Conatus Pharmaceuticals Inc
Form 10-K
March 28, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-K

(Mark One)

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2013

OR

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

FOR THE TRANSITION PERIOD FROM _____ TO _____

Commission file number: 001-36003

CONATUS PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

Delaware	**20-3183915**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
4365 Executive Dr., Suite 200	
San Diego, CA	**92121**
(Address of Principal Executive Offices)	**(Zip Code)**

(858) 558-8130

(Registrant s Telephone Number, Including Area Code)

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

Title of each class:	**Name of each exchange on which registered:**
Common Stock, par value $0.0001 per share	**The NASDAQ Global Market**

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

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

Indicate by a check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934. Yes ¨ No x

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to 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 the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

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

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

As of March 14, 2014, the aggregate market value of the registrant s common stock held by non-affiliates of the registrant was approximately $87.8 million, based on the closing price of the registrant s common stock on The NASDAQ Global Market of $11.10 per share. The registrant has elected to use March 14, 2014 as the calculation date, as on June 30, 2013 (the last business day of the registrant s most recently completed second fiscal quarter) the registrant was a privately-held concern.

As of March 14, 2014, the registrant had 15,632,000 shares of common stock ($0.0001 par value) outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive proxy statement to be filed with the Securities and Exchange Commission by April 30, 2014 pursuant to Regulation 14A in connection with the registrant s 2014 Annual Meeting of Stockholders are incorporated by reference into Part III of this report.

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For the Year Ended December 31, 2013

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PART I

FORWARD-LOOKING STATEMENTS AND MARKET DATA

This annual report on Form 10-K contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this annual report, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated products, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. This annual report on Form 10-K also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

In some cases, you can identify forward-looking statements by terms such as may, will, should, expect, plan, anticipate, could, intend, target, project, contemplates, believes, estimates, predicts, potential or negative of these terms or other similar expressions. The forward-looking statements in this annual report are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward- looking statements speak only as of the date of this annual report and are subject to a number of risks, uncertainties and assumptions, including those described in Part I, Item 1A, Risk Factors. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

We use our registered trademark, CONATUS PHARMACEUTICALS, in this annual report. This annual report also includes trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, trademarks and tradenames referred to in this annual report appear without the ® and symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these trademarks and tradenames.

We maintain a website at www.conatuspharma.com, to which we regularly post copies of our press releases as well as additional information about us. Our filings with the Securities and Exchange Commission, or SEC, are available free of charge through our website as soon as reasonably practicable after being electronically filed with or furnished to the SEC. Interested persons can subscribe on our website to email alerts that are sent automatically when we issue press releases, file our reports with the SEC or post certain other information to our website. Information contained in our website does not constitute a part of this report or our other filings with the SEC.

ITEM 1. BUSINESS

Overview

We are a biotechnology company focused on the development and commercialization of novel medicines to treat liver disease. We are developing our lead compound, emricasan, for the treatment of patients with chronic liver disease and acute exacerbations of chronic liver disease. Emricasan is a first-in-class, orally active pan-caspase protease inhibitor designed to reduce the activity of all ten human caspases, which are enzymes that mediate inflammation and cell death, or apoptosis. We believe that by reducing the activity of these enzymes,

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emricasan has the potential to interrupt the progression of liver disease and potentially provide treatment options in multiple areas of liver disease. We have observed compelling preclinical and clinical trial results that suggest emricasan may have clinical utility in slowing progression of liver diseases regardless of the original cause of the disease. To date, emricasan has been studied in over 500 subjects in ten clinical trials. In a randomized Phase 2b clinical trial in patients with liver disease, emricasan demonstrated a statistically significant, consistent, rapid and sustained reduction in elevated levels of two key biomarkers of inflammation and cell death, alanine aminotransferase, or ALT, and cleaved Cytokeratin 18, or cCK18, respectively, both of which are implicated in the severity and progression of liver disease.

We have designed a comprehensive clinical program to demonstrate the therapeutic benefit of emricasan across the spectrum of fibrotic liver disease. Our initial development strategy targets indications for emricasan with high unmet clinical need and small, potentially orphan, patient populations, such as patients with acute-on-chronic liver failure, or ACLF, and chronic liver failure, or CLF. ACLF and CLF are potential orphan indications in both the United States and European Union, or the EU. We plan to submit applications for orphan drug designations for ACLF in the United States and the EU in the second half of 2014. Although we plan to focus primarily on the development of emricasan for ACLF and CLF, we also plan to evaluate the compound in patients who have developed liver fibrosis post-orthotopic liver transplant, or POLT, due to hepatitis C virus, or HCV, infection and have subsequently achieved sustained viral response, or SVR, following anti-HCV therapy, or POLT-HCV-SVR, as well as in patients with non-alcoholic steatohepatitis, or NASH. We were granted orphan drug designation in late 2013 by the United States Food and Drug Administration, or the FDA, for the treatment of POLT patients with reestablished fibrosis to delay the progression to cirrhosis and end-stage liver disease.

Target Therapeutic Area	Description of Patient Population	Development Plans
Acute-on-Chronic Liver Failure	ACLF occurs in patients who have compensated or decompensated cirrhosis but are in relatively stable condition until an acute event sets off a rapid worsening of liver function.	Our planned clinical trials in ACLF will evaluate whether emricasan can halt the progression of decompensation to multi-organ failure or death in an acutely decompensating cirrhotic patient population. We initiated a Phase 2b ACLF clinical trial in the second half of 2013, and we plan to submit applications for orphan drug designations for ACLF in the United States and the EU in the second half of 2014.
Chronic Liver Failure	Patients with CLF suffer from compensated or decompensated cirrhosis.	Our planned clinical trials in CLF will assess whether emricasan can delay or prevent disease progression. We plan to initiate a Phase 2 CLF clinical trial in the second half of 2014.

Post Liver Transplant Clearance of Hepatitis C Virus Infection with Sustained Viral Response	In patients with POLT-HCV-SVR, liver fibrosis may persist for many years.	We plan to initiate a placebo-controlled (sponsor open) Phase 2b clinical trial tracking biomarkers and histology in POLT patients who respond to antiviral therapy but still have underlying liver fibrosis in the second half of 2014.
Non-alcoholic Steatohepatitis	NASH patients suffer from inflammation due to fat buildup in the liver.	We recently initiated a Phase 2 clinical trial in the United States for non-alcoholic fatty liver disease, or NAFLD, and NASH. Our goal is to accumulate sufficient and relevant clinical data to allow rapid advancement of emricasan once appropriate regulatory pathways are defined.

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Our Team

Our senior management team includes former senior executives of Idun Pharmaceuticals, Inc., or Idun, and our Chief Medical Officer, who was the clinical program leader for emricasan during its development at Pfizer Inc. At Idun, these senior executives discovered and led the development of emricasan, Idun s lead asset, which was then known as IDN-6556, until the company was sold to Pfizer in July 2005 for approximately $298 million. We acquired the global rights to emricasan from Pfizer, where it was known as PF-3491390, in July 2010. At both Idun and Pfizer, emricasan was being developed for the treatment of liver fibrosis. As a result of our collective experience, we believe we can successfully develop emricasan for the treatment of liver diseases, including ACLF, CLF and POLT-HCV-SVR. We believe we can accumulate sufficient and relevant clinical data to allow rapid development of emricasan once appropriate regulatory pathways are defined in NASH.

Our Strategy

Our strategy is to develop and commercialize medicines to treat liver disease and associated fibrotic indications in areas of high unmet medical need. The key elements of our strategy are to:

Develop emricasan as a treatment for liver diseases with high unmet clinical need and in small, potentially orphan, patient populations. We believe that by inhibiting the caspases responsible for inflammation and apoptosis in the liver, emricasan has the potential to stabilize and improve liver function and to slow liver fibrosis progression in patients with liver disease. We are focused on developing emricasan for high unmet clinical need and small, potentially orphan, patient populations, including ACLF, CLF and POLT-HCV-SVR. We believe that because these indications represent targeted patient populations, the size and cost of the required clinical trials will be manageable for a company of our size.

Pursue accelerated pathways for regulatory approval in the United States and the EU. Based on our discussions with regulatory authorities in the United Kingdom and Germany, we have designed a clinical trial for ACLF that could suffice as a single registration trial in the EU if the results are compelling. However, the FDA may require additional registration trials for ACLF. Other indications may also require more than one registration trial. We plan to discuss our registration strategy for ACLF and CLF with the FDA after we have received data from our initiated Phase 2b ACLF clinical trial.

Build our own sales and marketing capabilities to commercialize emricasan for indications that target small, potentially orphan, patient populations in North America and the EU. If emricasan is approved for ACLF, CLF or POLT-HCV-SVR in North America or the EU, we intend to build our own commercial organization to market the product for these indications. Specifically, we plan to build a focused, specialized sales force to target the key physicians who treat these indications in these geographic locations, including hepatologists and other liver specialists in tertiary care and transplant centers.

Evaluate strategic partnerships to maximize the commercial potential of emricasan. We plan to evaluate opportunities to partner emricasan with pharmaceutical companies that have established sales and marketing capabilities in regions outside of North America and the EU. We may also partner with a pharmaceutical company that has global capabilities to evaluate emricasan in non-orphan indications for

which we believe it may also be effective, such as liver fibrosis from viral hepatitis, alcoholic hepatitis and NASH.

Overview of Liver Disease

The liver is the largest internal organ in the human body and its proper function is indispensable for many critical metabolic functions, including the regulation of lipid and sugar metabolism, the production of important proteins, including those involved in blood clotting, and purification of blood. There are over 100 described diseases of the liver, and because of its many functions, these can be highly debilitating and life-threatening unless effectively treated. Liver diseases can result from injury to the liver caused by a variety of insults,

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including HCV, hepatitis B virus, or HBV, obesity, chronic excessive alcohol use or autoimmune diseases. Regardless of the underlying cause of the disease, there are important similarities in the disease progression including increased inflammatory activity and excessive liver cell apoptosis, which if unresolved leads to fibrosis. Fibrosis, if allowed to progress, will lead to cirrhosis, or excessive scarring of the liver, and eventually reduced liver function. Some patients with liver cirrhosis have a partially functioning liver and may appear asymptomatic for long periods of time, which is referred to as compensated liver disease. When the liver is unable to perform its normal functions this is referred to as decompensated liver disease. Many people with active liver disease remain undiagnosed largely because liver disease patients are often asymptomatic for many years. The National Institutes of Health, or NIH, estimates that 5.5 million Americans have chronic liver disease or cirrhosis, and liver disease is the twelfth leading cause of death in the United States. According to the European Association for the Study of the Liver, 29 million Europeans have chronic liver disease and liver disease represents approximately two percent of deaths annually. In the United States, more than 5,000 liver transplants are performed in adults and more than 500 in children annually, with approximately 17,000 patients still awaiting transplant.

Liver disease is often first detected as hepatitis, which is defined as inflammation of the liver. Hepatitis is easily detected by a routine laboratory test to measure blood levels of the liver enzyme ALT. ALT is elevated in almost all liver diseases and represents an overall measure of liver inflammation and liver cell death. As liver disease progresses, fibrotic scar tissue will begin to replace healthy liver tissue and over time will reduce the liver s ability to function properly. A liver biopsy is used to diagnose fibrosis and determine how much liver scarring has developed. If fibrosis is allowed to progress, it will lead to cirrhosis. As liver cirrhosis becomes progressively worse, all aspects of liver function will dramatically decline.

ACLF occurs in patients who are in relatively stable condition until an acute event sets off a rapid deterioration of liver function. The morbidity and mortality of the patient population with ACLF is high. If the patient survives the acute decompensating event, they may return to a stable state. Patients with CLF suffer from continual disease progression which may eventually lead them to require liver transplantation. Despite advances in liver transplantation, morbidity and mortality in the CLF patient population remains high with some patients ineligible for a liver transplant and others unable to be matched with a suitable donor liver.

Patients who receive liver transplants as a result of HCV infection are at risk of residual HCV still being present in the patient s blood, which can immediately infect the new liver, thus increasing the risk of accelerated inflammation and fibrosis. Even after successful treatment with drugs designed to clear the HCV infection, fibrotic changes in the liver may persist for many years. Liver fibrosis can be scored using the standard Ishak Fibrosis Score, which stages the severity of fibrosis and/or cirrhosis on a 0-6 scale. We are planning to initiate a placebo-controlled clinical trial in the POLT-HCV-SVR population with liver fibrosis in the second half of 2014. If emricasan demonstrates the ability to halt the progression of fibrosis in this population, we believe that this could serve as a basis to evaluate emricasan for additional indications in patients at earlier stages of liver fibrosis resulting from HCV, HBV, obesity, chronic excessive alcohol use or autoimmune diseases.

The Role of Apoptosis, Necrosis and Inflammation in Liver Disease

The death of cells and resulting inflammation play an important role in the progression of many liver diseases. In general, cells can die by either of two major mechanisms, apoptosis, a form of programmed cell death, or necrosis. Both of these mechanisms can produce a state of acute and/or chronic inflammation as shown in Figure 1.

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Figure 1. Apoptosis and Necrosis: The Two Main Pathways of Liver Cell Death

High levels of noxious stimuli can rapidly overwhelm the cell s natural protective mechanisms, leading to a rupture of the cell and subsequent release of its contents into the surrounding tissue. This process is known as necrosis and results in a highly pro-inflammatory response, further damaging the surrounding tissue. In contrast, the programmed cell death mechanism, termed apoptosis, is a highly controlled and tightly regulated process that involves the orderly condensation and dismantling of the cell leading to its subsequent rapid and specific removal from the surrounding tissue by specialized cells. However, under conditions of excessive stress as often observed in disease, the production of apoptotic cells outpaces the body s ability to effectively remove them from the surrounding tissue. This results in an accumulation of shed cell fragments known as apoptotic bodies which are taken up by surrounding cells and can stimulate additional cell death. Disease-driven excessive apoptosis results in the development of scar tissue or fibrosis which can lead to tissue destruction and eventually reduce the capacity of an organ to function normally.

Markers of Liver Cell Death

ALT is an enzyme that is produced in liver cells and is naturally found in the blood of healthy individuals. In liver disease, liver cells are damaged and as a consequence, ALT is released into the blood increasing ALT levels above the normal range. Physicians routinely test blood levels of ALT to monitor the health of a patient s liver. ALT level is a clinically important biochemical marker of the severity of liver inflammation and ongoing liver disease. Elevated levels of ALT represent general markers of liver cell death and inflammation without regard to any specific mechanism. Aspartate aminotransferase, or AST, is a second enzyme found in the blood that is produced in the liver and routinely measured by physicians along with ALT. As with ALT, AST is often elevated in liver disease and, like ALT, is considered an overall marker of liver inflammation. We have measured both ALT and AST levels in our clinical trials and have observed similar effects of emricasan on both enzymes. However, because ALT is considered more liver specific and the pattern of changes we have observed in AST levels has been similar to those seen in ALT levels, our discussion will focus primarily on ALT.

Another important marker of liver cell death is a protein fragment called cCK18. During apoptosis, a key structural protein within the cell called Cytokeratin 18, or CK18, is specifically cleaved by caspases which results in the release of cCK18 into the blood stream. cCK18 is easily detected in the blood with a commercially-available test and is a mechanism-specific biomarker of apoptosis and caspase activity. Importantly, cCK18 is also present in healthy subjects and multiple studies have demonstrated an approximate basal level in healthy subjects.

Numerous independent clinical trials and published studies have demonstrated the utility of cCK18 for detecting and gauging the severity of ongoing liver disease across a variety of disease etiologies. These studies

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have demonstrated correlations between disease and cCK18 levels in patients with ACLF, CLF, HCV, NASH and various other liver disease indications. For example, it has been shown that in HCV patients, the severity of liver disease was correlated with cCK18 levels and apoptosis, such that the more severe the disease, the higher the serum level of cCK18. In ACLF patients, studies have shown that blood levels of cCK18 were higher in non-surviving patients than in patients that survived. In CLF patients, studies have shown that cCK18 levels are elevated and correlate with liver inflammation and cholestasis. In POLT patients with recurrent HCV, it has been shown that cCK18 levels and apoptosis were significantly elevated in liver biopsies as determined by immunohistochemical analysis. We believe these studies demonstrate the relationship between elevated cCK18 levels and severity of liver disease and that cCK18 is a valid and important biomarker of excessive apoptosis in liver disease.

Emricasan

Emricasan is a first-in-class, proprietary and orally active caspase protease inhibitor designed to slow or halt the progression of chronic liver disease caused by fibrosis and cirrhosis. To date, emricasan has been administered to over 500 subjects in six Phase 1 and four Phase 2 clinical trials and has been generally well-tolerated in both healthy volunteers and patients with liver disease. In particular, we have completed two placebo-controlled Phase 2 clinical trials in patients with liver disease showing statistically significant reductions in ALT levels that occur rapidly, within as little as one day after initiation of therapy, and are maintained throughout the treatment period. In our 204-patient Phase 2b clinical trial, we also measured cCK18, an important biomarker of apoptosis and disease severity. Statistically significant reductions in cCK18 were demonstrated in this clinical trial as early as three hours post-dosing and were maintained for the duration of dosing. Emricasan has been generally well-tolerated in all of the clinical trials. Emricasan has also been extensively profiled in in vitro tests and studied in many preclinical models of human disease.

Mechanism of Action

Emricasan works by inhibiting caspases, which are a family of related enzymes that play an important role as modulators of critical cellular functions, including functions that result in apoptosis and inflammation. Caspase activation and regulation is tightly controlled through a number of mechanisms. All caspases are expressed as enzymatically inactive forms known as pro-caspases which can be activated following a variety of cellular insults or stimuli. Seven caspases are specifically involved in the process of apoptosis while three caspases specifically activate pro-inflammatory cytokines and are not directly involved in apoptosis as shown in Figure 2.

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Figure 2. Emricasan is a Potent Inhibitor of Apoptotic and Inflammatory Caspases

Caspase mediated apoptosis is driven primarily by the activity of caspases 3 and 7 which, by virtue of their enzymatic activity, cleave a wide variety of cellular proteins and result in dismantling of the cell. Other apoptotic caspase family members are principally involved in sensing and transmitting signals from either outside or inside the cell. These signals converge to activate pro-caspases 3 and 7, enabling them to carry out the process of apoptosis.

CK18 is one key structural protein that is cleaved by caspases 3 and 7 in a highly specific manner. The product of this cleavage is a small protein fragment, cCK18. This fragment is contained within the apoptotic cell fragments and is easily detected in serum using a commercially available monoclonal antibody assay. This monoclonal antibody, M30, is used routinely in clinical trials as a measure of apoptosis.

While healthy individuals have normal levels of apoptosis, excessive levels of apoptosis associated with disease can overwhelm the body s normal clearance mechanisms. Reducing excessive levels of apoptosis reestablishes balance between apoptotic activity and normal clearance mechanisms and brings inflammation and other drivers of disease progression under control. As a result, we believe targeting caspases that drive both apoptosis and inflammation in disease offers a unique and potentially powerful therapeutic approach for the treatment of both acute and chronic liver disease.

Testing in vitro enzyme assays demonstrated that emricasan efficiently inhibits all human caspases at low nanomolar concentrations. Preclinical studies have demonstrated that emricasan is highly selective for the caspase family of enzymes with little to no activity against other enzyme systems. These studies have also shown that emricasan potently inhibits the apoptosis of cells regardless of the apoptotic stimuli and that it is a potent

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inhibitor of caspase-mediated pro-inflammatory cytokines. Emricasan has been examined in various preclinical models of liver disease. In these models, caspase activity was demonstrated to be inhibited, as determined by histological examination, in liver tissue. Based on our evaluation of emricasan in in vitro systems, cellular assays and disease models, we believe emricasan s mechanism of action has been well characterized.

Clinical Data

To date, emricasan has been studied in over 500 subjects in six Phase 1 clinical trials and four Phase 2 clinical trials. This includes a total of 153 healthy volunteers, 306 subjects with elevated ALT levels and 53 liver transplant subjects receiving single or multiple doses of emricasan ranging from 1 to 500 mg per day orally or 0.1 to 10 mg/kg per day intravenously for up to 12 weeks. Emricasan has demonstrated evidence of a beneficial effect on serological biomarkers in patients with chronic liver disease independent of the cause of disease. Favorable changes have been observed in functional biomarkers of liver damage and inflammation, such as ALT and AST, and mechanistic biomarkers, such as cCK18 and caspase activity, indicating that emricasan works by the presumed mechanism of action of inhibiting apoptosis of liver cells. Importantly, clinical trials have also demonstrated that emricasan does not inhibit normal levels of caspase activity in healthy individuals. Emricasan has been generally well-tolerated in clinical trials completed to date.

Phase 2b Dose Response Study in HCV Patients (Study A8491003)

Study A8491003, or the 003 trial, was a Phase 2b, randomized, multicenter, placebo-controlled, double-blind, parallel group, dose response trial. The clinical trial was designed to evaluate the safety and efficacy of emricasan in patients with chronic HCV infection who were unresponsive to antiviral therapy and who had compensated liver disease with or without fibrosis. Patients with cirrhosis or hepatocellular carcinoma were excluded from the clinical trial. The clinical trial enrolled 204 HCV patients across three oral emricasan dose arms of twice-daily, or BID, 5 mg, 25 mg and 50 mg and one placebo arm. The primary endpoint in the study was changes from baseline in ALT and AST levels over a period of 12 weeks. This study also measured cCK18 levels and caspase 3 and 7 activity as exploratory biomarkers. In this clinical trial, emricasan treatment resulted in statistically significant reductions in the primary endpoints of ALT and AST levels as well as statistically significant reductions in cCK18 levels and caspase 3 and 7 activity.

