorities' full knowledge of the position and all relevant facts.

Achillion Pharmaceuticals, Inc.

Notes to Financial Statements—(Continued)
(in thousands, except per share amounts)

The Company did not have any unrecognized tax benefits as of December 31, 2014. The Company reviews all tax positions to ensure the tax treatment selected is sustainable based on its technical merits and that the position would be sustained if challenged.

Segment Information

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

Accounting Standards Updates

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, "Revenue from Contracts with Customers (Topic 606)," which supersedes all existing revenue recognition requirements, including most industry-specific guidance. ASU No. 2014-09 requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. ASU No. 2014-09 will be effective on January 1, 2017. The Company does not believe ASU No. 2014-09 will have a material effect on its financial position and results of operations.

In August 2014, FASB issued ASU No. 2014-15, "Presentation of Financial Statements – Going Concern." ASU No. 2014-15 provides guidance regarding management's responsibility to evaluate whether there exists substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosures in certain circumstances. ASU No. 2014-15 is effective for annual reporting periods beginning after December 15, 2016, and interim periods thereafter. The Company does not believe ASU No. 2014-15 will have a material effect on its financial position and results of operations.

3. Financing Activities

Public Offerings

The Company sold 3,236 shares of its common stock between December 22, 2014 and December 31, 2014 pursuant to the Sales Agreement, dated November 8, 2012, between the Company and Cantor Fitzgerald & Co. (the "Cantor Sales Agreement"). In connection with these sales, as of December 31, 2014, the Company received $48,316 in net proceeds and had $5.6 million in subscriptions receivable, as a portion of the sales under the Cantor Sales Agreement closed in January 2015. In January 2015, the Company received the remaining $5.6 million in net proceeds from the portion of the sales that closed in January 2015. See Note 18, Subsequent Events.

In February 2013, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Citigroup Global Markets, Inc. and Leerink Swann LLC as representatives of the several underwriters named therein (the "Underwriters"), related to a public offering of shares of the Company's common stock, par value $0.001 per share, at a price of $8.40 per share less underwriting discounts and commissions. The Company issued and sold to the Underwriters an aggregate of 16,894 shares of common stock in connection with the Offering. The offering resulted in net proceeds to the Company of $133,211.

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.

Achillion Pharmaceuticals, Inc.

Notes to Financial Statements—(Continued)
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4. Earnings (Loss) Per Share

Basic earnings (loss) per share ("EPS") is calculated in accordance with Accounting Standards Codification ("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. 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. The calculations of basic and diluted net loss per share are as follows:

	Years Ended December 31,		
	2014	2013	2012
	(in thousands)		
Net loss (numerator)	$(69,008)	$(58,947)	$(47,127)
Weighted-average shares, in thousands (denominator)	98,367	93,983	73,965
Basic and diluted net loss per share	$ (0.70)	$ (0.63)	$ (0.64)

Potentially dilutive securities outstanding as of December 31, 2014, 2013 and 2012 are as follows:

	Years Ended December 31,		
	2014	2013	2012
	(in thousands)		
Stock Options	9,493	9,083	7,112
Warrants	2,844	5,338	5,358

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 NS4A 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.

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

Achillion Pharmaceuticals, Inc.

Notes to Financial Statements—(Continued)
(in thousands, except per share amounts)

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. The Company did not receive any payment 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.

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. The Ora Agreement was amended in April 2013. Under the terms of the Ora Agreement, Ora has assumed 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 has agreed to pay the Company 15% 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 the Ora 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 sublicensee(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 any milestone payments upon achievement of the milestone by Ora or its sublicensee(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 $79,215 and $124,532 as of December 31, 2014 and 2013, respectively, is valued based on level 2 inputs. The Company's investments consist mainly of corporate debt securities and government sponsored bond obligations. Fair value is determined by taking into

(in thousands, except per share amounts)

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 years ended December 31, 2013 and 2014. The Company has assessed these as level 2 within the fair value hierarchy of ASC 820. 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.

The unrealized (loss) gain from marketable securities was $(12), $6, and $19 at December 31, 2014, 2013 and 2012, respectively.

As of December 31, 2014, none of the Company's investments were determined to be other than temporarily impaired.

The following table summarizes the Company's investments:

	December 31, 2014				December 31, 2013			
	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value
Commercial Paper	$ 4,747	$ 3	—	$ 4,750	$ 14,190	$ 9	—	$ 14,199
Corporate Debt Securities	58,452	1	(16)	58,437	95,036	27	(25)	95,038
Government and Agency Securities	16,028	1	(1)	16,028	15,300	1	(6)	15,295
Total	$79,227	$ 5	(17)	$79,215	$124,526	$ 37	(31)	$124,532

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

	As of December 31,	
	2014	2013
Government	16,028	15,295
Banking	18,925	24,847
Industrial	44,262	84,390
Total	$79,215	$124,532

7. Prepaid Expenses and Other Current Assets

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

	As of December 31,	
	2014	2013
Prepaid research and development costs	$ 221	$ 691
Tax credit receivable	678	183
Maintenance agreements	387	371
Interest receivable	551	1,115
Other prepaid expenses	64	92
Total	$1,901	$2,452

Achillion Pharmaceuticals, Inc.

Notes to Financial Statements—(Continued)
(in thousands, except per share amounts)

8. Fixed Assets, net

A summary of property and equipment is as follows:

	As of December 31,	
	2014	2013
Laboratory equipment	$ 3,461	$ 2,912
Office equipment	989	807
Leasehold improvements	3,017	2,981
	7,467	6,700
Less—accumulated depreciation and amortization	(5,741)	(5,435)
Total	$ 1,726	$ 1,265

Depreciation expense was $488, $390, and $402 for the years ended December 31, 2014, 2013 and 2012, respectively.

9. Accrued Expenses

Accrued expenses consist of the following:

	As of December 31,	
	2014	2013
Accrued compensation	$ 846	$ 554
Accrued research and development expenses	4,727	3,276
Accrued professional expenses	649	432
Other accrued expenses	224	259
Total	$6,446	$4,521

Accrued research and development expenses are comprised of amounts owed to third-party contract research organizations, ("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,	
	2014	2013
2011 Credit Facility, payable in equal monthly installments through March 2015, with fixed interest of 6.44% per annum	$ 56	$ 347
2014 Credit Facility, payable in equal monthly installments through October 2017, with fixed interest of 6.30% per annum	418	—
Total long-term debt	474	347
Less: current portion	(195)	(291)
Total long-term debt, net of current portion	$ 279	$ 56

Achillion Pharmaceuticals, Inc.

Notes to Financial Statements—(Continued)
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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 ("Webster"). Under the 2011 Credit Facility, the Company could draw down equipment loan advances for the purchase of new laboratory equipment through March 2013. In connection with the Master Security Agreement, the Company granted Webster a security interest in equipment to be purchased under the Credit Facility

In October 2014, the Company entered into a Master Security Agreement for a $1,000 Capital Expenditure Line of Credit (the "2014 Credit Facility") with Webster. Under the 2014 Credit Facility, the Company can draw down equipment loan advances for the purchase of new laboratory equipment through October 2015. In connection with the Master Security Agreement, the Company granted Webster a security interest in equipment to be purchased under the Credit Facility. In October, 2014, Webster advanced $440 to the Company under the Credit Facility.

The fair value for this debt is 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, 2014, the Company had 5,000 authorized shares of undesignated preferred stock of which no shares were issued and outstanding.

Common Stock

At December 31, 2014, the Company had 200,000 authorized shares of $0.001 par value common stock of which 103,594 shares were issued and outstanding and 14,095 shares were reserved for future issuance.

Warrants

At December 31, 2014, there were 2,844 warrants outstanding with a weighted average exercise price of $3.13 and a weighted average remaining contractual life of 2.64 years.

Stock Subscription Receivable

In December 2014, the Company issued 3,236 shares of common stock under a sales agreement with Cantor Fitzgerald. Sales of the Company's common stock under the agreement with Cantor Fitzgerald were 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. The offering resulted in net proceeds to the Company of $48,316. $5,611 of the proceeds related to the common stock issuance were not received until January 2015 and were recorded as a stock subscription receivable as of December 31, 2014.

In December 2014, the Company issued 19 shares of common stock upon the exercise of stock options. The proceeds of $126 were not received until January 2015 and were recorded as a stock subscription receivable as of December 31, 2014.