As shown in Figure 3 below, the changes in ALT demonstrated in the 003 trial were statistically significant in each of the emricasan treatment groups compared with the placebo group. The decreases in ALT were seen by day seven, the first time post-dosing that ALT was measured, and the decreases were maintained throughout the treatment period (up to 12 weeks) in all emricasan treatment groups. Discontinuation of emricasan at the end of the treatment period was followed by a gradual return of ALT towards baseline levels.

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Figure 3. Change in ALT (Mean ± SEM(1)) from Baseline Following BID Dosing in Subjects with HCV

(1) Standard Error of the Mean.
(2) Upper limit of normal for males.

In addition to ALT levels, the 003 trial also examined changes in AST levels. As shown in Figure 4 below, the reductions in AST levels demonstrated in the 003 trial were also statistically significant in each of the emricasan treatment groups compared with the placebo group. Consistent with the ALT results, reductions in AST levels were seen as early as seven days and were maintained throughout the treatment period. At the end of treatment, AST levels gradually returned to baseline levels. During the 003 trial, biochemical flare, which is defined as ALT or AST values twice as high as the baseline value while on emricasan treatment, or overshoot, which is defined as ALT or AST values twice as high as the baseline value after stopping emricasan treatment, occurred in patients randomized to both placebo and emricasan. Twenty-one patients in the clinical trial experienced flare and/or overshoot; six of these patients had both flare and overshoot; six of these patients had flare only; and nine of these patients had overshoot only. Of the six patients with flare and overshoot, four were in the placebo group, one was in the 5 mg group and one was in the 25 mg group. Of the six patients with flare only, two were in the placebo group, one was in the 5 mg group and three were in the 50 mg group. Of the nine patients with overshoot only, one was in the placebo group, five were in the 5 mg group, two were in the 25 mg group and one was in the 50 mg group. These data suggest that the occurrence may be part of the natural variability of ALT or AST levels in the patient population under study. All subjects were followed up until levels had returned to baseline levels and there were no reports by the investigator of any clinical concern.

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Figure 4. Change in AST (Mean ± SEM(1)) from Baseline Following BID Dosing in Subjects with HCV

(1) Standard Error of the Mean.
(2) Upper limit of normal for males.

The 003 trial data also provide evidence that emricasan reduces cCK18 levels from baseline in patients with elevated cCK18 levels, as shown in Figure 5 below. Statistically significant reductions in cCK18 levels were reported as early as three hours after dosing and were still evident following ten weeks of treatment, within each of the 5 mg, 25 mg and 50 mg dose arms compared to baseline values in the relevant dose group. Importantly, in the 003 trial, after ten weeks of dosing, cCK18 levels in all emricasan treatment groups were similar to the baseline level of cCK18 in healthy volunteers as established in our Phase 1 clinical trial (see the description of study IDN-6556-03 below) and as generally reported from independent trials. We believe this observation suggests that normal levels of caspase activity remain intact. We also believe that by returning apoptosis to normalized levels, emricasan may enable the balance between apoptosis and the body s normal clearance mechanism for apoptosis to be restored.

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Figure 5. Change in cCK18 from Baseline Following BID Dosing in Subjects with HCV

The 003 trial also included measurements of caspase 3 and 7 enzymatic activity. As shown in Figure 6 below, emricasan significantly reduced caspase 3 and 7 activity in a pattern similar to its effect on cCK18. We believe these data demonstrate that emricasan rapidly reduces elevated levels of caspase enzymatic activity and, as a consequence, excessive apoptosis in these patients. Since caspase 3 and 7 are known to be involved in the cleavage of CK18 which produces cCK18, we also believe these data suggest that the effect of emricasan on cCK18 is a result of inhibiting caspase activity. In addition, consistent with the cCK18 data, emricasan did not eliminate all caspase 3 and 7 activity in these patients. We believe this suggests that emricasan does not interfere with normal base levels of caspase activity or apoptosis, which is important in establishing the overall safety profile of emricasan.

Figure 6. Change in Caspase 3 and 7 Enzymatic Activity from Baseline Following BID Dosing in Subjects with HCV

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In the 003 trial, emricasan was generally observed to be well-tolerated. The most commonly reported adverse events in emricasan-treated subjects were headache, fatigue, nausea and diarrhea, most of which were mild to moderate in severity. Thirteen subjects withdrew from the study including seven in the placebo group, three from the 5 mg, two from the 50 mg and one from the 25 mg emricasan groups. Nineteen adverse events reported by 14 subjects were considered severe with the greatest incidence in the placebo and 5 mg emricasan-treated groups (seven events each) and the lowest incidence in the 25 mg treatment group (one event). Severe adverse events were varied and showed no pattern across the treatment groups. The majority of adverse events had been resolved by the end of the study and the numbers of continuing events were similar for each of the patient cohorts. In addition, no concerning changes in any of the laboratory parameters and no clinically relevant changes in vital signs, electrocardiograms, physical examinations or liver ultrasound scans could be attributed to emricasan.

Phase 2 Ascending Dose Study in Patients with Hepatic Impairment (Study A8491004)

Study A8491004, or the 004 trial, was a Phase 2, randomized, multicenter, placebo-controlled, double-blind, ascending dose trial in 105 patients with mild to moderate hepatic impairment. The clinical trial was designed to evaluate the safety, tolerability and pharmacokinetics, or PK, of several dosing regimens of orally administered emricasan in these patients. The secondary objective of the clinical trial was to evaluate the effects of emricasan on ALT and AST, as markers of efficacy. The clinical trial was conducted at seven study sites and emricasan was administered orally for up to three times daily for 14 days. The study predominantly included patients with HCV liver disease and also included limited numbers of patients with liver disease attributed to other causes, including HBV, NASH and primary biliary cirrhosis/primary sclerosing cholangitis. While once-daily, or QD, and BID dosing in the HCV patients demonstrated significant reductions in ALT from baseline, the BID dosing cohorts demonstrated greater percentage decreases of ALT levels than QD dosing.

In the 004 trial, 25 HCV patients were administered emricasan once per day for 14 days. As set forth in Figure 7 below, ALT reductions were rapid and sustained during the 14-day dosing period with a 30% to 40% reduction from baseline. While ALT decreases were statistically significantly different than placebo for QD dosing at 25 mg, 100 mg and 200 mg (p-values ranging from 0.0041 to <0.0001), those seen at a QD dose of 5 mg were less dramatic. After treatment with emricasan was completed, ALT levels returned to pre-treatment levels.

Figure 7. Percentage Change in ALT from Baseline Following QD Dosing in Subjects with HCV

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The 004 trial also examined BID and three times daily, or TID, dosing of emricasan. In the clinical trial, 30 patients received BID dosing at different dose levels and six patients were treated TID. As set forth in Figure 8 below, ALT reductions were rapid and sustained during the 14-day dosing period. In general, decreases in ALT were more pronounced than with QD dosing, with ALT reductions from baseline ranging from 39% to 56%. One cohort of patients was treated with 5 mg TID dosing. The results from this dosing group were similar to the BID dosing groups. Patients with liver disease from causes other than HCV were dosed at 100 mg BID. Most of these patients had reductions in ALT similar to those observed in the HCV patients. All dosing groups were statistically significantly different than placebo (p-values ranging from 0.0041 to <0.0001).

Figure 8. Percentage Change in ALT from Baseline Following BID and TID Dosing in Subjects with HCV

In all of the patient populations in this study, emricasan was generally well-tolerated. The most commonly reported adverse events related to emricasan were upper abdominal pain, dyspepsia, fatigue, dizziness and headache. No subject was discontinued due to an adverse event. Importantly, in both the HCV and HBV infected patients studied, no increases in viral load parameters were observed.

Phase 2 Ascending Dose Crossover Study in Patients with HCV and Liver Fibrosis (Study A8491010)

Study A8491010 was a Phase 2, randomized double-blind, placebo-controlled crossover dose response study of emricasan in 24 patients with chronic HCV infection and liver fibrosis conducted by Pfizer. This study assessed the effects of BID dosing of emricasan on ALT and AST levels in these patients. For each patient, the study consisted of a screening visit, a two-week baseline period, three 14-day study periods separated by a minimum washout period of two weeks and a two-week follow-up period after the last treatment period. Each patient was to receive three of five possible treatments (emricasan 0.5, 1, 2.5, 5 mg or placebo) BID for 13 days and QD on the final day of each study period. This clinical trial was voluntarily discontinued early due to an unanticipated finding of inflammatory infiltrates in mice in a preclinical study that was ongoing concurrently with the clinical study and was unrelated to this Phase 2 clinical trial. Pfizer notified the FDA of the findings in mice and the discontinuation of the clinical trial, which resulted in the agency placing a clinical hold on the study of emricasan in 2007. At the time the clinical hold was imposed, 18 of 24 subjects had completed study A8491010. Because the study was discontinued prematurely, formal statistical tests were not performed. However, reductions in ALT in the 5 mg BID dose group were similar to the results of the 5 mg BID dose groups in the 003 and 004 trials. As described in the Emricasan History section below, the clinical hold was lifted in January 2013.

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Clinical Studies in Organ Preservation in Transplant Patients

Preclinical studies demonstrated that emricasan is effective in protecting organs from damage that can occur during transplantation due to ischemia or reduced oxygen during isolation of donor organs and reperfusion injury resulting from rapid exposure to oxygen following transplantation.

Study A8491002 was a Phase 2 randomized, placebo-controlled, double-blind, parallel group study to evaluate the effects of emricasan when administered in liver transplantation storage and flush solutions used in the preparation of the donated liver and when administered to the recipient via IV during the first 24 hours after liver transplantation. Ninety-nine patients were randomized into one of four groups. In the first group, the liver was treated with placebo in the storage and flush solution and the patient was given placebo following transplantation. In the second group the liver was treated with 15 µg/mL emricasan in the storage and flush solution, but the patient received placebo following transplantation. The third group was treated with a lower concentration of emricasan, 5 µg/mL, in the storage and flush solution and the patient received 0.5 mg/kg emricasan for 24 hours by IV administration following transplantation. The fourth group was treated with 15 µg/mL emricasan in the storage and flush solution and the patient received 0.5 mg/kg emricasan for 24 hours by IV administration following transplantation.

The co-primary endpoints were peak absolute change from baseline in ALT and AST measured up to three days post-transplantation. Large increases in both ALT and AST occurred in all groups reflecting liver injury typically occurring after liver transplantation. The outcome on the co-primary endpoints was not different between the placebo and the treatment groups possibly due to the short duration of drug treatment (24 hours) following transplantation. Serum markers of liver cell apoptosis, cCK18, were reduced in all groups receiving drug as compared to placebo. In addition, the level of liver cell apoptosis in liver tissue as determined by quantitation of cells with caspase 3 and 7 activity was reduced in all groups receiving emricasan, suggesting that the drug has activity through the anticipated mechanism of action.

Generally, the adverse events reported in the study were reflective of the severity of disease in the patient population. There were 1,240 adverse events reported in the 99 subjects, with similar numbers reported across the four study groups, as discussed above. There were 79 serious adverse events (6.4%) reported by 32 patients in this study. Of all the adverse events, 15 events were reported as possibly treatment-related but none were reported as probably or definitely treatment-related. The type and frequency of adverse events was similar across all groups, including placebo. There were deaths reported in all treatment groups (two in the placebo treatment group and one in each of the emricasan treatment groups). These data in total support the conclusion that treatment with emricasan in this study has been generally well-tolerated.

Health Canada study NCT01653899, an investigator sponsored clinical trial, has been initiated at the University of Alberta to evaluate the safety and efficacy of islet cell culture and short-term (14 days) oral administration of emricasan in subjects with established Type 1 diabetes mellitus with unstable glycemic control. Health Canada approved the application in April 2012 and the clinical trial is underway. This clinical trial is an open label pilot study funded by a grant from the Juvenile Diabetes Research Foundation. Patients enrolled in this clinical trial are not able to adequately regulate their blood glucose levels with insulin. The patients undergo pancreatic islet cell transplantation, a procedure referred to as the Edmonton procedure, with the goal of eliminating their need for insulin. One objective of this clinical trial is to determine whether emricasan can improve upon the success rate of this so-called Edmonton procedure by reducing the amount of islet cell death after transplantation. Patients are dosed orally for 14 days following islet transplantation and are then monitored for their ability to control blood glucose without the need for insulin.

Phase 1 Clinical Trials

We have conducted six Phase 1 clinical trials in subjects with both single and multiple-dose administration of emricasan. The objective of these trials was to examine the safety, tolerability and PK of emricasan. As shown in Figure 9 below, emricasan was generally well-tolerated in all six Phase 1 clinical trials.

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Figure 9. Emricasan Phase 1 Clinical Trial Summary

Trial Design	Subjects	Dosing/ Days	Outcome
Safety and PK study in healthy and liver impaired subjects	76 (US)	QD/7 days	Well tolerated; improved liver enzymes (ALT)
Randomized, open label, PK dose proportionality study in healthy subjects	24 (US)	Single dose	Well tolerated; PK profiled
Randomized, placebo-controlled, drug-drug interaction, or DDI, study with ketoconazole in health subjects	24 (EU)	Single dose	Well tolerated; no drug-drug-interaction with ketoconazole
Double blind, randomized, placebo-controlled, PK multiple (escalating) dose study in healthy subjects	32 (EU)	BID/14 days	Well tolerated; PK profiled
Randomized, double-blind, parallel group placebo-controlled, PK multiple (escalating) dose study in health Asian subjects	20 (EU, Asia)	BID/15 days	Well tolerated; no difference in PK in Asian population
Randomized, placebo-controlled, DDI study with cyclosporine and measurement of cCK18 levels in health subjects	15 (EU)	QD/BID/10 days	Well tolerated; no effect on cyclosporine; no effect on cCK18 levels

To understand the activity of emricasan on caspase activity in healthy subjects, a Phase 1 clinical trial (study IDN-6556-03) in 15 subjects was conducted. In the clinical trial, the levels of cCK18 in healthy human subjects was measured pre-dosing and then after dosing at different time intervals up to 12 hours post dosing. In this study, patients were administered 25 mg of emricasan BID as part of a drug-drug interaction study for 24 days with blood levels of cCK18 measured serially on days one, 17 and 24. As shown in Figure 10 below, dosing with emricasan did not cause meaningful decreases in cCK18 from predose levels in healthy subjects. We believe this demonstrates that emricasan does not interfere with the normal level of caspase activity and apoptosis in humans.

Figure 10. Mean Serum Levels of cCK18 in Healthy Subjects Following 25 mg BID of Emricasan in 15 Subjects

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Emricasan History

Emricasan was initially discovered and developed by researchers at Idun, where the company was developing a new class of drugs that modulate caspases involved in the apoptosis and inflammation pathways. Idun, co-founded by Nobel Prize winner H. Robert Horvitz, Ph.D. for his work in the apoptosis field, was uniquely positioned as a leading expert in translating apoptosis research into drug development candidates. Emricasan was Idun s lead program when Pfizer acquired the company for approximately $298 million in 2005.

When we acquired emricasan through the acquisition of Idun from Pfizer in 2010, emricasan was on clinical hold in the United States due to an observation of inflammatory infiltrates in mice that Pfizer saw in a preclinical study and reported to the FDA in 2007. Pfizer performed additional preclinical studies attempting to characterize the nature of the inflammatory infiltrates, but did not carry out a formal carcinogenicity study to evaluate whether or not the infiltrates progressed to cancer. These infiltrates observed in mice were not observed in any other species. In 2008, Pfizer stopped work on the program. After acquiring emricasan in 2010, we conducted a thorough internal review of these studies and commissioned several independent experts to review all of the available data. The analysis provided by these experts unanimously concluded that these inflammatory infiltrates did not represent pre-cancerous lesions, nor were these infiltrates likely to progress to cancer. Additionally, a comprehensive analysis of available apoptosis literature supported the conclusion that the infiltrates were not likely to be precursors to cancer.

In April 2011, we met with the FDA to discuss plans for reinitiating clinical development of emricasan. We proposed conducting a carcinogenicity study designed to reproduce the previously observed findings of inflammatory infiltrates and determine whether they progress to cancer. We proposed using the Tg.rasH2 transgenic mouse model, which is known to be predisposed toward tumor development. The FDA agreed with the study design and agreed that if the study reproduced the previously observed inflammatory infiltrates, but did not produce cancer, the issue which generated the clinical hold would be resolved.

This study was completed successfully in 2012. The inflammatory infiltrates were reproduced, and there was no evidence of tumor formation. In summary, treatment with emricasan for 26-weeks did not result in an increase in the incidence of tumors in Tg.rasH2 mice. The results were submitted to the FDA in preparation for a meeting in October 2012. The FDA reviewed the data and agreed with the study conclusion. We subsequently filed a new investigational new drug application, or IND, for emricasan for HCV-POLT, which was formally cleared in January 2013, effectively removing the clinical hold. In addition, the FDA has accepted this Tg.rasH2 carcinogenicity study as one of two carcinogenicity studies required for registration. We plan to perform a two-year rat carcinogenicity study as the second carcinogenicity study. We have submitted the Phase 2b ACLF clinical trial to our United States IND, and we are initiating clinical trial sites in the United States. We plan to conduct the Phase 2 CLF clinical trial under this IND in the United States. The data from our initiated Phase 2b ACLF clinical trial being conducted in the United Kingdom and the United States will be used in support of our planned end of Phase 2b meetings with both the United States and EU regulatory authorities, at which point we will evaluate in which jurisdictions to conduct such trials, and make any additional required regulatory filings in such jurisdictions prior to commencing such trials.

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Our Clinical Development Plans

We have designed a comprehensive clinical program to demonstrate the therapeutic benefit of emricasan across the spectrum of fibrotic liver disease. We plan to study emricasan in patients with established liver cirrhosis, both compensated and decompensated disease, such as patients with ACLF, CLF, POLT-HCV-SVR or NASH.

Emricasan in ACLF

Medical Need and Market Opportunity

ACLF occurs in patients who have compensated or decompensated cirrhosis but are usually relatively stable. In these patients, some acute event sets off a rapid deterioration of liver function. The cause of this acute episode of decompensation may include toxins, such as alcohol, metabolic abnormalities and infections. The morbidity and mortality of patients with ACLF is high. According to a 2011 publication in the Journal of Hepatology, the in-hospital mortality rate for these acute deteriorating patients is greater than 50% and the total annual charges associated with ICU admissions alone are $3 billion, equating to a mean charge of $116,000 per admission.

Liver function in ACLF patients deteriorates rapidly. Although the exact mechanisms remain unclear, massive liver cell loss involving excessive apoptosis and necrosis are known contributing factors leading to progressive dysfunction. There is evidence that serum markers of caspase-driven apoptosis such as cCK18 are elevated in these patients. In addition, independent studies have shown that increased cCK18 levels in this patient population are associated with worse prognosis.

The rapid deterioration in liver function, which may be exacerbated by an altered immune response, leads to life-threatening complications such as renal failure, increased susceptibility to infection, hepatic coma and systemic hemodynamic dysfunction. Current goals of the medical treatment for ACLF are to reverse precipitating factors, support failing organs and prevent further deterioration in liver function in order to give the liver time to repair. Medical intervention for ACLF involves treatment of the underlying cause of the acute event. Patients who progress to multi-organ failure may require specific therapies for this such as medications for cardiac failure, mechanical ventilation for respiratory failure or dialysis for renal failure. Liver transplantation is required in some subjects to improve survival and quality of life. There are currently no approved therapies with a specific indication for the treatment of ACLF, and to our knowledge, there are only a limited number of clinical trials currently being conducted in patients with either liver cirrhosis or liver failure. We believe the ACLF population is in high medical need of an efficacious and well-tolerated therapy to prevent progression to multi-organ failure and, ultimately, premature death.

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Development Plans

We plan to study emricasan in patients with established liver cirrhosis and decompensated liver disease with our first opportunity for regulatory approval expected to be in the ACLF patient population. Our planned trials in ACLF will evaluate whether emricasan can halt the progression of decompensation to multi-organ failure, requirement for liver transplant or death in an acutely decompensating cirrhotic patient population. Two studies are planned in this patient population as follows.

Phase 2b Dose Ranging Clinical Trial

We initiated a 60-patient Phase 2b dose ranging clinical trial in ACLF patients in the United Kingdom in September 2013 and started opening additional sites in the United States in January 2014. Patients will be equally randomized to receive either placebo, 5 mg, 25 mg or 50 mg emricasan BID orally. The primary objective in this 28-day dosing trial is to evaluate the PK and pharmacodynamics together with the safety of emricasan to determine whether any dosing adjustments are needed in this critically ill patient population. We plan to measure changes in liver function (creatinine, bilirubin and International Normalized Ratio), changes in biomarkers (ALT, cCK18, Caspase 3/7 and Interleukin 18), time to clinical worsening, or TTCW, which is defined as the first occurrence of liver transplant, progression to next organ failure or death and changes in extra-hepatic organ function.

This trial was initially focused on a precisely defined subpopulation of critically ill patients. The initial enrollment criteria proved to be too restrictive for timely patient recruitment and delayed completion of the trial. We announced in March 2014 that we were amending our protocol to revise inclusion and exclusion criteria and address the most common causes for patient screening failures. We expect this amendment to increase enrollment rates and allow more timely progress toward trial completion.

This trial was designed primarily as a dose-ranging and safety study to determine whether any dosing adjustments are needed in this challenging patient population. To support dose selection in our overall clinical development program, we intend to evaluate PK data from three clinical trials, including: a subset of patients in the ACLF trial, our ongoing trial in patients with severe renal impairment, and a planned clinical trial in patients with hepatic impairment. PK data from these three trials are expected in the second half of 2014, and together, these trials should provide more comprehensive data across a range of critically ill patients and allow us to establish appropriate dosing for potential future studies in both the ACLF and CLF patient populations. We also expect the revised ACLF protocol to increase the pace of enrollment of patients which should provide information on directional movement of biomarkers and functional parameters in individual patients in the same timeframe.