12. Stock-Based Compensation

1998 Stock Option Plan

The Company's 1998 Stock Option Plan ("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.

Achillion Pharmaceuticals, Inc.

Notes to Financial Statements—(Continued)
(in thousands, except per share amounts)

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 ("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.

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Notes to Financial Statements—(Continued)
(in thousands, except per share amounts)

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, 2014, there were 1,716 shares available to be granted under the 2006 Plan.

A summary of the status of the Company's stock option activity for the year ended December 31, 2014 is presented in the table and narrative below:

	2014	
	Options	Weighted Average Exercise Price
Outstanding at January 1, 2014	9,083	$ 5.14
Granted	2,224	11.02
Exercised	(1,364)	3.07
Forfeited	(326)	3.48
Cancelled	(124)	5.16
Outstanding at December 31, 2014	9,493	$ 6.88
Options exercisable at December 31, 2014	4,768	$ 5.73
Options vested and expected to vest at December 31, 2014	8,889	$ 6.84

The following table summarizes information about stock options outstanding at December 31, 2014:

	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	210	4.0	$ 1.05	210	$ 1.05
$2.01 – $4.00	3,918	7.6	3.08	2,165	3.10
$4.01 – $6.00	377	3.2	5.16	368	5.15
$6.01 – $8.00	1,836	7.7	7.45	1,058	7.40
$8.01 – $10.00	1,119	8.0	8.70	566	8.64
$10.01 – $12.00	51	7.9	10.65	24	10.65
$12.01 – $14.00	1,655	9.9	13.44	50	13.24
$14.01 – $16.00	323	2.0	14.75	323	14.75
$16.01 – $20.00	4	2.1	19.00	4	19.00
	9,493	7.6	$ 6.88	4,768	$ 5.73

As of December 31, 2014, the intrinsic value of the options outstanding and options vested was $53,817 and $31,986, 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, 2014, 2013 and 2012 was $7,855, $790, and $6,206, respectively.

Achillion Pharmaceuticals, Inc.

Notes to Financial Statements—(Continued)
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The weighted-average, grant-date fair value of options granted during the years ended December 31, 2014, 2013 and 2012 was $8.50, $3.29, and $6.15, respectively. The weighted-average, grant-date fair value of options vested at December 31, 2014, 2013 and 2012 was $4.13, $3.52 and $3.31, respectively.

The weighted average remaining contractual life is 6.2 years for options exercisable and 7.6 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 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,		
	2014	2013	2012
Expected term of option	5.0 - 6.25 years	5.0 - 6.1 years	5.0 - 6.1 years
Expected volatility	92% - 96%	87% - 94%	88% - 90%
Risk free interest rate	1.81 - 2.02%	1.01 - 2.10%	0.83 - 1.33%
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, 2014, 2013 and 2012 was $7,177, $5,760, and $3,643, 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, 2014, 2013 and 2012 was $0, $69, and $197, 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, 2014, the total compensation cost related to options not yet recognized in the financial statements is approximately $24,738, net of estimated forfeitures, and the weighted average period over which it is expected to be recognized is 1.7 years.

Achillion Pharmaceuticals, Inc.

Notes to Financial Statements—(Continued)
(in thousands, except per share amounts)

Compensation expense related to option grants made to employees and consultants is included in research and development and general and administrative expense as follows:

	For the Years Ended December 31,		
	2014	2013	2012
Research and development	$ 2,713	$ 2,146	$ 1,333
General and administrative	4,464	3,682	2,507
Total	$ 7,177	$ 5,828	$ 3,840

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 $96, $92, and $92, respectively, for the years ended December 31, 2014, 2013 and 2012, respectively, which is included in general and administrative expenses. As of December 31, 2014, there were 42 shares available for future issuance under the 2006 ESPP Plan.

The assumptions used to value options granted under the 2006 ESPP Plan are as follows:

	For the Years Ended December 31,		
	2014	2013	2012
Expected term of option	6 months	6 months	6 months
Expected volatility	67% - 130%	47% - 141%	61% - 91%
Risk free interest rate	0.06 - 0.08%	0.11 - 0.14%	0.12 - 0.16%
Expected dividend yield	0%	0%	0%

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 technologies. Included in the accompanying 2014, 2013 and 2012 statements of comprehensive loss is $140, $140, and $153, 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.