Phase 3 Registration Clinical Trial

The Phase 3 registration trial for ACLF is expected to be an international study that will include approximately 400 patients with the inclusion and exclusion criteria determined from the results of the Phase 2b clinical trial. Based on our discussions with regulatory authorities in the United Kingdom and Germany, we believe that the ACLF Phase 3 clinical trial could suffice as a single registration trial for these geographies if the results are compelling. We will discuss a similar strategy for emricasan approval in the United States with the FDA at our end of Phase 2 meeting to be held after the completion of our Phase 2b clinical trial. We plan to submit applications for orphan drug designations for ACLF in the United States and the EU in the second half of 2014.

Subject to the results of our planned clinical trials and any regulatory-approved product labeling, we currently anticipate that emricasan, if approved for this indication, would be prescribed by physicians to be dosed for up to six months in the ACLF patient population.

Emricasan in CLF

Medical Need and Market Opportunity

The subset of CLF patients that we intend to study suffer from liver cirrhosis, potentially both compensated or decompensated. The continual disease progression may eventually lead such CLF patients to require

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orthotopic liver transplantation, in which the diseased liver is replaced by a donor liver. The cause of the chronic decompensation or liver failure may vary and, similar to ACLF, includes infections, such as subacute bacterial peritonitis, HCV or HBV, metabolic causes, such as NASH, autoimmune diseases and alcohol. Eventually, these patients will progress to the point where, if eligible, they may require transplantation. There are notable differences between the ACLF and CLF populations. In ACLF, patients have an acute insult that triggers a decompensatory event that may be reversed whereas in CLF, the insult is of a chronic nature and it is likely that, if left untreated, the liver function will continue to steadily deteriorate. Objectives for the management of patients with CLF include specific treatment of any identifiable causes for deterioration in liver function, such as HCV or HBV, and prevention of the development or progression of signs of decompensation, namely ascites, hepatic encephalopathy and esophageal varices, with or without hemorrhage, in order for the patient to be eligible for transplant. Similar therapies as those employed for the management of ACLF and mentioned above are generally employed. Independent published studies have shown that cCK18 levels are elevated in CLF patients and correlate with extent of liver inflammation and cholestasis. Although we are not planning to exclusively study patients with CLF on the liver transplant waitlist, many of these patients may also be included in the trial. According to the United States Department of Health and Human Services, there were over 5,800 adult liver transplants performed in the United States in 2011 and approximately 2,500 died while waiting for transplant and another 500 subsequently became ineligible for a liver transplant. We estimate that there are approximately 5,000 CLF patients within our target population on the transplant waitlist in the United States and the EU. The median wait time for a liver transplant for the subset of patients we plan to study is 106 days and the mortality rate is approximately 25% during that time frame, according to the United Network for Organ Sharing database. We estimate that there will be at least the same number of patients with CLF who are not candidates for liver transplantation but who might also benefit from emricasan. Given its mechanism of action, emricasan has the potential to improve patients ability to survive longer while waiting for a liver transplant or potentially help make them eligible for transplant.

Development Plans

Patients with CLF suffer from continual disease progression which may eventually lead them to require orthotopic liver transplantation. Our planned trials in CLF will assess whether emricasan can stabilize decompensation and provide patients with chronic decompensation additional time to obtain a liver transplant. In addition, we are exploring expanding future trials to also include patients with cirrhosis who still maintain near normal liver function (compensated disease state). In this population, the goal is expected to be delay and/or prevention of progression to the decompensated disease state. We plan to initiate a Phase 2 clinical trial in patients with CLF in the second half of 2014 with dosing based on data from the ACLF Phase 2b clinical trial and additional PK trials in patients with severe renal failure and hepatic failure. It is expected that emricasan will be dosed for up to three months and the endpoints in this trial will include changes in biomarkers (ALT, AST and cCK18 levels) and measures of liver function, as well as other clinically meaningful parameters.

Subject to the results of our planned clinical trials and any regulatory-approved product labeling, we currently anticipate that emricasan, if approved for this indication, would be prescribed by physicians to be dosed for up to three months in the CLF patient population.

Emricasan in POLT-HCV-SVR

Medical Need and Market Opportunity

Patients with HCV who receive orthotopic liver transplants are at risk for recurrent HCV infections in the transplanted organs. Many of these patients will experience accelerated development of fibrosis and progression to cirrhosis of the transplanted liver due to the recurrence of HCV. Even after successful treatment with drugs designed to clear the HCV

infection, fibrotic changes in the liver may persist for many years. The HCV landscape is expected to continue to evolve dramatically over the next five to ten years with the introduction of interferon-free regimens with greater efficacy and tolerability over the current antiviral therapies.

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Development Plans

We were granted orphan drug designation in late 2013 by the FDA for the treatment of POLT patients with reestablished fibrosis to delay the progression to cirrhosis and end-stage liver disease. Also in late 2013, clinical trial results presented at the American Associate for the Study of Liver Diseases, or AASLD, Liver Meeting showed that the administration of sofosbuvir, a new HCV antiviral being developed by Gilead Sciences, in combination with ribavirin, in patients who have developed liver fibrosis post-orthotopic liver transplant due to HCV, was well-tolerated and achieved a preliminary SVR rate of 77% four weeks after dosing was completed. As a result, we have revised our clinical development strategy in the POLT patient population to move forward with a placebo-controlled (sponsor open) Phase 2b clinical trial tracking biomarkers and histology in POLT-HCV-SVR patients. The clinical trial in POLT-HCV-SVR patients is expected to be initiated in the second half of 2014. Only approximately 30% of non-transplant HCV patients with fibrosis and SVR show histological signs of fibrosis improvement two years after virus clearance. Our clinical trial is designed to gain insight as to the ability of emricasan treatment to improve the liver recovery process in POLT-HCV-SVR patients.

Emricasan in NASH

Medical Need and Market Opportunity

NASH is a severe form of NAFLD where fat builds up in the liver and patients suffer from inflammation and damage and NASH can lead to cirrhosis. According to the NIH, NASH affects two to five percent of people in the United States. NASH is one of the leading causes of cirrhosis in adults in the United States and up to 25% of adults with NASH may have cirrhosis. The condition is more common in adults who are obese, diabetic, or have high cholesterol or high triglycerides.

Development Plans

In order to broaden the potential for emricasan as an antifibrosis treatment, and consistent with our analysis of the outcome of the AASLD FDA Workshop on Trial Designs and Endpoints for Liver Disease Secondary to Nonalcoholic Fatty Liver Disease (NAFLD) held in September 2013, we initiated a Phase 2 clinical trial in March 2014 in patients with NAFLD, including the subset of patients with inflammatory and/or fibrotic NASH. Emricasan has demonstrated activity in preclinical models of both NASH and NAFLD. In preclinical models of NASH, emricasan inhibited apoptosis, fibrosis and inflammation associated with experimental NASH. In a preclinical model of NAFLD, emricasan reduced inflammation of adipose tissue, resolved hepatic steatosis and improved metabolic parameters by reducing fasting glucose and insulin levels. We believe that these preclinical data provide support for evaluating emricasan in patients with NASH. We also believe that with preliminary clinical proof of concept, we can accumulate sufficient and relevant clinical data to allow rapid advancement of emricasan in NASH once there is more clarity on the appropriate treatment populations and the Phase 3 endpoints that will be acceptable to regulatory authorities. The recently initiated Phase 2 NAFLD/NASH clinical trial is a double-blind, placebo-controlled trial and is designed to enroll approximately 40 patients at four planned United States clinical sites. Patients will be randomized 1:1 to receive either 25 mg of emricasan or placebo twice daily for 28 days and will be followed for another 28 days. The primary endpoint in this exploratory proof-of-concept trial is a reduction of elevated levels of key biomarkers implicated in patients with NAFLD/NASH. The clinical trial will also evaluate the safety and tolerability of emricasan in the target patient population. Clinical endpoints suitable to support approval of new treatments for NASH have not yet been fully defined, and we are participating in regulatory discussions with respect to such clinical endpoints.

Potential Dosing of Emricasan

Subject to the results of our planned clinical trials and any regulatory-approved product labeling, we currently anticipate that emricasan, if approved, would be prescribed by physicians to be dosed for up to six months in the ACLF patient population, up to three months in the CLF patient population and up to two years in the POLT-HCV-SVR and NASH patient populations.

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Future Indications

Due to its mechanism of action and the presence of apoptosis and inflammation in many liver diseases, we believe there may be several patient populations that could potentially benefit from emricasan, including those that have previously failed HCV treatment and those with alcoholic liver disease, NAFLD, viral hepatitis and other chronic liver diseases. At this time, we do not plan to explore these indications; however we may seek partners to pursue the evaluation of these potential indications. We are currently supporting a pilot study funded by the National Institute on Alcohol Abuse and Alcoholism in patients with alcoholic hepatitis. This exploratory study is a placebo-controlled study which is being conducted at three centers in the United States over four years and will assess patient survival as the primary endpoint.

Commercialization Strategy

We expect that the majority of ACLF, CLF and POLT-HCV-SVR patients will be treated at tertiary care centers and transplant centers and therefore can be addressed with a targeted sales force. We intend to build our own commercial infrastructure in North America and the EU to target these centers. We believe we are well-positioned to retain commercialization rights for emricasan for ACLF, CLF and POLT-HCV-SVR in the United States and the EU. We intend to consider opportunities to partner in other territories or for other indications. In indications where there are more advanced drug candidates by other companies, we intend to utilize insight from their programs and accumulate sufficient and relevant clinical data to allow rapid development of emricasan in such indications. We also expect that potential future partners may influence the development of our commercialization strategy.

Manufacturing

Pfizer completed a significant portion of the manufacturing process optimization needed to provide an efficient synthesis of active pharmaceutical ingredient, or API, and scale-up for registration trials. API was successfully produced under current Good Manufacturing Practices, or cGMP, conditions, and a strategy to scale up the API for commercialization is in development. We believe the quantities we acquired from Pfizer are sufficient to support our initiated Phase 2b ACLF clinical trial and Phase 2 NAFLD/NASH clinical trial and planned Phase 2b POLT-HCV-SVR clinical trial and Phase 2 CLF clinical trial. However, we will need to identify and qualify a new third-party manufacturer of API prior to commercialization of emricasan and, if our estimates regarding our supply are incorrect, prior to the completion of our planned clinical trials. Both API and the drug product have demonstrated sufficient stability characteristics in our studies conducted to date. A number of dosage forms are being developed including capsule, powder-in-capsule, tablet and alternate dosage forms suitable for pediatric administration.

Competition

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Although we believe that we hold a leading position in our understanding of caspase inhibition related to liver disease, our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. We believe the key competitive factors that will affect the development and commercial success of our drug candidates are efficacy, safety and tolerability profile, reliability, convenience of dosing, price and reimbursement.

There are currently no therapeutic products approved for the treatment of ACLF, CLF, POLT-HCV-SVR or NASH. There are a number of marketed therapeutics used in each of these diseases to try to remove the underlying cause of

the disease and prevent further liver injury. For example, if the liver damage is a result of

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HBV or HCV, marketed antiviral medications may be used to treat the virus that led to liver damage. If the liver damage is a result of alcoholic hepatitis, marketed alcohol addiction drugs may be used. If the liver damage is a result of obesity, diet and exercise may be prescribed along with marketed therapeutics. If the liver damage is a result of NASH, marketed drugs such as insulin sensitizers (e.g., metformin), antihyperlipidemic agents (e.g., gemfibrozil), pentoxifylline and ursodiol are generally used, although none of these are approved for NASH. In addition to the marketed drugs for those indications, there are drugs in development for each of these indications. Although these marketed therapies and those in development may be efficacious, all of them take time to show an effect and as long as the underlying conditions persist there will continue to be damage to the liver. In NASH for example, drugs in development have differing mechanisms of action and it is currently unknown whether any single drug candidate will eliminate liver inflammation and halts liver disease progression into advanced fibrosis. For each of these indications, emricasan is the only therapeutic we are aware of that is being developed specifically to reduce the level of apoptosis in the liver and as a result it may be used with these other therapies.

In addition, the HCV landscape is expected to continue to evolve dramatically over the next five to ten years with the introduction of new interferon-free regimens with greater efficacy and tolerability over the current antiviral therapies. However, we expect that there will continue to be a significant unmet need in the HCV-POLT population, including patients with fibrosis after antiviral treatments to clear their HCV infection.

Material Contracts

Pfizer Inc.

In July 2010, we entered into a Stock Purchase Agreement with Pfizer pursuant to which we acquired all of the outstanding capital stock of Idun, a wholly-owned subsidiary of Pfizer at the time, in consideration for an upfront payment of $250,000 and a promissory note in the principal amount of $1.0 million. The promissory note matures in July 2020, subject to acceleration upon specified events of default, including a change of control transaction, our failure to timely pay any principal or interest when due, our failure to timely provide certain financial information to Pfizer, the creation of any lien on our property other than permitted liens, any disposition of our business or property other than permitted transfers, our payment of dividends or other distributions on our equity securities, our incurrence of any indebtedness other than permitted indebtedness, our involvement in liquidation, dissolution, bankruptcy or similar proceedings, our failure to notify Pfizer of certain material adverse events, our failure to repay any indebtedness that causes an aggregate of $2.0 million or more in such indebtedness to accelerate in maturity and the rendering of certain judgments against us. The note bears interest at 7% per year, compounded quarterly. Interest is payable on a quarterly basis during the term of the note. We have the right to prepay the promissory note at any time. In July 2013, the note was amended to become convertible into shares of our common stock following the completion of our initial public offering, at the option of the holder, at a price per share equal to the fair market value of our common stock on the date of conversion. We will also be required to make additional payments to Pfizer totaling $18.0 million upon the achievement of specified regulatory milestones relating to emricasan.

Idun Pharmaceuticals, Inc.

In January 2013, we conducted a spin-off of our subsidiary Idun (which we had acquired from Pfizer in the transaction described above), to our stockholders at that time. Immediately prior to the spin-off, all rights relating to emricasan were distributed to us pursuant to a distribution agreement. The assets remaining in Idun at the time of the spin-off consisted solely of intellectual property rights and license and collaboration agreements unrelated to emricasan. The spin-off was conducted as a dividend of all of the outstanding capital stock of Idun to our stockholders and, as a result, we no longer own any capital stock of Idun. The aggregate value of Idun at the time of the spin-off was deemed to be $9.6 million based on the valuation of an independent appraisal firm.

Also in connection with the spin-off, we contributed $500,000 to Idun to provide for its initial working capital requirements and entered into a transition services agreement to provide operating services to Idun,

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generally consisting of accounting support, technology license administration and intellectual property maintenance. Under the transition services agreement, Idun was required to pay us for all direct costs as well as overhead and general and administrative expenses incurred in performing these services. As of December 31, 2013, Idun had paid $56,000 to us for services provided under the transition services agreement. The initial term of the transition services agreement ended on December 31, 2013 and was not renewed.

Idun Sublicense Agreement

In March 2013, we entered into a sublicense agreement with Idun in which we were granted the right to use the patent rights and know-how related to the screening and identification of emricasan. These rights were previously granted to Idun under license agreements with Thomas Jefferson University, or TJU. Under the sublicense, we are required to pay directly to TJU a royalty of less than one percent on net sales of emricasan. We also have the right to grant further sublicenses to third parties and are required to pay TJU a portion of any such sublicense revenue we receive. The sublicense agreement will expire upon the date which there are no longer any valid claims in any patents or patent applications sublicensed to us, unless earlier terminated. Idun may terminate the agreement if we substantially fail to perform or otherwise materially breach any of the material terms, covenants or provisions of the sublicense agreement, and we do not cure any such breach within 60 days of receipt of written notice from Idun specifying the breach. Our obligations under the agreement include, among others, using reasonable efforts to commercialize emricasan, timely paying the royalties set forth in the sublicense agreement and timely paying a portion of any sublicense revenue we receive if we grant further sublicenses under the sublicense agreement. We are currently in full compliance with these obligations. The agreement may also be terminated if the underlying license agreements between Idun and TJU are terminated. The underlying license agreements may be terminated by either Idun or TJU if the other party substantially fails to perform or otherwise materially breaches any of the material terms, covenants or provisions of the underlying license agreements and the breaching party does not cure any such breach within 90 days of receipt of written notice from the non-breaching party specifying the breach. Idun may also elect upon 30 days prior written notice to terminate its rights and obligations under one of the underlying license agreements with respect to any patent applications or patents licensed to it, or to terminate such underlying license agreement in its entirety. In the event that either of the underlying license agreements are terminated, Idun is obligated to assign and transfer to TJU all rights under sublicenses granted by Idun. We do not depend on the sublicense agreement for the further development or commercialization of emricasan and we would not experience a material adverse effect if the sublicense agreement were terminated.

Intellectual Property

The proprietary nature of, and protection for, our drug candidates and discovery programs and know-how are important to our business. We have sought patent protection in the United States and internationally for emricasan, crystalline forms of emricasan and certain methods of treatment with emricasan. In addition, we have patent protection covering certain other preclinical stage compounds. Our policy is to pursue, maintain and defend patent rights whether developed internally or licensed from third parties and to protect the technology, inventions and improvements that are commercially important to the development of our business.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our current and future drug candidates and the methods used to develop and manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our products depends on the extent to which we have rights under valid and enforceable patents that cover these activities. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in

protecting our drug candidates, discovery programs and processes. For this and more comprehensive risks related to our intellectual property, please see Risk Factors Risks Related to Our Intellectual Property.

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Our patent portfolio for emricasan contains patents directed to the composition of matter, crystalline forms and methods of use. As of December 31, 2013 we have received three United States patents and corresponding foreign patents and patent applications directed to the composition of matter. Foreign patents have been granted in Australia, Austria, Belgium, Canada, China, Denmark, Europe, Finland, France, Germany, Great Britain, Greece, Hong Kong, India, Ireland, Israel, Italy, Japan, Luxembourg, Mexico, Netherlands, Portugal, Singapore, South Africa, South Korea, Spain, Sweden and Switzerland. Patent applications are pending in Poland. We expect that the composition of matter patent, if the appropriate maintenance, renewal, annuity or other governmental fees are paid, will expire in 2018 (United States) and 2019 (international). It is possible that the term of a composition of matter patent in the United States could be extended up to five additional years under the provisions of the Hatch-Waxman Act. Patent term extension may be available in certain foreign countries upon regulatory approval.

Our patent portfolio includes patents directed to crystalline forms and methods of use of emricasan. As of December 31, 2013 we have received one United States patent and corresponding foreign patents and patent application directed to crystalline forms of emricasan. Foreign patents have been granted in Australia, Canada, Mexico, Singapore, South Africa, South Korea and Taiwan. We received notification from the European Patent Office of intention to grant a patent on the patent application in Europe. Additional applications are pending in Argentina, China, Hong Kong, India, Israel, Japan, Norway and Thailand. We expect that the crystalline forms and methods of use patent, if the appropriate maintenance, renewal, annuity or other governmental fees are paid, will expire in 2028 (United States) and 2027 (international). It is possible that the term of a crystalline forms patent in the United States could be extended up to five additional years under the provisions of the Hatch-Waxman Act. Patent term extension may be available in certain foreign countries upon regulatory approval.

Our patent portfolio includes patents directed to certain methods of use of emricasan. As of December 31, 2013, we have received five United States patents and corresponding foreign patents and patent applications directed to methods of use of emricasan. Foreign patents have been granted in Europe, France, Germany, Great Britain, Ireland, Italy, Japan and Spain. We expect that the methods of use patents, if the appropriate maintenance, renewal, annuity or other governmental fees are paid, will expire in 2017.

Government Regulation

Government authorities in the United States (at the federal, state and local level) and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug products such as those we are developing. Emricasan and any other drug candidates that we develop must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in foreign countries.

United States Drug Development Process

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act, or FDCA, and implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any

agency or judicial enforcement action could have a material

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adverse effect on us. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- Completion of extensive preclinical laboratory tests, preclinical animal studies and formulation studies in accordance with applicable regulations, including the FDA s Good Laboratory Practice, or GLP, regulations;
- Submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- Performance of adequate and well-controlled human clinical trials in accordance with applicable regulations, including the FDA s current good clinical practice, or GCP, regulations to establish the safety and efficacy of the proposed drug for its proposed indication;
- Submission to the FDA of a new drug application, or NDA, for a new drug product;
- A determination by the FDA within 60 days of its receipt of an NDA to accept the NDA for filing and review;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the drug is produced to assess compliance with the FDA s cGMP, regulations to assure that the facilities, methods and controls are adequate to preserve the drug s identity, strength, quality and purity;
- Potential FDA audit of the preclinical and/or clinical trial sites that generated the data in support of the NDA; and
- FDA review and approval of the NDA.

Before testing any compounds with potential therapeutic value in humans, the drug candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the drug candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human studies. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the IND on clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a drug candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trial.

Clinical trials involve the administration of the drug candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the clinical trial sponsor s control, in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers issues such as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

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

Phase 1. The drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion, the side effects associated with increasing doses, and if possible, to gain early evidence of effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

Phase 2. The drug is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases or conditions and to determine dosage tolerance, optimal dosage and dosing schedule. Phase 2 clinical trials can be further divided into Phase 2a and Phase 2b clinical trials. Phase 2a clinical trials are typically are smaller and shorter in duration and generally consist of patient exposure-response trials which focus on proving the hypothesized mechanism of action. Phase 2b clinical trials are typically higher enrolling and longer in duration and generally consist of patient dose- ranging trials which focus on finding the optimum dose at which the drug shows clinical benefit with minimal side effects.

Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall benefit/risk ratio of the product and provide an adequate basis for product approval. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA. Phase 3 clinical trials usually involve several hundred to several thousand participants.

Post-approval studies, or Phase 4 clinical trials, may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 studies.

The FDCA permits the FDA and an IND sponsor to agree in writing on the design and size of clinical trials intended to form the primary basis of a claim of effectiveness in an NDA. This process is known as a Special Protocol Assessment, or SPA. An SPA agreement may not be changed by the sponsor or the FDA after the clinical trial begins except with the written agreement of the sponsor and the FDA, or if the FDA determines that a substantial scientific issue essential to determining the safety or effectiveness of the drug was identified after the testing began. For certain types of protocols, including carcinogenicity protocols, stability protocols and Phase 3 protocols for clinical trials that will form the primary basis of an efficacy claim, the FDA has agreed under its performance goals associated with the Prescription Drug User Fee Act, or PDUFA, to provide a written response on most protocols within 45 days of receipt. However, the FDA does not always meet its PDUFA goals, and additional FDA questions and resolution of issues leading up to an SPA agreement may result in the overall SPA process being much longer, if an agreement is reached at all.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk for human subjects. Phase 1, Phase 2 and Phase 3 clinical trials may fail to be completed successfully within any specified period, if at all. The FDA, the IRB or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the

research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution 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. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or data monitoring committee. This group provides authorization for whether or not a trial may move forward at designated checkpoints based on access to certain data from the study. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

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

FDA Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The application includes both negative or ambiguous results of preclinical and clinical trials as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug product to the satisfaction of the FDA. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances.

In addition, under the Pediatric Research Equity Act, or PREA, an NDA or supplement to an NDA must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted. However, if only one indication for a product has orphan designation, a pediatric assessment may still be required for any applications to market that same product for the non-orphan indication(s).

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has ten months from the 60-day filing date in which to complete its initial review of a standard NDA and respond to the applicant and six months for a priority NDA. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs, and the review process is often significantly extended by FDA requests for additional information or clarification.

After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use and whether the product is being manufactured in accordance with cGMP to assure and preserve the product s identity, strength, quality and purity. The FDA may refer applications for novel drug or biological products or drug or biological products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved 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.

Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product 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 may inspect one or more clinical sites to assure

compliance with GCP requirements. After the FDA evaluates the application, manufacturing process and manufacturing facilities, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. For example, the FDA may require Phase 4 testing which involves clinical trials designed to further assess a drug safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA may also determine that a risk evaluation and mitigation strategy, or REMS, is necessary to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Following approval of an NDA with a REMS, the sponsor is responsible for marketing the drug in compliance with the REMS and must submit periodic REMS assessments to the FDA.

Orphan Drug Designation

In the United States, under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition. Such diseases and conditions are those that affect fewer than 200,000 individuals in the United States, or if they affect more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a drug product available in the United States for these types of diseases or conditions will be recovered from sales of the product. Orphan product designation must be requested before submitting an NDA. If the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by that agency. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, but it can lead to financial incentives, such as opportunities for grant funding toward clinical trial costs, tax advantages and user-fee waivers.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug marketing exclusivity for a period of seven years. Orphan drug marketing exclusivity generally prevents the FDA from approving another application, including a full NDA, to market the same drug or biological product for the same indication for seven years, except in limited circumstances, including if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. For purposes of small molecule drugs, the FDA defines same drug as a drug that contains the same active chemical entity and is intended for the same use as the drug in question. A designated orphan drug may not receive orphan drug marketing exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Orphan drug marketing exclusivity rights in the United States may be lost if the

FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

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We have submitted applications for orphan drug designation for emricasan for the treatment of fibrosis in HCV-POLT patients in the United States and the EU. In late 2013, we received orphan drug designation from the FDA for the treatment of POLT patients with reestablished fibrosis to delay the progression to cirrhosis and end-stage liver disease. In the EU, we withdrew the application based on feedback from the applicable regulatory body that emricasan may have efficacy in fibrosis outside of the HCV-POLT patient population. We plan to submit applications for orphan drug designation for ACLF in the United States and EU in the second half of 2014.

Expedited Development and Review Programs

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drug products that meet certain criteria. Specifically, new drugs are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. Unique to a Fast Track product, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable and the sponsor pays any required user fees upon submission of the first section of the NDA.

Any product submitted to the FDA for approval, including a product with a Fast Track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Drug products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, 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. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

The FDA may also accelerate the approval of a designated breakthrough therapy, which is a drug that is intended, 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 drug 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 sponsor of a breakthrough therapy may request the FDA to designate the drug as a breakthrough therapy at the time of, or any time after, the submission of an IND for the drug. If FDA designates a drug as a breakthrough therapy, it must take actions appropriate to expedite the development and review of the application, which may include holding meetings with the sponsor and the review team throughout the development of the drug; providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review; assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and

taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment.

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Fast Track designation, priority review, accelerated approval and breakthrough therapy designation do not change the standards for approval but may expedite the development or approval process. We plan to explore rapid approval opportunities (e.g., Fast Track designation, priority review, accelerated approval and/or breakthrough therapy designation) for emricasan as appropriate for our targeted indications.

Post-Approval Requirements

Any drug products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements and complying with FDA promotion and advertising requirements, which include, among other requirements, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations that are not described in the drug s approved labeling (known as off-label use), limitations on industry sponsored scientific and educational activities and requirements for promotional activities involving the internet. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA, including, among other things, recall or withdrawal of the product from the market. In addition, changes to the manufacturing process are strictly regulated and depending on the significance of the change, may require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

The FDA also may require Phase 4 testing and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product s approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures, such as a REMS. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA s policies may change, which could delay or prevent regulatory approval of our products under development.

United States Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of the use of our drug candidates, some of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product

development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the

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product s approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may intend to apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain competing marketing applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain 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 drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, 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 to one of the patents listed with the FDA by the innovator NDA holder. The FDCA also provides three years of marketing exclusivity for an NDA or supplement to an existing 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, clinical investigations to support new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of any 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 and clinical trials necessary to demonstrate safety and effectiveness.

Other types of non-patent marketing exclusivity include orphan drug exclusivity under the Orphan Drug Act, which may offer a seven-year period of marketing exclusivity as described above, and pediatric exclusivity under the Best Pharmaceuticals for Children Act, which may add six months to existing exclusivity periods and patent terms. This six-month pediatric exclusivity may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued Written Request for such a trial.

Foreign Government Regulation

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales, promotion and distribution of our products.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign 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 similar process that requires the submission of a clinical trial application much like an IND prior to the commencement of human clinical trials. In the EU, for example, a clinical trial application, or CTA, must be submitted to each country s national health authority and an independent ethics committee, much like the FDA and IRB requirements in the United States, respectively. Once the CTA is approved in accordance with a country s requirements, clinical trials may proceed.

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The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of a new drug under EU regulatory systems, we must submit a marketing authorization application. The application used to file the NDA in the United States is similar to that required in the EU, with the exception of, among other things, country-specific document requirements.

For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject in those countries to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Reimbursement

Sales of our products will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health care programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly reducing reimbursements for medical products and services. In addition, the United States government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures and adoption of more restrictive policies in jurisdictions with existing controls and measures could further limit our net revenue and results. Decreases in third-party reimbursement for our drug candidates or a decision by a third-party payor to not cover our drug candidates could reduce physician usage of our products once approved and have a material adverse effect on our sales, results of operations and financial condition.

Fraud and Abuse Laws

We will also be subject to several healthcare regulation and enforcement by the federal government and the states and foreign governments in which we will conduct our business once our products are approved. The laws that may affect our ability to operate include:

the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;

the federal healthcare programs Anti-Kickback Law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;

federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; and

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

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Employees

As of March 26, 2014, we had 24 employees, 22 of whom are full-time, seven of whom hold Ph.D. or M.D. degrees, 13 of whom were engaged in research and development activities and 11 of whom were engaged in business development, finance, information systems, facilities, human resources or administrative support. None of our employees is subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

Research and Development

We have invested $6.9 million, $5.5 million, $9.5 million and $47.8 million in research and development for the years ended December 31, 2013, 2012 and 2011, and for the period from July 13, 2005 (inception) to December 31, 2013, respectively.

About Conatus

We were incorporated under the laws of the state of Delaware in 2005. Our principal executive offices are located at 4365 Executive Dr., Suite 200, San Diego, California 92121, and our telephone number is (858) 558-8130. Our website address is www.conatuspharma.com. The information in or accessible through our website is not incorporated into, and is not considered part of, this filing.

Financial Information about Segments

We operate only in one business segment, which is the commercialization and development of pharmaceutical products. See note 2 to our consolidated financial statements included in this annual report on Form 10-K. For financial information regarding our business, see Management s Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and related notes.

Available Information

We file electronically with the Securities and Exchange Commission, or SEC, our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended. We make available on our website at www.conatuspharma.com, free of charge, copies of these reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The public may read or copy any materials we file with the SEC at the SEC s Public Reference Room at 100 F Street NE, Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that website is www.sec.gov. The information in or accessible through the SEC and our website are not incorporated into, and are not considered part of, this filing. Further, our references to the URLs for these websites are intended to be inactive textual references only.

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ITEM 1A. RISK FACTORS

You should carefully consider the following risk factors, together with the other information contained in this annual report on Form 10-K, including our consolidated financial statements and the related notes and Management s Discussion and Analysis of Financial Condition and Results of Operations, before making a decision to purchase or sell shares of our common stock. We cannot assure you that any of the events discussed in the risk factors below will not occur. These risks could have a material and adverse impact on our business, results of operations, financial condition and growth prospects. If that were to happen, the trading price of our common stock could decline. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations or financial condition.

Risks Related to Our Business and Industry

Our business is dependent on the success of a single drug candidate, emricasan, which will require significant additional clinical testing before we can seek regulatory approval and potentially launch commercial sales.

Our future success depends on our ability to obtain regulatory approval for, and then successfully commercialize our only drug candidate, emricasan. We have not completed the development of any drug candidates, we currently generate no revenues from sales of any drugs, and we may never be able to develop a marketable drug. Emricasan will require additional clinical and non-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenues from product sales. We are not permitted to market or promote emricasan before we receive regulatory approval from the United States Food and Drug Administration, or FDA, or comparable foreign regulatory authorities, and we may never receive such regulatory approvals.

Our clinical development plan for emricasan includes a Phase 2b clinical trial in patients with acute-on-chronic liver failure, or ACLF, a Phase 2 clinical trial in patients with chronic liver failure, or CLF, a Phase 2b clinical trial in patients who have developed liver fibrosis post-orthotopic liver transplant, or POLT, due to hepatitis C virus, or HCV, infection and have subsequently achieved sustained viral response, or SVR, following anti-HCV therapy, or POLT-HCV-SVR, and a Phase 2 clinical trial in patients with non-alcoholic steatohepatitis, or NASH. The POLT-HCV-SVR trial alone will not be sufficient to support the filing of a new drug application, or NDA, in the United States; therefore at least one additional clinical trial will be required to support the filing of an NDA. We recently initiated the Phase 2b ACLF clinical trial and the Phase 2 non-alcoholic fatty liver disease, or NAFLD, and NASH clinical trial, and we expect to initiate the Phase 2 CLF clinical trial and the exploratory or pilot Phase 2b POLT-HCV-SVR clinical trial in the second half of 2014. There is no guarantee that these clinical trials will commence or be completed on time or at all, and the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials. Even if such regulatory authorities agree with the design and implementation of our clinical trials, we cannot guarantee you that such regulatory authorities will not change their requirements in the future. In addition, even if the clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit emricasan for approval. To the extent that the results of the clinical trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, approval of emricasan may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of emricasan.

We cannot anticipate when or if we will seek regulatory review of emricasan for any indication. We have not previously submitted an NDA to the FDA, or similar drug approval filings to comparable foreign authorities. An NDA must include extensive preclinical and clinical data and supporting information to establish the drug candidate s safety

and effectiveness for each desired indication. The NDA must also include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of an NDA

is a lengthy, expensive and uncertain process and may not be obtained. We have not received marketing approval for any drug candidate, and we cannot be certain that emricasan will be successful in clinical trials or receive regulatory approval for any indication. If we do not receive regulatory approvals for and successfully commercialize emricasan on a timely basis or at all, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market emricasan, our revenues will be dependent, in part, on our ability to commercialize emricasan as well as the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for the treatment of ACLF, CLF, POLT-HCV-SVR or NASH are not as significant as we estimate, our business and prospects will be harmed.

Emricasan was the subject of a clinical hold imposed by the FDA while under development by Pfizer Inc. due to a preclinical observation. Although the clinical hold has been lifted, any adverse side effects or other safety risks associated with emricasan could delay or preclude approval of the drug candidate, cause us to suspend or discontinue our clinical trials or limit the commercial profile of emricasan.

When we acquired emricasan from Pfizer in 2010, emricasan was on clinical hold in the United States due to an observation of inflammatory infiltrates in mice that Pfizer saw in a preclinical study and reported to the FDA in 2007. Pfizer performed additional preclinical studies attempting to characterize the nature of the inflammatory infiltrates, but did not carry out a formal carcinogenicity study to evaluate whether or not the infiltrates progressed to cancer. These infiltrates observed in mice were not observed in any other species. In 2008, Pfizer stopped work on the program. After acquiring emricasan, we conducted a thorough internal review of these studies, commissioned several independent experts to review the data and, based on guidance from the FDA, conducted a 6-month carcinogenicity study in the Tg.rasH2 transgenic mouse model, which is known to be predisposed toward tumor development. This study was completed in 2012. There was no evidence of drug-related tumorgenicity in our carcinogenicity study, and after further discussions with the FDA, we were cleared in January 2013 to proceed with our previously planned HCV-POLT clinical trial, formally lifting emricasan from clinical hold in the United States. Emricasan was never placed on clinical hold outside the United States. We cannot assure you that emricasan will not be placed on clinical hold in the future for similar or unrelated reasons.

In addition, undesirable side effects caused by emricasan could result in the delay, suspension or termination of our clinical trials by us, the FDA or other regulatory authorities or institutional review boards, or IRBs, for a number of reasons. To date, over 500 subjects have received emricasan in Phase 1 and Phase 2 clinical trials. The most commonly reported treatment-related adverse events in emricasan-treated subjects were upper abdominal pain, dizziness, headache, fatigue, nausea and diarrhea. Although most of the adverse events reported in relation to emricasan in these trials were mild to moderate, results of our anticipated future trials could reveal a high and unacceptable severity and prevalence of these or other side effects, including, potentially, more severe side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of emricasan for any or all targeted indications. In addition, the drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims. Even if regulatory authorities granted approval of emricasan, if adverse events caused regulatory authorities to impose a restrictive label or if physicians perceptions of emricasan s safety caused them to limit their use of the drug, our ability to generate sufficient sales of emricasan could be limited. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

Clinical drug development involves uncertain outcomes, and results of earlier studies and trials may not be predictive of future trial results.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. For example, in late 2011 we ceased clinical development of a drug candidate, CTS-1027, for which we had incurred approximately $31.3 million in research and development expenses prior to such time. The results of preclinical studies and early clinical trials of

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emricasan may not be predictive of the results of later-stage clinical trials. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or safety profiles, notwithstanding promising results in earlier trials.

Emricasan has been the subject of six Phase 1 and four Phase 2 clinical trials. Although we believe emricasan has demonstrated evidence of a beneficial effect in patients with chronic liver disease independent of the cause of disease, we are now seeking to evaluate emricasan in targeted indications within liver disease, including certain indications for which the safety and efficacy of emricasan have not been previously evaluated. Specifically, we recently initiated a Phase 2b ACLF clinical trial and a Phase 2 NAFLD/NASH clinical trial and expect to initiate a Phase 2b POLT-HCV-SVR clinical trial and a Phase 2 CLF clinical trial in the second half of 2014. The development program for emricasan to date has focused primarily on the treatment of HCV patients and the evaluation of the drug candidate in liver disease generally. We cannot be certain that any of our planned clinical trials will be successful, and failure in one indication may have negative consequences for the development of emricasan for other indications. For example, any safety concerns observed in our ACLF clinical trials could limit the prospects for regulatory approval for another indication such as POLT-HCV-SVR, CLF or NASH. Any such failure may harm our business, prospects and financial condition.

The FDA regulatory approval process is lengthy and time-consuming, and if we experience significant delays in the clinical development and regulatory approval of emricasan, our business will be substantially harmed.

We may experience delays in commencing and completing clinical trials of emricasan. For example, based on recent data regarding a new HCV antiviral being developed by Gilead Sciences, we chose to delay and change our previously planned Phase 2b/3 HCV-POLT clinical trial to a Phase 2b POLT-HCV-SVR clinical trial. We may also experience delays in commencing and completing other clinical trials of emricasan. We do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Although we recently initiated a Phase 2b ACLF clinical trial and a Phase 2 NAFLD/NASH clinical trial and are targeting the initiation of a Phase 2b POLT-HCV-SVR clinical trial and a Phase 2 CLF clinical trial in second half of 2014, any of our planned clinical trials may be delayed for a variety of reasons, including delays related to:

- the availability of financial resources for us to commence and complete our planned clinical trials;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining IRB approval at each clinical trial site;
- obtaining regulatory approval for clinical trials in each country;
- recruiting suitable patients to participate in a clinical trial;

having patients complete a clinical trial or return for post-treatment follow-up;

clinical trial sites deviating from trial protocol or dropping out of a trial;

adding new clinical trial sites;

developing one or more new formulations or routes of administration; or

manufacturing sufficient quantities of our drug candidate for use in clinical trials.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for

the clinical trial, the design of the clinical trial, competing clinical trials and clinicians and patients perceptions as to the potential advantages of the drug candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. In addition, significant numbers of patients who enroll in our clinical trials may drop out during the clinical trials as a result of being offered a liver transplant in the case of ACLF or CLF patients, a potential curative therapy or other reasons. For example, recent data regarding a new HCV antiviral being developed by Gilead Sciences suggesting the potential availability of a curative therapy for HCV infection in HCV-POLT patients has caused us to delay and change our previously planned Phase 2b/3 HCV-POLT clinical trial to a Phase 2b POLT-HCV-SVR clinical trial based on the analysis of the impact of such data on our ability to recruit and maintain patient compliance during the proposed two years of dosing with emricasan. We believe we have appropriately accounted for such increased risk of dropout rates in our trials when determining expected clinical trial timelines in our initiated Phase 2b ACLF clinical trial and Phase 2 NAFLD/NASH clinical trial and planned Phase 2 CLF clinical trial and Phase 2b POLT-HCV-SVR clinical trial, but we cannot assure you that our assumptions are correct, or that we will not experience higher numbers of dropouts than anticipated, which would result in the delay of completion of such trials beyond our expected timelines.

We could encounter delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of emricasan in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs in the institutions in which such trials are being conducted, the Data Monitoring Committee for such trial, or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience termination of, or delays in the completion of, any clinical trial of emricasan, the commercial prospects for emricasan will be harmed, and our ability to generate product revenues will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly. Furthermore, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of emricasan.

The clinical trials for emricasan involve a high degree of uncertainty and risk of failure, and some of our development activities involve indications with little or no previous drug candidate development activities as well as patient populations with critical illnesses and potential challenges for enrollment and participation in clinical trials.

Our business involves the development of new drugs, which is a highly risky undertaking and involves a lengthy process and high degree of uncertainty. Some of our clinical trials for emricasan may involve indications and patient populations that have had little or no previous development activities by us or others in our industry. For example, to our knowledge the Phase 2b clinical trial in ACLF is the first clinical trial evaluating the effect of a small molecule in this patient population.

In connection with clinical trials, we face risks that:

- IRBs may delay approval of, or fail to approve, a clinical trial at a prospective site;

there may be a limited number of, and significant competition for, suitable patients for enrollment in the clinical trials, particularly in orphan populations such as ACLF;

there may be slower than expected rates of patient recruitment and enrollment;

patients may fail to complete the clinical trials;

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there may be an inability or unwillingness of patients or medical investigators to follow our clinical trial protocols;

there may be an inability to monitor patients adequately during or after treatment;

there may be termination of the clinical trials by one or more clinical trial sites;

unforeseen ethical or safety issues may arise;

conditions of patients may deteriorate rapidly or unexpectedly, which may cause the patients to become ineligible for a clinical trial or may prevent emricasan from demonstrating efficacy or safety;

patients may die or suffer other adverse effects for reasons that may or may not be related to emricasan being tested;

we may not be able to sufficiently standardize certain of the tests and procedures that are part of our clinical trials because such tests and procedures are highly specialized and involve a high degree of expertise;

emricasan may not prove to be efficacious in all or some patient populations;

the results of the clinical trials may not confirm the results of earlier trials;

the results of the clinical trials may not meet the level of statistical significance required by the FDA or other regulatory agencies; and

emricasan may not have a favorable risk/benefit assessment in the disease areas studied.

We cannot assure you that our ongoing clinical trials or any future clinical trial for emricasan will be started or completed on schedule, or at all. Any failure or significant delay in completing clinical trials for emricasan would harm the commercial prospects for emricasan and adversely affect our financial results. Difficulties and failures can occur at any stage of clinical development, and we cannot assure you that we will be able to successfully complete the development and commercialization of emricasan in any indication.

If we are unable to obtain regulatory approval of emricasan, we will not be able to commercialize this drug candidate and our business will be adversely impacted.

We have not obtained regulatory approval for any drug candidate. If we fail to obtain regulatory approval to market emricasan, our only drug candidate, we will be unable to sell emricasan, which will significantly impair our ability to generate any revenues. To receive approval, we must, among other things, demonstrate with substantial evidence from

clinical trials that the drug candidate is both safe and effective for each indication for which approval is sought, and failure can occur in any stage of development. Satisfaction of the approval requirements typically takes several years and the time and money needed to satisfy them may vary substantially, based on the type, complexity and novelty of the pharmaceutical product. We have not commenced any Phase 3 clinical trials of emricasan to date, and we cannot predict if or when our planned clinical trials will generate the data necessary to support an NDA and if, or when, we might receive regulatory approvals for emricasan.