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Notes to Financial Statements—(Continued)
(in thousands, except per share amounts)

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, 2014, 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, 2014, 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 and Contingencies

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 $262, $238, and $203 for the years ended December 31, 2014, 2013 and 2012.

Operating Leases

The Company leases its operating facility located in New Haven, Connecticut. The lease agreement requires 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 $83 and $98 at December 31, 2014 and 2013, respectively.

Achillion Pharmaceuticals, Inc.

Notes to Financial Statements—(Continued)
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The future minimum annual lease payments under this operating lease at December 31, 2014 are as follows:

Year Ended December 31,	
2015	$ 638
2016	$ 662
2017	$ 168
Total	$1,468

Rent expense under operating leases was approximately $617, for each of the years ended December 31, 2014, 2013 and 2012.

From time to time, in the ordinary course of business, the Company is subject to litigation and regulatory examinations as well as information gathering requests, inquiries and investigations.

On May 5, 2014, the lead plaintiffs in the previously disclosed consolidated class action lawsuit originally filed in October 2013 against the Company and certain of its current and former officers in the United States District Court for the District of Connecticut voluntarily dismissed all of their claims without prejudice. The Court approved the voluntary dismissal and closed the case on May 6, 2014. A dismissal without prejudice does not prevent the litigation of the same claims in a subsequent action.

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,		
	2014	2013	2012
Deferred:			
Federal and state	$ 29,287	$ 28,554	$ 3,293
Valuation allowance	(29,287)	(28,554)	(3,293)
Total deferred	$ —	$ —	$ —

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Notes to Financial Statements—(Continued)
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A reconciliation of the statutory tax rates to the effective tax rates is as follows:

	Years Ended December 31,		
	2014	2013	2012
Federal statutory rate	(34.0)%	(34.0)%	(34.0)%
State tax, net of federal benefit	(5.0)	(5.0)	(5.0)
Other	0.07	0.07	0.05
Share-based compensation	(0.56)	2.90	(2.51)
Valuation allowance	39.49	36.03	41.46
	0%	0%	0%

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

	As of December 31,	
	2014	2013
Gross deferred tax assets:		
Net operating losses	$ 154,019	$ 127,687
Tax credits (federal and state)	11,419	9,734
Share-based compensation	5,378	4,140
Other	601	569
	$ 171,417	$ 142,130
Less—valuation allowance	(171,417)	(142,130)
Net deferred tax asset	$ —	$ —

At December 31, 2014 and 2013, the Company had gross deferred income tax assets of approximately $171,417 and $142,130, 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, 2014 and 2013, the Company had available the following net operating loss and credit carryforwards:

	As of December 31,	
	2014	2013
Federal net operating loss carryforwards	$360,598	$297,270
State net operating loss carryforwards	418,879	354,869
Federal research and development credit carryforwards	7,007	5,693
State research and development credit carryforwards	4,412	4,041

The Company's federal net operating loss carryforwards expire commencing in 2018 through 2034 and state net operating loss carryforwards which expire commencing in 2020 through 2034. The Company's federal research and development credit carryforwards expire commencing in 2028 through 2033. The Connecticut research and development carryforwards have no expiration period.

Achillion Pharmaceuticals, Inc.

Notes to Financial Statements—(Continued)
(in thousands, except per share amounts)

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 $11,086 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 public groups in the stock of a corporation by more than 50 percentage points over a three-year period. The Company completed a review of its changes in ownership through December 31, 2011, and determined that it had three ownership changes since inception. The changes of ownership will result in approximately $55,429 of net operating loss carryforwards that the Company expects to expire unutilized and approximately $4,066 of research and development credit carryforwards that the Company expects 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. The Company will continue to update its analysis of ownership changes and the potential limitations on its 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 2003 through 2014 in federal and the State of Connecticut jurisdictions.

The Company did not have any unrecognized tax benefits as of December 31, 2013 and 2014.

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, 2014, 2013 and 2012, the Company recorded a benefit of approximately $678, $183, and $554, respectively, for the estimated proceeds from this exchange. This benefit is recorded as a reduction of research and development expenditures.

16. Related Party Transactions

Nicole Vitullo

In connection with Domain Associates, LLC's ("Domain") agreement to invest in the Company, 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.

Achillion Pharmaceuticals, Inc.

Notes to Financial Statements—(Continued)
(in thousands, except per share amounts)

As of December 31, 2014, Domain was the beneficial owner of approximately 7% of the Company's total issued and outstanding shares of common stock.

17. Unaudited Quarterly Results

The following tables summarize unaudited quarterly financial data for the years ended December 31, 2014 and 2013. 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.

	2014 Quarters			
	First	Second	Third	Fourth
Total operating revenue	$ —	$ —	$ —	$ —
Total operating expenses	16,235	15,766	15,764	21,661
Net loss	(16,088)	(15,657)	(15,667)	(21,596)
Net loss per share—basic and diluted	$ (0.17)	$ (0.16)	$ (0.16)	$ (0.21)
Weighted average number of shares outstanding—basic and diluted	96,792	97,017	99,031	100,579

	2013 Quarters			
	First	Second	Third	Fourth
Total operating revenue	$ —	$ —	$ —	$ —
Total operating expenses	11,793	20,113	14,076	13,495
Net loss	(11,738)	(19,940)	(13,919)	(13,350)
Net loss per share—basic and diluted	$ (0.14)	$ (0.21)	$ (0.14)	$ (0.14)
Weighted average number of shares outstanding—basic and diluted	85,850	96,580	96,648	96,705

18. Subsequent Events

As discussed in Note 3, Financing Activities, the Company sold 3,236 shares of its common stock between December 22, 2014 and December 31, 2014 pursuant to the Cantor Sales Agreement. In January 2015, the Company received $5.6 million in net proceeds from the portion of the sales that closed in January 2015.

On February 18, 2015, the Company sold an aggregate of 13,800 shares of its common stock at a price to the public of $10.25 per share in a follow-on underwritten public offering and received $132.6 million in net proceeds, after deducting underwriting discounts and commissions and offering expenses.

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EXHIBIT INDEX

	Exhibit No.	Description	Incorporated by Reference			Filed with this 10-K
			Form	SEC Filing date	Exhibit Number	
	3.1	Amended and Restated Certificate of Incorporation of the Registrant, as amended.	10-K	03/08/12	3.1	
	3.2	Amended and Restated Bylaws of the Registrant.	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/A	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	Form of Common Warrant issued by the Registrant pursuant to the Securities Purchase Agreement dated as of August 5, 2008.	S-3	10/06/08	10.3	
	10.5	Form of Common Warrant issued by the Registrant pursuant to the Securities Purchase Agreement dated as of August 18, 2010.	S-3	09/17/10	10.2	
	10.6	Sales Agreement, dated as of November 8, 2012 by and between the Registrant and Cantor Fitzgerald & Co.	10-Q	11/8/12	10.2	
	10.7	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	
	10.8	Amendment No. 2 to Lease, dated as of March 31, 2010, by and between the Registrant and WE George Street, LLC.	8-K	04/06/10	10.1	
#	10.9	1998 Stock Option Plan, as amended, March 30, 2001.	S-1	03/31/06	10.17	
#	10.10	Form of Incentive Stock Option Agreement under the 1998 Stock Option Plan.	S-1	03/31/06	10.19	
#	10.11	Form of Incentive Stock Option Agreement for Non-Executives under the 1998 Stock Option Plan.	S-1	03/31/06	10.20	
#	10.12	Form of Nonstatutory Stock Option Agreement under the 1998 Stock Option Plan.	S-1	03/31/06	10.21	
#	10.13	2006 Stock Incentive Plan as amended September 18, 2006, March 9, 2010, June 10, 2010, April 11, 2012 and June 5, 2012.	8-K	06/11/12	99.3	
#	10.14	Form of Nonstatutory Stock Option Agreement under the 2006 Stock Incentive Plan.	8-K	12/22/10	99.1	