Emricasan could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;

- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that emricasan is safe and effective for any of its proposed indications;

- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;

- we may be unable to demonstrate that emricasan s clinical and other benefits outweigh its safety risks;

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- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

- the data collected from clinical trials of emricasan may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of an NDA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;

- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and

- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failure to obtain regulatory approval to market emricasan, which would significantly harm our business, prospects, financial condition and results of operations. In addition, even if we were to obtain approval, regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials or the imposition of a risk evaluation and mitigation strategy, or REMS, requiring substantial additional post-approval safety measures. Moreover, any approvals that we obtain may not cover all of the clinical indications for which we are seeking approval, or could contain significant limitations in the form of narrow indications, warnings, precautions or contra-indications with respect to conditions of use. In such event, our ability to generate revenues would be greatly reduced and our business would be harmed.

Even if we obtain and maintain regulatory approval for emricasan in one jurisdiction, we may never obtain regulatory approval for emricasan in any other jurisdiction, which would limit our market opportunities and adversely affect our business.

Obtaining and maintaining regulatory approval for emricasan in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA grants marketing approval for a drug candidate, comparable regulatory authorities in foreign countries must also approve the manufacturing, marketing and promotion of the drug candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials. In many countries outside the United States, a drug candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for our products is also subject to approval. We expect to submit a marketing authorization application, or MAA, to the European Medicines Agency, or EMA, for approval of emricasan in the EU. As with the FDA, obtaining approval of an MAA from the EMA is a similarly lengthy and expensive process and the EMA has its own procedures for approval of drug candidates. Even if a product is approved, the FDA or the EMA, as the case may be, may limit the indications for which the product may be marketed, require extensive warnings on the product labeling, require a REMS or require expensive and time-consuming clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States and the EU also have requirements for approval of drug candidates with which we must comply prior to marketing in those countries. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or

delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Also, regulatory approval for any drug candidate may be withdrawn. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of emricasan will be harmed, which would adversely affect our business, prospects, financial condition and results of operations.

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Even if we receive regulatory approval for emricasan, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, emricasan, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with emricasan.

Any regulatory approvals that we receive for emricasan may be subject to limitations on the approved indicated uses for which emricasan may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the drug candidate. The FDA may also require a REMS in order to approve emricasan, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves emricasan, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for emricasan will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practices, or cGMPs, and current good clinical practices, or cGCPs, for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with emricasan, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of emricasan, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of emricasan; and
- injunctions or the imposition of civil or criminal penalties.

The FDA s and other regulatory authorities policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of emricasan. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

Even if we obtain regulatory approval for emricasan, the product may not gain market acceptance among physicians, patients, tertiary care centers, transplant centers and others in the medical community.

If emricasan is approved for commercialization, its acceptance will depend on a number of factors, including:

- the clinical indications for which emricasan is approved;
- physicians, major operators of tertiary care centers and transplant centers and patients considering emricasan as a safe and effective treatment;
- the potential and perceived advantages of emricasan over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;

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the timing of market introduction of emricasan as well as competitive products;

the cost of treatment in relation to alternative treatments;

the availability of adequate reimbursement and pricing by third-party payors and government authorities;

relative convenience and ease of administration; and

the effectiveness of our sales and marketing efforts.

If emricasan is approved but fails to achieve market acceptance among physicians, patients or others in the medical community, we will not be able to generate significant revenues, which would have a material adverse effect on our business, prospects, financial condition and results of operations.

Coverage and reimbursement may be limited or unavailable in certain market segments for emricasan, which could make it difficult for us to sell emricasan profitably.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will cover and the amount of reimbursement. Reimbursement by a third-party payor 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 coverage and reimbursement approval for a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

We intend to seek approval to market emricasan in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for emricasan, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the EU, the pricing of prescription pharmaceuticals and

biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval for a drug candidate. In addition, market acceptance and sales of emricasan will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for emricasan and may be affected by existing and future health care reform measures.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, the Medicare Modernization Act of 2003 revised the payment methodology for many products under Medicare in the United States. This has resulted in lower rates of reimbursement. In 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively, the Healthcare Reform Act, was enacted. The Healthcare Reform Act, among other things, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees on

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manufacturers of certain branded prescription drugs, requires manufacturers to participate in a discount program for certain outpatient drugs under Medicare Part D and promotes programs that increase the federal government s comparative effectiveness research, which will impact existing government healthcare programs and will result in the development of new programs. An expansion in the government s role in the United States healthcare industry may further lower rates of reimbursement for pharmaceutical products.

Other legislative changes have been proposed and adopted in the United States since the Healthcare Reform Act was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation s automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. On March 1, 2013, the President signed an executive order implementing sequestration, and on April 1, 2013, the 2% Medicare payment reductions went into effect. The ATRA also, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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

- the demand for emricasan, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell emricasan, we may not be able to generate product revenues.

We currently do not have a commercial organization for the marketing, sales and distribution of pharmaceutical products. In order to commercialize emricasan, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. We expect that the majority of all ACLF, CLF and POLT-HCV-SVR patients will be treated at tertiary care centers and transplant centers and therefore can be addressed with a targeted sales force. We intend to build our own commercial infrastructure in North America and the EU to target these centers, but will evaluate opportunities to partner with pharmaceutical companies that have established sales and marketing capabilities to commercialize emricasan in ACLF, CLF and POLT-HCV-SVR outside of North America and Europe. We may also partner with a pharmaceutical company that has global capabilities to evaluate emricasan in non-orphan indications for which we believe it may also be effective.

The establishment and development of our own sales force or the establishment of a contract sales force to market emricasan will be expensive and time-consuming and could delay any commercial launch. Moreover, we

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cannot be certain that we will be able to successfully develop this capability. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. We also face competition in our search for third parties to assist us with the sales and marketing efforts of emricasan. To the extent we rely on third parties to commercialize emricasan, if approved, we may have little or no control over the marketing and sales efforts of such third parties and our revenues from product sales may be lower than if we had commercialized emricasan ourselves. In the event we are unable to develop our own marketing and sales force or collaborate with a third-party marketing and sales organization, we would not be able to commercialize emricasan.

A variety of risks associated with marketing emricasan internationally could materially adversely affect our business.

We plan to seek regulatory approval for emricasan outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market (with low or lower prices) rather than buying them locally;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;

challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;

production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

If we fail to develop and commercialize any other drug candidates, we may be unable to grow our business.

Although we currently have no plans to do so, we may seek to develop and commercialize drug candidates in addition to emricasan, which is currently our only drug candidate. If we decide to pursue the development and

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commercialization of any additional drug candidates, we may be required to invest significant resources to acquire or in-license the rights to such drug candidates or to conduct drug discovery activities. In addition, any other drug candidates will require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, extensive clinical trials and approval by the FDA and applicable foreign regulatory authorities. All drug candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the drug candidate will not be shown to be sufficiently safe and/or effective for approval by regulatory authorities. In addition, we cannot assure you that we will be able to acquire, discover or develop any additional drug candidates, or that any additional drug candidates we may develop will be approved, manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives. Research programs to identify new drug candidates require substantial technical, financial and human resources whether or not we ultimately identify any candidates. If we are unable to develop or commercialize emricasan or any other drug candidates, our business and prospects will suffer.

We cannot be certain that emricasan or any other drug candidates that we develop will produce commercially viable drugs that safely and effectively treat liver or other diseases. Even if we are successful in completing preclinical and clinical development and receiving regulatory approval for one commercially viable drug for the treatment of one disease, we cannot be certain that we will also be able to develop and receive regulatory approval for other drug candidates for the treatment of other forms of that disease or other diseases. If we fail to develop a pipeline of potential drug candidates other than emricasan, we will not have any prospects for commercially viable drugs should our efforts to develop and commercialize emricasan be unsuccessful, and our business prospects would be harmed significantly.

We face significant competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Although we believe that we hold a leading position in our understanding of caspase inhibition related to liver disease, our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis drug products that are more effective or less costly than emricasan. We believe the key competitive factors that will affect the development and commercial success of our drug candidates are efficacy, safety and tolerability profile, reliability, convenience of dosing, price and reimbursement.

There are currently no therapeutic products approved for the treatment of ACLF, CLF, POLT-HCV-SVR or NASH. There are a number of marketed therapeutics used in each of these diseases to try to remove the underlying cause of the disease and prevent further liver injury. For example, if the liver damage is a result of hepatitis B virus or HCV infection, marketed antiviral medications may be used to treat the virus that led to liver damage. If the liver damage is a result of alcoholic hepatitis, marketed alcohol addiction drugs may be used. If the liver damage is a result of obesity, diet and exercise may be prescribed along with marketed therapeutics. If the liver damage is a result of NASH, marketed drugs such as insulin sensitizers (e.g., metformin), antihyperlipidemic agents (e.g., gemfibrozil),

pentoxifylline and ursodiol may be used, although none of these are approved for NASH. In addition to the marketed drugs for those indications, there are drugs in development for each of these indications. Although these marketed therapies and those in development may be efficacious, all

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of them take time to show an effect and as long as the underlying conditions persist there will continue to be damage to the liver. In NASH for example, drugs in development have differing mechanisms of action and it is currently unknown whether any single drug candidate will eliminate liver inflammation and halts liver disease progression into advanced fibrosis. For each of these indications, emricasan is the only therapeutic we are aware of that is being developed specifically to reduce the level of apoptosis in the liver and as a result it may be used with these other therapies. Our estimates of disease prevalence consider the presence of these other treatments. In addition, the HCV landscape is expected to continue to evolve dramatically over the next five to ten years with the introduction of new interferon-free regimens and next generation interferon-free regimens, which may reach the market by as early as 2014, with greater efficacy and tolerability over the current antiviral therapies.

Even if we obtain regulatory approval for emricasan, the availability and price of our competitors products could limit the demand, and the price we are able to charge, for emricasan. We will not achieve our business plan if the acceptance of emricasan is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to emricasan, or if physicians switch to other new drug products or choose to reserve emricasan for use in limited circumstances. Our inability to compete with existing or subsequently introduced drug products would have a material adverse impact on our business, prospects, financial condition and results of operations.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make emricasan less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval or discovering, developing and commercializing medicines before we do, which would have a material adverse impact on our business.

We may not be able to obtain orphan drug exclusivity for emricasan for any indication.

In the United States, under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition. Such diseases and conditions are those that affect fewer than 200,000 individuals in the United States, or if they affect more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a drug product available in the United States for these types of diseases or conditions will be recovered from sales of the product. Orphan product designation must be requested before submitting an NDA. If the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by that agency. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, but it can lead to financial incentives, such as opportunities for grant funding toward clinical trial costs, tax advantages and user-fee waivers.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug marketing exclusivity for a period of seven years. Orphan drug marketing exclusivity generally prevents the FDA from approving another application, including a full NDA, to market the same drug or biological product for the same indication for seven years, except in limited circumstances, including if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. For purposes of small molecule drugs, the FDA defines same drug as a drug that contains the same active chemical entity and is intended for the same use as the drug in question. A designated orphan drug may not receive orphan drug marketing exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Orphan drug marketing exclusivity rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

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The criteria for designating an orphan medicinal product in the EU are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. The application for orphan designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the marketing authorization application if the orphan designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The ten-year market exclusivity in the EU may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if:

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;
- the applicant consents to a second orphan medicinal product application; or
- the applicant cannot supply enough orphan medicinal product.

We originally applied for orphan drug designation for emricasan for the treatment of fibrosis in HCV-POLT patients in the United States and the EU. The FDA granted an orphan drug designation for emricasan for the treatment of POLT patients with reestablished fibrosis to delay the progression to cirrhosis and end-stage liver disease. In the EU, we withdrew the application based on feedback from the applicable regulatory body that emricasan may have efficacy in fibrosis outside of the HCV-POLT patient population. We plan to submit applications for orphan drug designations for ACLF in the United States and the EU in the second half of 2014. We cannot assure you that we will be able to obtain orphan drug exclusivity for emricasan in any jurisdiction for the target indications in a timely manner or at all, or that a competitor will not obtain orphan drug exclusivity that could block the regulatory approval of emricasan for several years. If we are unable to obtain orphan drug designation in the United States or the EU, we will not receive market exclusivity which might affect our ability to generate sufficient revenues. If a competitor is able to obtain orphan exclusivity that would block emricasan s regulatory approval, our ability to generate revenues would be significantly reduced which would harm our business prospects, financial condition and results of operations.

We may be unable to maintain or effectively utilize orphan drug exclusivity for emricasan for any indication.

We received orphan drug designation from the FDA for emricasan for the treatment of POLT patients with reestablished fibrosis to delay the progression to cirrhosis and end-stage liver disease. We may be unable to obtain FDA approval for emricasan for this orphan population or any other orphan population, or we may be unable to

successfully commercialize emricasan for such orphan populations due to risks that include:

- the orphan patient populations may change in the size;
- there may be changes in the treatments options for patients that may provide alternative treatments to emricasan;
- the development costs may be greater than projected revenue of drug sales for the orphan indications;

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the FDA may disagree with the design or implementation of our clinical trials;

there may be difficulties in enrolling patients for clinical trials;

emricasan may not prove to be efficacious in the orphan patient populations;

clinical trial results may not meet the level of statistical significance required by the FDA; and

emricasan may not have a favorable risk/benefit assessment in the orphan indication.

If we are unable to obtain FDA approval for emricasan for any orphan population or are unable to successfully commercialize emricasan for such orphan population, it could harm our business prospects, financial condition and results of operations.

We may form or seek strategic alliances in the future, and we may not realize the benefits of such alliances.

We may form or seek strategic alliances, create joint ventures or collaborations or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to emricasan and any future drug candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for emricasan because it may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view emricasan as having the requisite potential to demonstrate safety and efficacy. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenues or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to emricasan could delay the development and commercialization of emricasan in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, including our President and Chief Executive Officer, Steven J. Mento, Ph.D., our Senior Vice President, R&D, and Chief Scientific Officer, Alfred P. Spada, Ph.D., and our Senior Vice President, Clinical Research, and Chief Medical Officer, Gary C. Burgess, M.B., Ch.B. M.Med. The loss of the services of any of our executive officers or other key employees and our inability to find suitable replacements could potentially harm our business, prospects, financial condition or results of operations.

Our scientific team has expertise in many different aspects of drug discovery and development. We conduct our operations at our leased facility in San Diego, California. This region is headquarters to many other biopharmaceutical

companies and many academic and research institutions. Competition for skilled personnel in our market is very intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms. In order to induce valuable employees to remain with our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies.

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Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain key man insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level, and senior scientific and medical personnel.

Many of the other biotechnology and pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They may also provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than what we can offer. If we are unable to continue to attract and retain high quality personnel, our ability to advance the development of emricasan and obtain regulatory approval and potentially commercialize this drug candidate will be limited.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of March 26, 2014, we had 24 employees, 22 of whom are full-time. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for emricasan, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize emricasan will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities. To date, we have used the services of outside vendors to perform tasks including clinical trial management, statistics and analysis, regulatory affairs, formulation development and other drug development functions. Our growth strategy may also entail expanding our group of contractors or consultants to implement these tasks going forward. Because we rely on numerous consultants, effectively outsourcing many key functions of our business, we will need to be able to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. However, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for emricasan or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize emricasan. Accordingly, we may not achieve our research, development and commercialization goals for emricasan.

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

Despite the implementation of security measures, our internal computer systems and those of our current and future CROs and other contractors and consultants are vulnerable to damage from computer viruses,

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unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties to manufacture emricasan and conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of emricasan could be delayed.

Business disruptions could seriously harm our future revenues and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce emricasan. Our ability to obtain clinical supplies of emricasan could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. Our corporate headquarters is located in California near major earthquake faults and fire zones. The ultimate impact on us, our significant suppliers and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

If emricasan is approved, we may be subject to healthcare laws, regulation and enforcement. Our failure to comply with those laws could have a material adverse effect on our results of operations and financial conditions.

Although we currently do not have any products on the market, if emricasan is approved, once we begin commercializing emricasan, we may be subject to additional healthcare regulation and enforcement by the

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federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. Such laws include, without limitation, state and federal anti-kickback, false claims, privacy and security and physician sunshine laws and regulations. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of emricasan.

We face an inherent risk of product liability as a result of the clinical testing of emricasan and will face an even greater risk if we commercialize any products. For example, we may be sued if emricasan allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of emricasan. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

decreased demand for emricasan;

injury to our reputation;

withdrawal of clinical trial participants;

initiation of investigations by regulators;

costs to defend the related litigation;

a diversion of management s time and our resources;

substantial monetary awards to trial participants or patients;

product recalls, withdrawals or labeling, marketing or promotional restrictions;

loss of revenue;

exhaustion of any available insurance and our capital resources;

the inability to commercialize emricasan; and

a decline in our share price.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently carry $5.0 million of product liability insurance covering our clinical trials. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. If we determine that it is prudent to increase our product liability coverage due to the commercial launch of any approved product, we may be unable to obtain such increased coverage on acceptable terms, or at all. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

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Risks Related to Our Reliance On Third Parties

We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize emricasan and our business could be substantially harmed.

We have and anticipate that we will continue to engage one or more third-party CROs in connection with our initiated and planned Phase 2 and Phase 3 clinical trials for emricasan. We rely heavily on these parties for execution of our clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and our reliance on our CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with cGCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for drug candidates in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these CROs fail to comply with applicable cGCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the cGCP regulations. In addition, our clinical trials must be conducted with drug product produced under cGMP regulations and will require a large number of test subjects. Our failure or any failure by our CROs to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of our CROs violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Our CROs are not our employees and, except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical, clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval for or successfully commercialize emricasan. As a result, our financial results and the commercial prospects for emricasan would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding CROs involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Although we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, prospects, financial condition and results of operations.

We rely completely on third parties to manufacture our preclinical and clinical drug supplies and we intend to rely on third parties to produce commercial supplies of emricasan, if approved. The development and commercialization of emricasan could be stopped, delayed or made less profitable if those third parties fail to obtain and maintain regulatory approval of their facilities, fail to provide us with sufficient quantities of drug product or fail to do so at acceptable quality levels or prices.

We do not currently have nor do we plan to acquire the infrastructure or capability internally to manufacture our clinical drug supplies for use in the conduct of our clinical trials, and we lack the resources and the capability to manufacture emricasan on a clinical or commercial scale. Instead, we rely on contract manufacturers for such production.

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We do not currently have any agreement with a manufacturer to produce the active pharmaceutical ingredient, or API, in emricasan. We acquired quantities of the API from Pfizer as part of our acquisition of the rights to the drug candidate. We believe the quantities we acquired from Pfizer are sufficient to support our initiated Phase 2b ACLF clinical trial and Phase 2 NAFLD/NASH clinical trial and planned Phase 2b POLT-HCV-SVR clinical trial and Phase 2 CLF clinical trial. However, we will need to identify and qualify a new third-party manufacturer of API prior to commercialization of emricasan and, if our estimates regarding our supply are incorrect, prior to the completion of our planned clinical trials. Any delay in identifying and qualifying a new manufacturer of API could delay the potential commercialization of emricasan, and, in the event that we do not have sufficient API to complete our planned clinical trials, it could delay such trials.

In addition, we do not currently have a long-term commitment for the production of finished emricasan drug product. Metrics, Inc., a contract manufacturer, has performed formulation and finished goods manufacturing for us based on purchase orders. We expect to continue to purchase finished drug product from Metrics, but currently have no long-term supply commitment with Metrics. If Metrics is unable to produce the amount of finished drug product we need, we may need to identify and qualify other third-party manufacturers of finished drug product in order to complete the clinical development and commercialization of emricasan. Metrics inability to produce the amount of finished drug product we need, or any delay in identifying and qualifying another manufacturer of finished drug product could delay our clinical trials and the potential commercialization of emricasan.

The facilities used by our contract manufacturers to manufacture emricasan must be approved by the applicable regulatory authorities, including the FDA, pursuant to inspections that will be conducted after an NDA or comparable foreign regulatory marketing application is submitted. We do not control the manufacturing process of emricasan and are completely dependent on our contract manufacturing partners for compliance with the FDA s requirements for manufacture of both the active drug substances and finished drug product. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA s strict regulatory requirements, they will not be able to secure or maintain FDA approval for the manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any other applicable regulatory authorities does not approve these facilities for the manufacture of emricasan or if it withdraws any such approval in the future, or if our suppliers or contract manufacturers decide they no longer want to supply or manufacture for us, we may need to find alternative manufacturing facilities, in which case we might not be able to identify manufacturers for clinical or commercial supply on acceptable terms, or at all, which would significantly impact our ability to develop, obtain regulatory approval for or market emricasan.

In addition, the manufacture of pharmaceutical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production and absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of emricasan or in the manufacturing facilities in which emricasan is made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability or other issues relating to the manufacture of emricasan will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our drug candidate to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial

programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

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If our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials by our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical, radioactive and hazardous materials. Although we believe that our manufacturers procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical, radioactive or hazardous materials. As a result of any such contamination or injury we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical radioactive or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Risks Related to Our Financial Position and Capital Requirements

We have a limited operating history, have incurred significant operating losses since our inception and anticipate that we will continue to incur losses for the foreseeable future.

Our operations began in 2005 and we have only a limited operating history upon which you can evaluate our business and prospects. Our operations to date have been limited to conducting product development activities for emricasan and performing research and development with respect to our clinical and preclinical programs. In addition, as an early-stage company, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the pharmaceutical area. Nor have we demonstrated an ability to obtain regulatory approval for or to commercialize a drug candidate. Consequently, any predictions about our future performance may not be as accurate as they would be if we had a history of successfully developing and commercializing pharmaceutical products.

We have incurred significant operating losses since our inception, including consolidated net losses of $15.6 million, $8.7 million and $12.0 million for the years ended December 31, 2013, 2012 and 2011, respectively. As of December 31, 2013, we had an accumulated deficit of $74.4 million. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders equity and working capital. Our losses have resulted principally from costs incurred in our research and development activities. We anticipate that our operating losses will substantially increase over the next several years as we execute our plan to expand our research, development and commercialization activities, including the clinical development and planned commercialization of our drug candidate, emricasan, and incur the additional costs of operating as a public company. In addition, if we obtain regulatory approval of emricasan, we may incur significant sales and marketing expenses. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or whether or when we will become profitable, if ever.

We have not generated any revenues to date from product sales. We may never achieve or sustain profitability, which could depress the market price of our common stock, and could cause our stockholders to lose all or a part of their investment.

Our ability to become profitable depends on our ability to develop and commercialize emricasan. To date, we have no products approved for commercial sale and have not generated any revenues from sales of any drug candidate, and we

do not know when, or if, we will generate revenues in the future. We do not anticipate

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generating revenues, if any, from sales of emricasan for at least the next several years and we will never generate revenues from emricasan if we do not obtain regulatory approval for emricasan. Our ability to generate future revenues depends heavily on our success in:

- developing and securing United States and/or foreign regulatory approvals for emricasan;
- manufacturing commercial quantities of emricasan at acceptable cost;
- achieving broad market acceptance of emricasan in the medical community and with third-party payors and patients;
- commercializing emricasan, assuming we receive regulatory approval; and
- pursuing clinical development of emricasan in additional indications.

Even if we do generate product sales, we may never achieve or sustain profitability. Our failure to become and remain profitable would depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations.

If we fail to obtain additional financing, we may be unable to complete the development and commercialization of emricasan.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the clinical development of emricasan, including our planned Phase 2 and Phase 3 clinical trials. If approved, we will require significant additional amounts in order to launch and commercialize emricasan, including building our own commercial capabilities to sell, market and distribute emricasan in the United States and the EU.

In July 2013, we received net proceeds of approximately $58.6 million from our initial public offering, or IPO, after deducting underwriting discounts, commissions and offering-related transaction costs. We believe that our existing cash and cash equivalents will be sufficient to fund our operations for at least the next 12 months. In particular, we expect that the net proceeds from our IPO will allow us to complete our initiated Phase 2b ACLF clinical trial and Phase 2 NAFLD/NASH clinical trial and planned Phase 2b POLT-HCV-SVR clinical trial and Phase 2 CLF clinical trial. However, changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We will require additional capital for the further development and commercialization of emricasan and may need to raise additional funds sooner if we choose to expand more rapidly than we presently anticipate.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of emricasan or other research and development initiatives. We also could be required to seek collaborators for emricasan at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights

to emricasan in markets where we otherwise would seek to pursue development or commercialization ourselves.

Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or drug candidate.

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional

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capital through the sale of equity or convertible debt securities, the ownership interests of our stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or drug candidate, or grant licenses on terms unfavorable to us.

Our ability to utilize 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 corporation 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 to offset its post-change income may be limited. As a result of our most recent private placements, our IPO and other transactions that have occurred over the past three years, we may have experienced an ownership change. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As of December 31, 2013, we had federal and state net operating loss carryforwards of approximately $43.2 million and $42.6 million, respectively, and federal and state research and development credits of $1.5 million and $0.8 million, respectively, which could be limited if we experience an ownership change.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

As widely reported, global credit and financial markets have experienced extreme disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, 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 could directly affect our ability to attain our operating goals on schedule and on budget.

At December 31, 2013, we had approximately $56.4 million of cash, cash equivalents and marketable securities. While we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents and marketable securities since December 31, 2013, no assurance can be given that deterioration of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or marketable securities or our ability to meet our financing objectives. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

Risks Related to Our Intellectual Property

If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

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Composition-of-matter patents on the active pharmaceutical ingredient and crystalline forms are generally considered to be the strongest form of intellectual property protection for pharmaceutical products, as such patents provide protection without regard to any method of use. We cannot be certain that the claims in our patent applications covering composition-of-matter and crystalline forms of emricasan will be considered patentable by the United States Patent and Trademark Office, or the USPTO, courts in the United States, or by the patent offices and courts in foreign countries. Method-of-use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products off-label. Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. Some of our patents related to emricasan were acquired from a predecessor owner and were therefore not written by us or our attorneys, and we did not have control over the drafting and prosecution of these patents. Further, the former patent owners might not have given the same attention to the drafting and early prosecution of these patents and applications as we would have if we had been the owners of the patents and applications and had control over the drafting and prosecution. In addition, the former patent owners may not have been completely familiar with United States patent law, possibly resulting in inadequate disclosure and/or claims. This could result in findings of invalidity or unenforceability of the patents we own or patents issuing with reduced claim scope.

In addition, the patent applications that we own or that we may license may fail to result in issued patents in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent applications we hold with respect to emricasan is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, emricasan. Further, if we encounter delays in our clinical trials, the period of time during which we could market emricasan under patent protection would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to emricasan. Furthermore, for applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. For applications containing a claim not entitled to priority before March 16, 2013, there is greater level of uncertainty in the patent law with the passage of the America Invents Act (2012) which brings into effect significant changes to the United States patent laws that are yet untried and untested, and which introduces new procedures for challenging pending patent applications and issued patents. A primary change under this reform is creating a first to file system in the United States. This will require us to be cognizant going forward of the time from invention to filing of a patent application.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not

otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result,

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we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

Third-party claims of intellectual property infringement may prevent or delay our drug discovery and development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Recently, under United States patent reform, new procedures including inter partes review and post grant review have been implemented. As stated above, this reform is untried and untested and will bring uncertainty to the possibility of challenge to our patents in the future. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing emricasan. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that emricasan may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of emricasan. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that emricasan may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of emricasan, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize the drug candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the drug candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize emricasan may be impaired or delayed, which could in turn significantly harm our business.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize emricasan. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of emricasan. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize emricasan, which could harm our business significantly.

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We may be involved in lawsuits to protect or enforce our patents, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

Interference proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

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, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

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Risks Related to Ownership of our Common Stock

The price of our stock may be volatile.

Prior to our IPO, there was no public market for our common stock. Since the commencement of trading in connection with our IPO in July 2013 through March 14, 2014, the sale price per share of our common stock on The NASDAQ Global Market has ranged from a low of $ 5.76 to a high of $15.67. The trading price of our common stock is likely to continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this Risk Factors section and elsewhere in this annual report, these factors include:

- the commencement, enrollment or results of our planned Phase 2 and Phase 3 clinical trials of emricasan or any future clinical trials we may conduct, or changes in the development status of emricasan;
- any delay in our regulatory filings for emricasan and any adverse development or perceived adverse development with respect to the applicable regulatory authority s review of such filings, including without limitation the FDA s issuance of a refusal to file letter or a request for additional information;
- adverse results or delays in clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval for emricasan;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved drug product or inability to do so at acceptable prices;
- our inability to establish collaborations if needed;
- our failure to commercialize emricasan;

additions or departures of key scientific or management personnel;

unanticipated serious safety concerns related to the use of emricasan;

introduction of new products or services offered by us or our competitors;

announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;

our ability to effectively manage our growth;

the size and growth, if any, of the ACLF, CLF, POLT-HCV-SVR and NASH markets and other targeted markets;

our ability to successfully enter new markets;

actual or anticipated variations in quarterly operating results;

our cash position;

our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;

publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;

changes in the market valuations of similar companies;

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overall performance of the equity markets;

sales of our common stock by us or our stockholders in the future;

trading volume of our common stock;

changes in accounting practices;

ineffectiveness of our internal controls;

disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;

significant lawsuits, including patent or stockholder litigation;

general political and economic conditions; and

other events or factors, many of which are beyond our control.

In addition, the stock market in general, and The NASDAQ Global Market and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this Risk Factors section and elsewhere in this annual report on Form 10-K could have a dramatic and material adverse impact on the market price of our common stock.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, our ability to pay cash dividends is currently prohibited by the terms of a promissory note in the principal amount of $1.0 million issued by us to Pfizer in July 2010. Any return to stockholders will therefore be limited to the appreciation of their stock.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of December 31, 2013, our executive officers, directors, 5% stockholders and their affiliates owned approximately 55% of our outstanding voting stock. Therefore, these stockholders have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational

documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that our stockholders may feel are in their best interests.

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute

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payments not previously approved. We could be an emerging growth company for up to five years following 2013, the year in which we completed our IPO, although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non-affiliates exceeds $700.0 million as of any June 30 before that time or if we have total annual gross revenue of $1.0 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31 or, if we issue more than $1.0 billion in non-convertible debt during any three year period before that time, we would cease to be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we may qualify as a smaller reporting company, which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of United States generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

We incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and The NASDAQ Global Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as say on pay and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years following their initial public offering. We are taking advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

The rules and regulations applicable to public companies may substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our consolidated net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may

incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

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Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

Persons who were our stockholders prior to our IPO in July 2013 continue to hold a substantial number of shares of our common stock that they are able to sell in the public market, subject in some cases to certain legal restrictions. Significant portions of these shares are held by a small number of stockholders. If these stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. The perception in the market that these sales may occur could also cause the trading price of our common stock to decline. As of March 14, 2014, we had 15,632,000 shares of common stock outstanding.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

The holders of 8,870,459 shares of our common stock as of March 14, 2014 (including shares issuable upon exercise of options and warrants) are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities, our stockholders may be materially diluted by subsequent sales and new investors could gain rights preferences and privileges senior to the holders of our common stock.

Pursuant to our 2013 equity incentive award plan, or the 2013 Plan, which became effective on the business day prior to the public trading date of our common stock, our management is authorized to grant stock options to our employees, directors and consultants. The number of shares available for future grant under the 2013 Plan will automatically increase each year by an amount equal to the least of (1) 1,000,000 shares of our common stock, (2) 5% of the outstanding shares of our common stock as of the last day of our immediately preceding fiscal year, or (3) such other amount as our board of directors may determine. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have

experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management s attention and resources, which could harm our business.

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We have broad discretion in the use of the net proceeds from our IPO and may not use them effectively.

Our management has broad discretion in the application of the net proceeds from our IPO. Because of the number and variability of factors that will determine our use of the net proceeds from our IPO, their ultimate use may vary substantially from their currently intended use. Our management might not apply our net proceeds in ways that ultimately improve our operating results or increase the value of our common stock. We expect to continue to use the net proceeds from our IPO to fund the clinical development of emricasan and to fund working capital and for general corporate purposes. The failure by our management to apply these funds effectively could harm our business. Pending their use, we have and may continue to invest the net proceeds from our IPO in primarily short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from our IPO in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, the president or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and

the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for our stockholders to elect directors of their choosing or cause us to take other corporate actions desired by certain stockholders. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

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If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. We currently have limited research coverage by securities and industry analysts. In the event one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We lease approximately 5,349 square feet of space for our headquarters in San Diego, California under an agreement that expires in June 2014. We have secured approximately 9,954 square feet of office space located in San Diego, California for when our currently leased space expires in June 2014, and the operating lease for the new office space has an initial term of 65 months with a renewal option for an additional five years.

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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PART II

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

Market Information

Our common stock has been traded on The NASDAQ Global Market since July 25, 2013 under the symbol CNAT. Prior to such time, there was no public market for our common stock. The following table sets forth, for the periods indicated, the high and low sale prices for our common stock on The NASDAQ Global Market. Since our common stock has only been traded on a public market since July 25, 2013, we have not set forth quarterly information with respect to the high and low sale prices for our common stock for the two most recent fiscal years.

	High	Low
Year Ended December 31, 2013		
Third Quarter (beginning July 25, 2013)	$ 11.24	$ 8.26
Fourth Quarter	$ 10.72	$ 5.76

Holders of Common Stock

As of March 14, 2014, there were 15,632,000 shares of our common stock outstanding and 49 holders of record of our common stock. This number was derived from our shareholder records and does not include beneficial owners of our common stock whose shares are held in the name of various dealers, clearing agencies, banks, brokers and other fiduciaries.

Dividend Policy

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings, if any, for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, our ability to pay cash dividends is currently prohibited by the terms of a promissory note in the principal amount of $1.0 million issued by us to Pfizer Inc. in July 2010. Any future determination related to our dividend policy will be made at the discretion of our board of directors.

Equity Compensation Plan Information

The following table summarizes securities available under our equity compensation plans as of December 31, 2013.

	Equity Compensation Plan Information		
Plan category	**Number of securities to be issued upon exercise of outstanding options,**	**Weighted-average exercise price of outstanding options, warrants and rights**	**Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))**

	warrants and rights (a)		(b)	(c)
Equity compensation plans approved by security holders	790,590	$	4.01	767,278
Equity compensation plans not approved by security holders				
Total	790,590	$	4.01	767,278

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Performance Graph

The information contained in this Performance Graph section shall not be deemed soliciting material or to be filed with the SEC, for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any filing of Conatus Pharmaceuticals Inc. under the Securities Act of 1933, as amended, or the Securities Act, or the Exchange Act.

The following graph shows a comparison from July 25, 2013, the date our common stock commenced trading on The NASDAQ Global Market, through December 31, 2013 of cumulative total return for our common stock, the NASDAQ Composite Index and the NASDAQ Biotechnology Index. Such returns are based on historical results and are not intended to suggest future performance. The graph assumes the investment of $100 on July 25, 2013 in our stock at the opening trading price of $11.00 and in the indices at the opening trading prices, with the reinvestment of dividends, although dividends have not been declared on our common stock.

	7/25/2013	7/31/13	8/31/13	9/30/13	10/31/13	11/30/13	12/31/13
Conatus Pharmaceuticals Inc.	$ 100.00	$ 82.91	$ 82.64	$ 91.36	$ 80.91	$ 58.00	$ 58.64
NASDAQ Composite	$ 100.00	$ 101.03	$ 100.01	$ 105.07	$ 109.20	$ 113.11	$ 116.36
NASDAQ Biotechnology	$ 100.00	$ 102.24	$ 100.11	$ 108.33	$ 106.11	$ 115.81	$ 117.27

Unregistered Sales of Equity Securities

From January 1, 2013 through December 31, 2013, we issued and sold the equity securities described below.

1. In May 2013, we issued and sold an aggregate of $1.0 million in principal amount of convertible promissory notes to existing investors. In connection with the issuance of these notes, we issued warrants which were exercisable for an aggregate of 1,124,026 shares of Series B convertible preferred stock at an initial exercise price per share of $0.90, for consideration equal to $0.0001 per warrant

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share. In connection with the completion of our initial public offering, or IPO, in July 2013, the notes (including accrued interest thereon) automatically converted into 91,948 shares of common stock and the warrants became exercisable for an aggregate of 136,236 shares of common stock, at an exercise price of $7.43 per share.

2. In July 2013, as consideration for entering into our credit facility we issued to lenders warrants to purchase up to an aggregate of 111,112 shares of our Series B convertible preferred stock, at an initial exercise price of $0.90 per share. In connection with the completion of our IPO in July 2013, the warrants became exercisable for an aggregate of 13,468 shares of common stock, at an exercise price of $7.43 per share.

3. From January 1, 2013 through December 31, 2013, we granted stock options to purchase an aggregate of 316,935 shares of our common stock at a weighted average exercise price of $9.44 per share, to certain of our employees, consultants and directors in connection with services provided to us by such persons. Of these, options to purchase 14,242 shares of common stock have been exercised as of December 31, 2013 for aggregate consideration of $28,175, at a weighted average exercise price of $1.98 per share.

The securities described in paragraphs (1) and (2) above were issued to investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(2) under the Securities Act and Regulation D promulgated thereunder relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. All purchasers of the equity securities described above represented to us in connection with their purchase that they were accredited investors and were acquiring the securities for their own account for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

The securities described in paragraph (3) above were issued pursuant to written compensatory plans or arrangements with our employees and directors, in reliance on the exemption from the registration requirements of the Securities Act provided by Rule 701 promulgated under the Securities Act or the exemption set forth in Section 4(2) under the Securities Act and Regulation D promulgated thereunder relative to transactions by an issuer not involving any public offering. All recipients either received adequate information about us or had access, through employment or other relationships, to such information.

All of the foregoing securities are deemed restricted securities for purposes of the Securities Act. All of the foregoing securities included appropriate legends setting forth that the securities had not been registered and the applicable restrictions on transfer. No underwriters were involved in the foregoing transactions.

Use of Proceeds

On July 24, 2013, our registration statement on Form S-1 (File No. 333-189305), which registered an aggregate amount of up to $69.0 million of our common stock, was declared effective by the SEC for our IPO. On July 25, 2013, we filed a Registration Statement pursuant to Rule 462(b) (File No. 333-190115), which registered an additional aggregate amount of up to $6.9 million of our common stock. At the closing of the IPO on July 30, 2013, we sold 6,000,000 shares of common stock at an IPO price of $11.00 per share and received gross proceeds of $66.0 million, which resulted in net proceeds to us of approximately $58.6 million, after underwriting discounts and commissions of approximately $4.6 million and offering-related transaction costs of approximately $2.8 million. None of the expenses associated with the IPO were paid to directors, officers, persons owning ten percent or more of any class of equity

securities, or to their associates, or to our affiliates. Stifel, Nicolaus & Company, Incorporated and Piper Jaffray & Co. acted as joint book-running managers and JMP Securities LLC and SunTrust Robinson Humphrey, Inc. acted as co-managers for the IPO. On August 23,

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2013, the underwriters 30-day over-allotment option to purchase an additional 900,000 shares of common stock in the IPO expired without being exercised and the IPO terminated.

We intend to use the net offering proceeds to fund the clinical development of emricasan and for working capital and general corporate purposes. Pending use of the net proceeds, we plan to invest the net proceeds from our IPO in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the United States government. Through December 31, 2013, the net proceeds have been applied as follows: $2.7 million towards the clinical development of emricasan and $5.0 million towards working capital and general corporate purposes.

Issuer Repurchases of Equity Securities

None.

ITEM 6. SELECTED FINANCIAL DATA

The following tables set forth a summary of our consolidated historical financial data as of, and for the periods ended on, the dates indicated. We have derived the consolidated statement of operations data for the years ended December 31, 2013, 2012 and 2011, and for the period from July 13, 2005 (inception) to December 31, 2013 and the consolidated balance sheet data as of December 31, 2013, 2012 and 2011 from our audited consolidated financial statements included elsewhere in this report. You should read the selected financial data in conjunction with the related notes included elsewhere in this report and Management s Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this report. Our historical results for any prior period are not necessarily indicative of our future results.

	Year Ended December 31,			Period from July 13, 2005 (Inception) to December 31, 2013
	2013	2012	2011	
Consolidated Statement of Operations Data:				
Operating expenses:				
Research and development	$ 6,947,439	$ 5,528,106	$ 9,486,619	$ 47,772,587
General and administrative	4,650,807	3,086,479	2,874,507	22,767,399
Total operating expenses	11,598,246	8,614,585	12,361,126	70,539,986
Other (expense) income:				
Interest income	22,144	25,547	28,274	1,380,894
Interest expense	(462,570)	(70,000)	(113,836)	(1,237,399)
Other (expense) income	(1,070)	1,358	(4,439)	240,329
Other financing (expense) income	(3,576,750)	(91,559)	454,547	(4,267,839)
Total other (expense) income	(4,018,246)	(134,654)	364,546	(3,884,015)
Net loss	$ (15,616,492)	$ (8,749,239)	$ (11,996,580)	$ (74,424,001)

Net loss per share applicable to common stockholders, basic and diluted	$ (0.63)	$ (8.60)	$ (11.86)
Weighted average shares outstanding used in computing net loss per share applicable to common stockholders, basic and diluted	7,358,201	1,016,951	1,011,649

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	December 31,		
	2013	2012	2011
Consolidated Balance Sheet Data:			
Cash, cash equivalents and marketable securities	$ 56,352,987	$ 8,025,564	$ 16,758,038
Working capital	54,081,487	6,688,847	15,202,374
Total assets	56,935,954	8,145,747	16,958,880
Convertible preferred stock warrant liability		160,345	68,786
Note payable	1,000,000	1,000,000	1,000,000
Convertible preferred stock		63,908,372	63,908,372
Total stockholders equity (deficit)	53,118,950	(58,335,871)	(49,739,275)

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

Overview

We are a biotechnology company focused on the development and commercialization of novel medicines to treat liver disease. We are developing our lead compound, emricasan, for the treatment of patients with chronic liver disease and acute exacerbations of chronic liver disease. Emricasan is a first-in-class, orally active pan-caspase protease inhibitor designed to reduce the activity of all ten human caspases, which are enzymes that mediate inflammation and cell death, or apoptosis. We believe that by reducing the activity of these enzymes, emricasan has the potential to interrupt the progression of liver disease and potentially provide treatment options in multiple areas of liver disease. We have observed compelling preclinical and clinical trial results that suggest emricasan may have clinical utility in slowing progression of liver diseases regardless of the original cause of the disease. To date, emricasan has been studied in over 500 subjects in ten clinical trials. In a randomized Phase 2b clinical trial in patients with liver disease, emricasan demonstrated a statistically significant, consistent, rapid and sustained reduction in elevated levels of two key biomarkers of inflammation and cell death, alanine aminotransferase, or ALT, and cleaved Cytokeratin 18, or cCK18, respectively, both of which are implicated in the severity and progression of liver disease.

We have designed a comprehensive clinical program to demonstrate the therapeutic benefit of emricasan across the spectrum of fibrotic liver disease. Our initial development strategy targets indications for emricasan with high unmet clinical need and small, potentially orphan, patient populations, such as patients with acute-on-chronic liver failure, or ACLF, and chronic liver failure, or CLF. ACLF and CLF are potential orphan indications in both the United States and European Union, or the EU. We plan to submit applications for orphan drug designations for ACLF in the United States and the EU in the second half of 2014. Although we plan to focus primarily on the development of emricasan for ACLF and CLF, we also plan to evaluate the compound in patients who have developed liver fibrosis post-orthotopic liver transplant, or POLT, due to hepatitis C virus, or HCV, infection and have subsequently achieved sustained viral response, or SVR, following anti-HCV therapy, or POLT-HCV-SVR, as well as in patients with non-alcoholic steatohepatitis, or NASH. We were granted orphan drug designation in late 2013 by the United States Food and Drug Administration, or the FDA, for the treatment of POLT patients with reestablished fibrosis to delay the progression to cirrhosis and end-stage liver disease.