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	Exhibit No.	Description	Incorporated by Reference			Filed with this 10-K
			Form	SEC Filing date	Exhibit Number	
#	10.15	Form of Incentive Stock Option Agreement under the 2006 Stock Incentive Plan.	8-K	12/22/10	99.2	
#	10.16	2006 Employee Stock Purchase Plan as amended September 18, 2006, March 9, 2010, and June 10, 2010.	10-K	02/20/13	10.23	
#	10.17	Employment Agreement dated April 5, 2011, between the Registrant and Gautam Shah, Ph.D.	8-K	04/08/11	10.5	
#	10.18	Second Amended and restated Employment Agreement and Supplemental Severance Agreement, dated March 9, 2010, and Supplemental Terms of Compensation, dated April 5, 2011, between the Registrant and Mary Kay Fenton.	8-K	04/08/11	10.2	
#	10.19	Employment Agreement, dated April 5, 2011, between the Registrant and Joseph Truitt.	8-K	04/08/11	10.6	
#	10.20	Employment Agreement, dated May 6, 2013 between the Registrant and David Apelian.	8-K	05/30/13	10.1	
#	10.21	Employment Agreement, dated May 28, 2013 between the Registrant and Milind Deshpande.	8-K	05/30/13	10.2	
#	10.22	Letter Agreement, dated May 23, 2014, between the Registrant and Milind Deshpande	10-Q	08/07/14	10.1	
	10.23	Form of Common Stock Warrant issued by the Registrant under Loan and Security Agreement of GE Capital Corporation and Oxford Finance Corporation.	10-K	03/05/08	10.14	
	10.24	Master Security Agreement between the Registrant and Webster Bank, National Association, dated as of October 3, 2014.	8-K	10/03/14	10.1	
	10.25	Master Security Agreement between the Registrant and Webster Bank, National Association, dated as of March 21, 2011.	8-K	03/25/11	10.1	
	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

Exhibit No.	Description	Incorporated by Reference			Filed with this 10-K
		Form	SEC Filing date	Exhibit Number	
101.CAL	XBRL Taxonomy Calculation Linkbase Document				X
101.INS	XBRL Instance Document				X
101.SCH	XBRL Taxonomy Extension Schema Document				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	XBRL Taxonomy Label Linkbase Document				X
101.PRE	XBRL Taxonomy Presentation Linkbase Document				X

Management contracts or compensatory plans or arrangement

† Indicates confidential treatment requested as to certain portions, which portions were omitted and filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Request.

Attached as Exhibit 101 to this report are the following formatted in XBRL (Extensible Business Reporting Language): (i) Balance Sheets at December 31, 2014 and December 31, 2013, (ii) Statements of Comprehensive Loss for the years ended December 31, 2014, 2013 and 2012, (iii) Statements of Stockholders' Equity and Comprehensive Loss for the years ended December 31, 2012, 2013 and 2014, (iv) Statements of Cash Flows for the years ended December 31, 2014, 2013 and 2012 and (v) Notes to Financial Statements.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-183152, 333-168902, 333-158241, 333-149729, 333-141661 and 333-138984) and Form S-3 (Nos. 333-194410, 333-184826, 333-183650 and 333-172594) of Achillion Pharmaceuticals, Inc. of our report dated March 5, 2015 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

Hartford, Connecticut
March 5, 2015

EXHIBIT 31.1

Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002

I, Milind S. Deshpande, certify that:

1. I have reviewed this Annual Report on Form 10-K of Achillion Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ MILIND S. DESHPANDE

Milind S. Deshpande
President and Chief Executive Officer

Dated: March 5, 2015

EXHIBIT 31.2

Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002

I, Mary Kay Fenton certify that:

1. I have reviewed this Annual Report on Form 10-K of Achillion Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ MARY KAY FENTON

Mary Kay Fenton
Chief Financial Officer

Date: March 5, 2015

EXHIBIT 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Achillion Pharmaceuticals, Inc. (the "Company") for the period ended December 31, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Milind S. Deshpande, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350 as adopted by Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 5, 2015

/s/ MILIND S. DESHPANDE

Milind S. Deshpande
President and Chief Executive Officer

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

EXHIBIT 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Achillion Pharmaceuticals, Inc. (the "Company") for the period ended December 31, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Mary Kay Fenton, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350 as adopted by Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 5, 2015

/s/ MARY KAY FENTON

Mary Kay Fenton
Chief Financial Officer

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