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Target Therapeutic Area	Description of Patient Population	Development Plans
Acute-on-Chronic Liver Failure	ACLF occurs in patients who have compensated or decompensated cirrhosis but are in relatively stable condition until an acute event sets off a rapid worsening of liver function.	Our planned clinical trials in ACLF will evaluate whether emricasan can halt the progression of decompensation to multi-organ failure or death in an acutely decompensating cirrhotic patient population. We initiated a Phase 2b ACLF clinical trial in the second half of 2013, and we plan to submit applications for orphan drug designations for ACLF in the United States and the EU in the second half of 2014.
Chronic Liver Failure	Patients with CLF suffer from compensated or decompensated cirrhosis.	Our planned clinical trials in CLF will assess whether emricasan can delay or prevent disease progression. We plan to initiate a Phase 2 CLF clinical trial in the second half of 2014.
Post Liver Transplant Clearance of Hepatitis C Virus Infection with Sustained Viral Response	In patients with POLT-HCV-SVR, liver fibrosis may persist for many years.	We plan to initiate a placebo-controlled (sponsor open) Phase 2b clinical trial tracking biomarkers and histology in POLT patients who respond to antiviral therapy but still have underlying liver fibrosis in the second half of 2014.
Non-alcoholic Steatohepatitis	NASH patients suffer from inflammation due to fat buildup in the liver.	We recently initiated a Phase 2 clinical trial in the United States for non-alcoholic fatty liver disease, or NAFLD, and NASH. Our goal is to accumulate sufficient and relevant clinical data to allow rapid advancement of emricasan once appropriate regulatory pathways are defined.

Since our inception, our primary activities have been organizational activities, including recruiting personnel, conducting research and development, including clinical trials, and raising capital. We have funded our operations since inception primarily through sales of equity securities and convertible promissory notes. From inception through December 31, 2013, we have received net proceeds of $119.6 million from such sales, including the completion of our initial public offering, or IPO, in July 2013 of 6,000,000 shares of common stock at an offering price of $11.00 per share. We received net proceeds of approximately $58.6 million from our IPO, after deducting underwriting discounts, commissions and offering-related transaction costs.

We have no products approved for sale. We have not generated any revenues to date, and we have incurred significant operating losses since our inception. We have never been profitable and have incurred consolidated net losses of

approximately $15.6 million, $8.7 million and $12.0 million in the years ended December 31, 2013, 2012 and 2011, respectively. As of December 31, 2013, we had an accumulated deficit of $74.4 million.

We expect to continue to incur significant operating losses and negative cash flows from operating activities for the foreseeable future as we continue the clinical development of emricasan and seek regulatory approval for and, if approved, pursue eventual commercialization of emricasan. As of December 31, 2013, we had cash, cash equivalents and marketable securities of approximately $56.4 million. To fund further operations, we will need to raise additional capital. We may obtain additional financing in the future through the issuance of our common stock in future public offerings, through other equity or debt financings or through collaborations or partnerships with other companies. Although it is difficult to predict future liquidity requirements, we believe that our existing

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cash, cash equivalents and marketable securities, together with interest thereon, including funds raised in the IPO, will be sufficient to fund our operations for at least the next 12 months, including the completion of our initiated Phase 2b ACLF clinical trial and Phase 2 NAFLD/NASH clinical trial and our planned Phase 2 CLF clinical trial and Phase 2 POLT-HCV-SVR clinical trial. We will need to raise additional funds to complete additional clinical trials of emricasan, to fund regulatory filings for emricasan in the United States and the European Union and for potential commercialization of emricasan.

However, successful transition to profitability is dependent upon achieving a level of revenues adequate to support our cost structure. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities and, unless and until we do, we will need to raise substantial additional capital through equity or debt financings or through collaborations or partnerships with other companies. We may not be able to raise additional capital on terms acceptable to us, or at all, and any failure to raise capital as and when needed could have a material adverse effect on our results of operations, financial condition and our ability to execute on our business plan.

JOBS Act

In April 2012, the Jumpstart Our Business Startups Act of 2012, or JOBS Act, was signed into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an emerging growth company. As an emerging growth company, we are electing not to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision not to take advantage of the extended transition period is irrevocable. In addition, we are in the process of evaluating the benefits of relying on the other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, if as an emerging growth company we choose to rely on such exemptions, we may not be required to, among other things, (i) provide an auditor s attestation report on our system of internal controls over financial reporting pursuant to Section 404, (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor s report providing additional information about the audit and the financial statements (auditor discussion and analysis) and (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the Chief Executive Officer s compensation to median employee compensation. These exemptions will apply for a period of five years following the completion of our IPO or until we no longer meet the requirements of being an emerging growth company, whichever is earlier.

Financial Overview

Revenues

We currently have no products approved for sale, and we have not generated any revenues to date. We have not submitted any drug candidate for regulatory approval. In the future, we may generate revenues from a combination of milestone payments, reimbursements and royalties in connection with any future collaboration we may enter into with respect to emricasan, as well as product sales from emricasan. However, we do not expect to receive revenues unless and until we receive approval for emricasan or potentially enter into collaboration agreements for emricasan. If we fail to achieve clinical success in the development of emricasan in a timely manner and/or obtain regulatory approval for this drug candidate, our ability to generate future revenues would be materially adversely affected.

Research and Development Expenses

The majority of our operating expenses to date have been incurred in research and development activities. In late 2011, we ceased clinical development of a drug candidate, CTS-1027, which we licensed from Roche Palo

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Alto LLC and F. Hoffman-La Roche Ltd., or collectively Roche, in 2006. In early 2012, the rights to this drug candidate reverted to Roche. Research and development expenses through 2011 were primarily devoted to this drug candidate. Starting in late 2011, research and development expenses have been focused on the development of emricasan. Since acquiring emricasan in 2010, we have incurred approximately $15.9 million in the development of emricasan through December 31, 2013. Our business model is currently focused on the broad development of emricasan in various liver diseases and is dependent upon our continuing to conduct research and a significant amount of clinical development. Our research and development expenses consist primarily of:

- expenses incurred under agreements with contract research organizations, or CROs, investigative sites and consultants that conduct our clinical trials and our preclinical studies;
- employee-related expenses, which include salaries and benefits;
- the cost of finalizing our chemistry, manufacturing and controls, or CMC, capabilities and providing clinical trial materials; and
- costs associated with other research activities and regulatory approvals.

Research and development costs are expensed as incurred.

At this time, due to the inherently unpredictable nature of preclinical and clinical development, we are unable to estimate with any certainty the costs we will incur in the continued development of emricasan. Clinical development timelines, the probability of success and development costs can differ materially from expectations.

We are currently focused on advancing emricasan in multiple indications, and our future research and development expenses will depend on its clinical success. In addition, we cannot forecast with any degree of certainty whether emricasan will be the subject of future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

Research and development expenditures will continue to be significant and will increase as we continue clinical development of emricasan over at least the next several years. We expect to incur significant development costs as we conduct our planned Phase 2 and Phase 3 clinical trials of emricasan, subject to receiving input from regulatory authorities.

The costs of clinical trials may vary significantly over the life of a project owing to factors that include but are not limited to the following:

- per patient trial costs;
- the number of patients that participate in the clinical trials;

the number of sites included in the clinical trials;

the countries in which the clinical trial is conducted;

the length of time required to enroll eligible patients;

the number of doses that patients receive;

the drop-out or discontinuation rates of patients;

potential additional safety monitoring or other studies requested by regulatory agencies;

the duration of patient follow-up; and

the efficacy and safety profile of the drug candidate.

We do not expect emricasan to be commercially available, if at all, for at least the next several years.

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General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance and business development functions. Other general and administrative expenses include costs related to being a public company, as well as facilities, travel, patent filing and maintenance, legal and consulting expenses.

We anticipate that our general and administrative expenses will increase in future periods, reflecting an expanding infrastructure and increased professional fees associated with being a public reporting company.

In addition, if emricasan receives regulatory approval, we expect to incur increased expenses associated with building a sales and marketing team. Some expenses may be incurred prior to receiving regulatory approval of emricasan. We do not expect to receive any such regulatory approval for at least the next several years.

Interest Income

Interest income consists primarily of interest income earned on our cash, cash equivalents and marketable securities.

Interest Expense

Interest expense consists of coupon interest on our $1.0 million promissory note payable to Pfizer Inc., interest accrued on the convertible promissory notes payable to certain existing investors issued in May 2013 and interest accrued pursuant to the loan and security agreement, or the credit facility, with Oxford Finance LLC, as collateral agent and a lender, and certain other lenders party thereto from time to time, including Silicon Valley Bank, through our prepayment of the outstanding advances under the credit facility in September 2013.

Other (Expense) Income

Other income includes a one-time, non-operating transaction associated with the receipt of a federal investment tax credit in 2010.

Other Financing (Expense) Income

Other financing (expense) income consists of the revaluation of our convertible preferred stock warrants issued in conjunction with our 2010 and 2013 bridge note financings.

Critical Accounting Policies and Significant Judgments and Estimates

Our management s discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions.

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While our significant accounting policies are more fully described in the notes to our audited consolidated financial statements appearing elsewhere in this annual report, we believe that the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our financial statements and understanding and evaluating our reported financial results.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing contracts and purchase orders, reviewing the terms of our vendor agreements, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time.

Examples of estimated accrued research and development expenses include:

- fees paid to CROs in connection with clinical trials;
- fees paid to investigative sites in connection with clinical trials;
- fees paid to vendors in connection with preclinical development activities; and
- fees paid to vendors related to product manufacturing, development and distribution of clinical supplies.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows and expense recognition. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual accordingly. Our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in our reporting changes in estimates in any particular period. We have not experienced any significant adjustments to our estimates to date. Clinical trial activities were minimal for the years ended December 31, 2011 and 2012. In the year ended December 31, 2013, we have increased our clinical trial activities and we expect our clinical trial activities to continue to increase as we initiate additional planned clinical trials.

Share-Based Compensation

We account for share-based compensation by measuring and recognizing compensation expense for all share-based payments made to employees and directors based on estimated grant date fair values. We use the straight-line method to allocate compensation cost to reporting periods over each optionee s requisite service period, which is generally the

vesting period. We estimate the fair value of our share-based awards to employees and directors using the Black-Scholes option pricing model. The Black-Scholes model requires the input of subjective assumptions, including the risk-free interest rate, expected dividend yield, expected volatility, expected term and the fair value of the underlying common stock on the date of grant, among other inputs. We account for stock options granted to non-employees, which primarily consists of members of our board of directors, using the fair value approach. Stock options granted to non-employees are subject to periodic revaluation over their vesting terms.

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Convertible Preferred Stock Warrant Liability

We have issued freestanding warrants exercisable for shares of our Series A and Series B convertible preferred stock. These warrants were classified as a liability in the accompanying consolidated balance sheets prior to the completion of our IPO in July 2013, as the terms for redemption of the underlying security were outside our control. The Series A warrants were recorded at fair value using the Black-Scholes option pricing model. The Series B warrants were recorded at fair value using a Monte Carlo model. The fair value of all warrants, except as noted below, was remeasured at each financial reporting date using the Black-Scholes option pricing method with any changes in fair value being recognized in other financing (expense) income, a component of other (expense) income, in the accompanying consolidated statements of operations. We ceased the remeasure of the fair value of the convertible warrant liability upon the exercise of the Series A warrants and conversion of the Series B warrants to common stock warrants, which occurred immediately prior to the completion of our IPO on July 30, 2013. Subsequent to such exercise and conversion, the warrants are classified as a component of stockholders equity and are no longer subject to remeasurement.

Net Operating Loss and Research and Development Tax Credit Carryforwards

At December 31, 2013, we had federal and state net operating loss carryforwards of approximately $43.2 million and $42.6 million, respectively. The federal and state loss carryforwards begin to expire in 2025 and 2015, respectively, unless previously utilized. At December 31, 2013, we also had federal and state research credit carryforwards of approximately $1.5 million and $0.8 million, respectively. The federal research credit carryforwards will begin expiring in 2026 unless previously utilized. The state research credit will carry forward indefinitely.

Utilization of the net operating losses and credits may be subject to a substantial annual limitation due to ownership change limitations provided by the Internal Revenue Code of 1986, as amended. The annual limitation may result in the expiration of our net operating losses and credits before we can use them. We have recorded a valuation allowance on all of our deferred tax assets, including our deferred tax assets related to our net operating loss and research and development tax credit carryforwards.

Results of Operations

Comparison of the Years Ended December 31, 2013, 2012 and 2011

Research and Development Expenses

Research and development expenses were $6.9 million in the year ended December 31, 2013, as compared to $5.5 million for the same period in 2012. The increase of $1.4 million was primarily due to an increase in personnel costs and external costs related to emricasan. Research and development related payroll expenses were $2.8 million in 2013 and $2.0 million in 2012. The increase of $0.8 million was primarily due to higher bonuses and higher headcount. For 2013, external research and development expenses for emricasan were $3.8 million, compared to $3.5 million in 2012. In 2013, costs for emricasan consisted primarily of clinical trial and manufacturing costs. In 2012, costs for emricasan consisted primarily of costs associated with preparing for clinical trials, including payments to consultants related to clinical trial design and regulatory submissions and the conduct of CMC studies and preclinical studies.

Research and development expenses were $5.5 million in the year ended December 31, 2012, as compared to $9.5 million for the same period in 2011. These expenses decreased primarily due to the discontinuation in 2011 of CTS-1027. External research and development expenses for CTS-1027 were $6.2 million in 2011 and less than $0.1 million in 2012. Research and development expenses for CTS-1027 in 2012 consisted primarily of expenses

associated with the termination of the clinical trial. In 2011, expenses for CTS-1027 consisted primarily of $5.6 million for payments to CROs and clinical trial sites and expenses related to drug substance procurement and processing, each in connection with the conduct of our clinical trial; the remainder was primarily spent on CMC studies. External research and development expenses for emricasan were $3.5 million in 2012 and

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$1.5 million in 2011. Research and development expenses related to emricasan in 2012 included $2.5 million for expenses associated with preparing for clinical trials, including payments to consultants related to clinical trial design and regulatory submissions and the conduct of CMC studies. The remainder was primarily for the conduct of preclinical studies. Substantially all of the emricasan expenses in 2011 were for the conduct of our preclinical and CMC studies. Research and development related payroll expenses were $2.0 million in 2012 and $1.8 million in 2011. The increase of $0.2 million was primarily due to the addition of a chief medical officer in late 2011.

General and Administrative Expenses

General and administrative expenses were $4.7 million, $3.1 million and $2.9 million for the years ended December 31, 2013, 2012 and 2011, respectively. The increase from 2012 to 2013 was primarily due to additional personnel costs and costs associated with being a public company, including increased accounting, legal, board of directors, investor relations and insurance expenses. The increase from 2011 to 2012 was primarily due to the addition of personnel and travel expenses.

Changes in components of Other (Expense) Income were as follows:

Interest Income

Interest income was $22,000 for the year ended December 31, 2013, as compared to $26,000 for the same period in 2012. Interest income consisted of interest earned on our cash and investment balances. Our interest income was not significant due to nominal cash and investment balances prior to the IPO and low interest earned on invested balances.

Interest income was $26,000 for the year ended December 31, 2012, as compared to $28,000 for the same period in 2011. Interest income consisted of interest earned on our cash and investment balances. Our interest income was not significant due to nominal cash and investment balances and low interest earned on invested balances.

Interest Expense

Interest expense was $463,000 for the year ended December 31, 2013, as compared to $70,000 for the same period in 2012. The increase was primarily due to interest and expenses associated with the aggregate of $1.0 million of convertible promissory notes we issued in May 2013 and the credit facility funded in July 2013.

Interest expense was $70,000 for the year ended December 31, 2012, as compared to $114,000 for the same period in 2011. The decrease was due to the conversion of convertible promissory notes that we issued in a 2010 bridge financing, or the 2010 bridge notes, into shares of our Series B convertible preferred stock in 2011, which resulted in no further interest charges on these notes.

Other (Expense) Income

Other (expense) income remained relatively unchanged at less than $5,000 for each of the years ended December 31, 2013, 2012 and 2011.

Other Financing (Expense) Income

Other financing expense was $3.6 million for the year ended December 31, 2013, as compared to $92,000 for the same period in 2012. Other financing expense for the two periods represent the revaluation of warrants to purchase Series A convertible preferred stock we issued in 2010, as well as the valuations of warrants to purchase Series B

convertible preferred stock we issued in May and July 2013. The increase in expense for the year ended

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December 31, 2013 was a result of the increase in the Company s stock price. Additionally, the write off of the debt discount associated with our bridge note financing is included in other financing expense for the year ended December 31, 2013.

Other financing expense was $92,000 for the year ended December 31, 2012, as compared to other financing income of $455,000 for the same period in 2011. The higher income in 2011 was due to the acceleration of the remaining amortization of the debt discount related to the 2010 bridge notes upon their conversion in 2011, offset by the revaluation of Series A convertible preferred stock warrants issued in connection with the 2010 bridge notes.

Liquidity and Capital Resources

We have incurred losses since inception and negative cash flows from operating activities for the years ended December 31, 2013, 2012 and 2011. As of December 31, 2013, we had an accumulated deficit of $74.4 million. We anticipate that we will continue to incur net losses for the foreseeable future as we continue the development and potential commercialization of emricasan and incur additional costs associated with being a public company.

Prior to our IPO in July 2013, we funded our operations primarily through private placements of equity and convertible debt securities. In July 2013, we completed our IPO of 6,000,000 shares of common stock at an offering price of $11.00 per share. We received net proceeds of approximately $58.6 million, after deducting underwriting discounts, commissions and offering-related transaction costs. At December 31, 2013, we had cash, cash equivalents and marketable securities of approximately $56.4 million. To fund further operations, we will need to raise additional capital. We plan to continue to fund losses from operations and capital funding needs through future equity and debt financing, as well as potential additional collaborations. The sale of additional equity or convertible debt could result in additional dilution to our stockholders. The incurrence of indebtedness would result in debt service obligations and could result in operating and financing covenants that would restrict our operations. No assurances can be provided that financing will be available in the amounts we need or on terms acceptable to us, if at all. If we are not able to secure adequate additional funding we may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. Any of these actions could materially harm our business, results of operations and future prospects.

In May 2013, we issued $1.0 million in aggregate principal amount of convertible promissory notes, which automatically converted into 91,948 shares of our common stock in connection with the completion of our IPO.

In July 2013, we entered into the credit facility. The credit facility provided funding for an aggregate principal amount of up to $15.0 million. The first term loan of the credit facility was funded in July 2013 in the aggregate principal amount of $1.0 million. On September 25, 2013, we prepaid the outstanding advances under the credit facility. Pursuant to the terms of the credit facility, we prepaid the outstanding principal balance of $1.0 million plus accrued and unpaid interest, a prepayment fee of $30,000, a final payment of $50,000 and the collateral agent s legal fees incurred with respect to the prepayment. Accordingly, the credit facility was terminated on September 25, 2013.

The following table sets forth a summary of the net cash flow activity for each of the periods set forth below:

	Year Ended December 31,		
	2013	**2012**	**2011**
Net cash used in operating activities	$ (10,631,717)	$ (8,564,207)	$ (12,095,572)
Net cash (used in) provided by investing activities	(48,396,707)	9,511,374	(13,988,575)

Net cash provided by financing activities	59,151,286	16,085	26,424,333
Net increase in cash and cash equivalents	$ 122,862	$ 963,252	$ 340,186

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Net cash used in operating activities was $10.6 million, $8.6 million and $12.1 million for the years ended December 31, 2013, 2012 and 2011, respectively. The primary use of cash was to fund our operations related to the development of our drug candidates in each of these periods.

Net cash used in investing activities was $48.4 million for the year ended December 31, 2013, which consisted primarily of cash used to purchase marketable securities. During the year ended December 31, 2012, investing activities provided cash of $9.5 million, which consisted primarily of proceeds from maturities of marketable securities. During the year ended December 31, 2011, investing activities used cash of $14.0 million, which consisted primarily of cash used to purchase marketable securities.

Financing activities in the years ended December 31, 2013, 2012 and 2011 provided net cash of $59.2 million, $16,000 and $26.4 million, respectively. Net cash provided in 2013 consisted primarily of the proceeds resulting from the IPO in July 2013. Financing activities in 2012 consisted of the exercise of common stock options. Financing activities in 2011 consisted of the issuance of 36,417,224 shares of Series B convertible preferred stock.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at December 31, 2013:

		Payments Due by Period			
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Long-term debt	$ 1,000,000				$ 1,000,000
Interest on long-term debt	460,833	70,000	140,000	140,000	110,833
Operating lease obligations	89,766	89,766			
Total	$ 1,550,599	$ 159,766	$ 140,000	$ 140,000	$ 1,110,833

Our commitments for operating leases relate primarily to our lease of office space in San Diego, California.

Our commitment for long-term debt relates to the $1.0 million promissory note issued to Pfizer in July 2010. The note bears interest at a rate of 7% per annum and matures in July 2020, subject to acceleration upon specified events of default. Interest is payable on a quarterly basis during the term of the note. In July 2013, the note was amended to become convertible into shares of our common stock following the completion of our IPO, at the option of the holder, at a price per share equal to the fair market value of our common stock on the date of conversion.

Under our July 2010 stock purchase agreement with Pfizer, we will be required to make payments to Pfizer totaling $18.0 million upon the achievement of specified regulatory milestones related to emricasan. As the timing of when these payments will actually be made is uncertain and the payments are contingent upon the completion of future activities, we have excluded these potential payments from the contractual obligations table above.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements (as defined by applicable regulations of the Securities and Exchange Commission) that are reasonably likely to have a current or future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

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ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Our cash, cash equivalents and marketable securities as of December 31, 2013 consisted of cash, money market funds, municipal bonds, debt securities in government sponsored entities and corporate debt securities. We are exposed to market risk related to fluctuations in interest rates and market prices. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of United States interest rates. However, because of the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our financial condition or results of operation.

Our long-term debt bears interest at a fixed rate and therefore has minimal exposure to changes in interest rates.

Foreign Currency Exchange Risk

We hold certain payroll related funds in pounds sterling and are therefore subject to fluctuations in foreign currency rates for United States dollars and pounds sterling in connection with those funds. To date we have not incurred any material effects from foreign currency changes on those funds. Such fluctuations are recorded in Other (Expense) Income.

Inflation Risk

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our business, financial condition or results of operations during the year ended December 31, 2013.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The consolidated financial statements and the reports of our independent registered public accounting firm required pursuant to this item are included in this report beginning on page F-1.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

As of December 31, 2013, our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, as of the end of the period covered by this annual report on Form 10-K. Based on such evaluation, our principal executive officer and principal financial officer have concluded that as of such date, our disclosure controls and procedures were effective.

Our management, including our principal executive officer and our principal financial officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all error and all fraud. A control system, no

matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within

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the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Management s Annual Report on Internal Control Over Financial Reporting

This annual report on Form 10-K does not include a report of management s assessment regarding internal control over financial reporting due to a transition period established by the rules of the Securities and Exchange Commission for newly public companies.

Attestation Report of the Registered Public Accounting Firm

This annual report on Form 10-K does not include an attestation report of our registered public accounting firm due to an exemption established by the JOBS Act for emerging growth companies.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting during the year ended December 31, 2013, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Entry into a Material Definitive Agreement.

On February 28, 2014, we entered into a lease agreement, or the Lease, with The Point Office Partners, LLC. Under the terms of the Lease, we will lease approximately 9,954 rentable square feet of office space located at 16745 West Bernardo Drive, San Diego, California from July 2014 through November 2019 with a renewal option for an additional five years. The monthly base rent will increase 3% annually from approximately $23,890 in 2014 to $27,695 in 2019.

The foregoing description of the Lease does not purport to be complete and is qualified in its entirety by reference to the Lease, a copy of which is filed as Exhibit 10.24 to this annual report on Form 10-K and is incorporated herein by reference.

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PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information required by this item will be contained in our definitive proxy statement to be filed with the Securities and Exchange Commission in connection with our 2014 Annual Meeting of Stockholders, or the Definitive Proxy Statement, which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2013, under the headings Election of Director, Corporate Governance, Our Executive Officers, and Section 16(a) Beneficial Ownership Reporting Compliance, and is incorporated herein by reference.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that applies to our officers, directors and employees, which is available on our website at www.conatuspharma.com. The Code of Business Conduct and Ethics contains general guidelines for conducting the business of our company consistent with the highest standards of business ethics and is intended to qualify as a code of ethics within the meaning of Section 406 of the Sarbanes-Oxley Act of 2002 and Item 406 of Regulation S-K. In addition, we intend to promptly disclose (1) the nature of any amendment to our Code of Business Conduct and Ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions and (2) the nature of any waiver, including an implicit waiver, from a provision of our code of ethics that is granted to one of these specified officers, the name of such person who is granted the waiver and the date of the waiver on our website in the future.

ITEM 11. EXECUTIVE COMPENSATION

Information required by this item will be contained in our Definitive Proxy Statement under the heading Executive Compensation and Other Information, and is incorporated herein by reference.

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

Information required by this item will be contained in our Definitive Proxy Statement under the heading Security Ownership of Certain Beneficial Owners and Management, and is incorporated herein by reference.

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

Information required by this item will be contained in our Definitive Proxy Statement under the headings Certain Relationships and Related Person Transactions, Board Independence and Committees of the Board of Directors and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Information required by this item will be contained in our Definitive Proxy Statement under the heading Independent Registered Public Accountants Fees, and is incorporated herein by reference.

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PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

1. Financial Statements.

The following consolidated financial statements of Conatus Pharmaceuticals Inc., together with the report thereon of Ernst & Young LLP, an independent registered public accounting firm, are included in this annual report on Form 10-K:

2. Finance Statement Schedules.

All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

3. Exhibits

A list of exhibits is set forth on the Exhibit Index immediately following the signature page of this annual report on Form 10-K and is incorporated herein by reference.

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Conatus Pharmaceuticals Inc. (a development stage company)

Index to Consolidated Financial Statements

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Conatus Pharmaceuticals Inc.

We have audited the accompanying consolidated balance sheets of Conatus Pharmaceuticals Inc. as of December 31, 2013 and 2012, and the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders equity (deficit), and cash flows for each of the three years in the period ended December 31, 2013 and for the period from July 13, 2005 (inception) to December 31, 2013. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company s internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Conatus Pharmaceuticals Inc. at December 31, 2013 and 2012, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2013 and for the period from July 13, 2005 (inception) to December 31, 2013, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

San Diego, California

March 28, 2014

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Conatus Pharmaceuticals Inc. (a development stage company)

Consolidated Balance Sheets

	December 31, 2013	December 31, 2012
Assets		
Current Assets:		
Cash and cash equivalents	$ 4,158,953	$ 4,036,091
Marketable securities	52,194,034	3,989,473
Prepaid and other current assets	545,504	76,184
Total current assets	56,898,491	8,101,748
Property and equipment, net	23,068	29,604
Other assets	14,395	14,395
Total assets	$ 56,935,954	$ 8,145,747
Liabilities, convertible preferred stock and stockholders equity (deficit)		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,494,435	$ 1,087,346
Accrued compensation	1,322,569	325,555
Total current liabilities	2,817,004	1,412,901
Convertible preferred stock warrant liability		160,345
Note payable	1,000,000	1,000,000
Series A Convertible Preferred Stock, $0.0001 par value; 0 and 44,827,538 shares authorized, 0 and 42,494,218 shares issued and outstanding at December 31, 2013 and 2012, respectively		32,208,532
Series B Convertible Preferred Stock, $0.0001 par value; 0 and 50,300,000 shares authorized, 0 and 36,417,224 shares issued and outstanding at December 31, 2013 and 2012, respectively		31,699,840
Stockholders equity (deficit):		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at December 31, 2013 and no shares authorized at December 31, 2012; no shares issued and outstanding at December 31, 2013		
Common stock, $0.0001 par value; 200,000,000 and 120,000,000 shares authorized at December 31, 2013 and 2012 respectively, 15,619,879 shares issued and 15,386,542 shares outstanding, excluding 233,337 shares subject to repurchase at December 31, 2013, 1,207,091 shares issued and 1,052,606 shares outstanding, excluding 154,485 shares subject to repurchase, at December 31, 2012	1,539	105
Additional paid-in capital	127,536,408	470,982
Accumulated other comprehensive income	11,497	551
Deficit accumulated during the development stage	(74,430,494)	(58,807,509)

Total stockholders equity (deficit)	53,118,950	(58,335,871)
Total liabilities, convertible preferred stock and stockholders equity (deficit)	$ 56,935,954	$ 8,145,747

See accompanying notes to consolidated financial statements.

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Conatus Pharmaceuticals Inc. (a development stage company)

Consolidated Statements of Operations and Comprehensive Loss

	Year Ended December 31,			Period from July 13, 2005 (Inception) to December 31, 2013
	2013	2012	2011	
Operating expenses:				
Research and development	$ 6,947,439	$ 5,528,106	$ 9,486,619	$ 47,772,587
General and administrative	4,650,807	3,086,479	2,874,507	22,767,399
Total operating expenses	11,598,246	8,614,585	12,361,126	70,539,986
Other (expense) income:				
Interest income	22,144	25,547	28,274	1,380,894
Interest expense	(462,570)	(70,000)	(113,836)	(1,237,399)
Other (expense) income	(1,070)	1,358	(4,439)	240,329
Other financing (expense) income	(3,576,750)	(91,559)	454,547	(4,267,839)
Total other (expense) income	(4,018,246)	(134,654)	364,546	(3,884,015)
Net loss	(15,616,492)	(8,749,239)	(11,996,580)	(74,424,001)
Other comprehensive income (loss):				
Net unrealized gains (losses) on marketable securities	10,946	5,014	(4,463)	11,497
Comprehensive loss	$ (15,605,546)	$ (8,744,225)	$ (12,001,043)	$ (74,412,504)
Reconciliation of net loss to net loss applicable to common stockholders:				
Net loss	$ (15,616,492)	$ (8,749,239)	$ (11,996,580)	$ (74,424,001)
Gain on extinguishment of convertible preferred stock	11,491,043			11,491,043
Deemed distribution from promissory note issuance	(474,561)			(474,561)
Net loss applicable to common stockholders, basic and diluted	$ (4,600,010)	$ (8,749,239)	$ (11,996,580)	$ (63,407,519)
Net loss per share applicable to common stockholders, basic and diluted	$ (0.63)	$ (8.60)	$ (11.86)	
Weighted average shares outstanding used in computing net loss per share applicable to common stockholders, basic and diluted	7,358,201	1,016,951	1,011,649	

See accompanying notes to consolidated financial statements.

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Conatus Pharmaceuticals Inc. (a development stage company)

Consolidated Statements of Convertible Preferred Stock and Stockholders Equity (Deficit)

	Series A Convertible Preferred Stock		Common Stock					
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Stockholders Deficit
Balance at July 13, 2005 (inception)		$		$	$	$	$	$
Issuance of common stock to founders at $0.00825 per share for cash			727,273	73	5,927			6,000
Net loss and comprehensive loss							(91,354)	(91,354)
Balance at December 31, 2005			727,273	73	5,927		(91,354)	(85,354)
Issuance of preferred stock at $0.75 per share, net of issuance costs of $174,012 and estimated fair value of tranche right of $0.04 per share in October and December 2006, for cash	7,333,334	4,029,181						
Issuance of preferred stock at $0.75 per share, in October and December, for conversion of notes payable and related	1,948,582	1,461,439						

accrued interest							
Issuance of preferred stock at $0.75 per share, in October and December, for share-based compensation in lieu of salaries	878,969	659,224					
Issuance of preferred stock at $0.75 per share, in October and December, for payment of license expense	333,333	250,000					
Issuance of common stock to founders at $0.2475 per share for cash			181,818	18	44,982		45,000
Share-based compensation					796		796
Net loss and comprehensive loss						(3,305,145)	(3,305,145)
Balance at December 31, 2006	10,494,218	6,399,844	909,091	91	51,705	(3,396,499)	(3,344,703)
Issuance of preferred stock at $0.75 per share, net of issuance costs of $19,095 in May 2007 for cash	29,333,334	21,980,905					
Issuance of preferred stock at $0.75 per share in May for payment of license expense	2,666,666	1,999,999					
Reclassification of tranche right upon second		1,827,784					

closing of preferred stock								
Vesting of early exercise of employee stock options			29,924	3	2,586			2,589
Share-based compensation					2,900			2,900
Net loss							(10,183,310)	(10,183,310)
Change in unrealized gains on investments						46,989		46,989
Balance at December 31, 2007	42,494,218	32,208,532	939,015	94	57,191	46,989	(13,579,809)	(13,475,535)
Vesting of early exercise of employee stock options			31,414	3	6,871			6,874
Share-based compensation					24,831			24,831
Net loss							(6,799,395)	(6,799,395)
Change in unrealized gains on investments						(42,231)		(42,231)
Balance at December 31, 2008	42,494,218	32,208,532	970,429	97	88,893	4,758	(20,379,204)	(20,285,456)

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Conatus Pharmaceuticals Inc. (a development stage company)

Consolidated Statements of Convertible Preferred Stock and Stockholders Equity (Deficit) (Continued)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock					
	Shares	Amount	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	T Stock De
at r 31,	42,494,218	$ 32,208,532		$	970,429	$ 97	$ 88,893	$ 4,758	$ (20,379,204)	$ (20,
f rcise yee ions					25,758	3	4,772			
sed ation							30,059			
									(6,979,099)	(6,
n ed nts								(4,718)		
at r 31,	42,494,218	32,208,532			996,187	100	123,724	40	(27,358,303)	(27,
f rcise yee ions					14,015	1	3,685			
sed ation							35,082			
									(10,703,387)	(10,
n ed nts								(40)		
at r 31,	42,494,218	32,208,532			1,010,202	101	162,491		(38,061,690)	(37,
of d 0.90 e, net			36,417,224	31,699,840						

ce										
52 in y and 011 and on of vable										
of rcise yee ions					1,919		1,176			
sed ation							159,690			
									(11,996,580)	(11,
n ed nts								(4,463)		
at r 31,	42,494,218	32,208,532	36,417,224	31,699,840	1,012,121	101	323,357	(4,463)	(50,058,270)	(49,
of rcise yee ions					40,485	4	3,601			
sed ation							144,024			
									(8,749,239)	(8,
n ed nts								5,014		
at r 31,	42,494,218	32,208,532	36,417,224	31,699,840	1,052,606	105	470,982	551	(58,807,509)	(58,

[Continued on the next page]

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Conatus Pharmaceuticals Inc. (a development stage company)

Consolidated Statements of Convertible Preferred Stock and Stockholders Equity (Deficit) (Continued)

Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock				
Shares	Amount	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage
42,494,218	$ 32,208,532	36,417,224	$ 31,669,840	1,052,606	$ 105	$ 470,982	$ 551	$ (58,807,509)
				92,561	9	5,817		
				3,030	1	272		
						257,451		
						(493,507)		(6,493)
						(474,561)		
				6,000,000	600	58,607,854		
				280,675	28	3,083,521		
(42,494,218)	(32,208,532)	(36,417,224)	(31,699,840)	7,865,722	787	63,907,448		
				91,948	9	1,011,472		

ts **x**						
				1,159,659		
						(15,616,492)
					10,946	
$	$	15,386,542	$ 1,539	$ 127,536,408	$ 11,497	$ (74,430,494)

See accompanying notes to consolidated financial statements.

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Conatus Pharmaceuticals Inc. (a development stage company)

Consolidated Statements of Cash Flows

	Year Ended December 31,			Period from July 13, 2005 (Inception) to December 31, 2013
	2013	2012	2011	
Operating activities				
Net loss	$ (15,616,492)	$ (8,749,239)	$ (11,996,580)	$ (74,424,001)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	10,446	9,066	10,951	209,712
Share-based compensation expense	257,451	144,024	159,690	654,833
Noncash other financing expense (income)	3,618,206	91,559	(454,547)	4,846,240
Acquisition of in-process research and development				1,250,000
Share-based compensation in lieu of salaries				659,224
Non-cash license expense				2,249,999
Amortization of premium on investments	199,182	171,810	282,673	77,566
Changes in operating assets and liabilities:				
Prepaid and other current assets	(469,320)	89,149	(68,107)	(545,504)
Other assets			102,239	(14,395)
Accounts payable and accrued expenses	407,089	(91,694)	175,670	1,494,435
Accrued compensation	961,721	(228,882)	(307,561)	1,274,796
Net cash used in operating activities	(10,631,717)	(8,564,207)	(12,095,572)	(62,267,095)
Investing activities				
Maturities of investments	4,725,000	19,838,000	18,936,000	105,507,865
Purchase of investments	(53,117,797)	(10,309,070)	(32,908,335)	(157,767,968)
Cash paid to acquire in-process research and development				(250,000)
Capital expenditures	(3,910)	(17,556)	(16,240)	(232,780)
Net cash (used in) provided by investing activities	(48,396,707)	9,511,374	(13,988,575)	(52,742,883)
Financing activities				
Issuance of promissory notes and warrants	1,001,439			7,201,673
Distribution to wholly owned subsidiary in connection with spin-off of Idun	(500,000)			(500,000)
			26,424,333	53,731,226

Issuance of preferred stock for cash, net of offering costs				
Issuance of common stock related to initial public offering, net of offering costs	58,608,454			58,608,454
Issuance of common stock for exercise of stock options and cash	41,393	16,085		127,578
Net cash provided by financing activities	59,151,286	16,085	26,424,333	119,168,931
Net increase in cash and cash equivalents	122,862	963,252	340,186	4,158,953
Cash and cash equivalents at beginning of period	4,036,091	3,072,839	2,732,653	
Cash and cash equivalents at end of period	$ 4,158,953	$ 4,036,091	$ 3,072,839	$ 4,158,953
Supplemental disclosure of cash flow information:				
Cash paid for interest	$ 88,583	$ 70,000	$ 70,000	$ 258,139
Supplemental schedule of non-cash investing and financing activities:				
Conversion of notes payable for preferred stock	$	$	$ 5,275,507	$ 6,736,946
Conversion of notes payable for common stock	$ 1,001,439	$	$	$ 1,001,439
Issuance of warrants in conjunction with debt	$ 625,792	$	$	$ 2,361,223
Issuance of note payable related to acquisition of in-process research and development	$	$	$	$ 1,000,000

See accompanying notes to consolidated financial statements.

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Conatus Pharmaceuticals Inc. (a development stage company)

Notes to Consolidated Financial Statements

1. Organization and Basis of Presentation

Conatus Pharmaceuticals Inc. (the Company) was incorporated in the state of Delaware on July 13, 2005. The Company is a biotechnology company focused on the development and commercialization of novel medicines to treat liver disease.

As of December 31, 2013, the Company has devoted substantially all of its efforts to product development and has not realized revenues from its planned principal operations. Accordingly, the Company is considered to be in the development stage.

The Company has a limited operating history and the sales and income potential of the Company s business and market are unproven. The Company has experienced net losses since its inception and, as of December 31, 2013, had an accumulated deficit of $74,430,494. The Company expects to continue to incur net losses for at least the next several years. Successful transition to attaining profitable operations is dependent upon achieving a level of revenues adequate to support the Company s cost structure. If the Company is unable to generate revenues adequate to support its cost structure, the Company may need to raise additional equity or debt financing. As of December 31, 2013, the Company had cash, cash equivalents and marketable securities of $56,352,987 and working capital of $54,081,487.

In July 2013, the Company implemented a 1-for-8.25 reverse stock split of its outstanding common stock. The accompanying consolidated financial statements give effect to the reverse split for all periods presented.

In July 2013, the Company completed its initial public offering (IPO) of 6,000,000 shares of common stock at an offering price of $11.00 per share. The Company received net proceeds of approximately $58.6 million, after deducting underwriting discounts and commissions and offering-related transaction costs.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements as of December 31, 2012 and for the years ended December 31, 2012 and 2011 include all the accounts of the Company and its wholly owned subsidiary, Idun Pharmaceuticals, Inc. (Idun). All intercompany balances and transactions have been eliminated in consolidation. In January 2013, the assets and rights related to the drug candidate emricasan were distributed from Idun to the Company. Following that distribution, Idun was spun off from the Company.

Use of Estimates

The preparation of consolidated 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 expenses during the reporting period. Actual results could differ from those estimates.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to significant risk on its cash. Additionally, the Company established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity.

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Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity from the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents include cash in readily available checking and money market accounts.

Investments

The Company classifies its investments as available-for-sale and records such assets at estimated fair value in the consolidated balance sheets, with unrealized gains and losses, if any, reported as a component of other comprehensive income (loss) within the consolidated statements of operations and comprehensive loss and as a separate component of stockholders equity (deficit). The Company invests its excess cash balances primarily in corporate debt securities and money market funds with strong credit ratings. Realized gains and losses are calculated on the specific identification method and recorded as interest income. There have been no realized gains and losses for the years ended December 31, 2013, 2012 and 2011, and for the period from July 13, 2005 (inception) to December 31, 2013.

At each balance sheet date, the Company assesses available-for-sale securities in an unrealized loss position to determine whether the unrealized loss is other-than-temporary. The Company considers factors including: the significance of the decline in value compared to the cost basis, underlying factors contributing to a decline in the prices of securities in a single asset class, the length of time the market value of the security has been less than its cost basis, the security s relative performance versus its peers, sector or asset class, expected market volatility and the market and economy in general. When the Company determines that a decline in the fair value below its cost basis is other-than-temporary, the Company recognizes an impairment loss in the year in which the other-than-temporary decline occurred. There have been no other-than-temporary declines in value of marketable securities for the years ended December 31, 2013, 2012 and 2011, and for the period from July 13, 2005 (inception) to December 31, 2013, as it is more likely than not the Company will hold the securities until maturity or a recovery of the cost basis.

Fair Value of Financial Instruments

The carrying amounts of prepaid and other current assets, accounts payable and accrued expenses are reasonable estimates of their fair value because of the short maturity of these items.

Property and Equipment

Property and equipment, which consists of furniture and fixtures, computers and office equipment and leasehold improvements, are stated at cost and depreciated over the estimated useful lives of the assets (three to five years) using the straight-line method. Leasehold improvements are amortized over the shorter of their estimated useful lives or the lease term.

Long-Lived Assets

The Company regularly reviews the carrying value and estimated lives of all of its long-lived assets, including property and equipment to determine whether indicators of impairment may exist which warrant adjustments to carrying values or estimated useful lives. The determinants used for this evaluation include management s estimate of the asset s ability to generate positive income from operations and positive cash flow in future periods as well as the strategic significance of the assets to the Company s business objective. Should an impairment exist, the impairment loss would be measured based on the excess of the carrying amount of the asset s fair value. The Company has not recognized any impairment losses through December 31, 2013.

Research and Development Expenses

All research and development costs are expensed as incurred.

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Income Taxes

The Company s policy related to accounting for uncertainty in income taxes prescribes a recognition threshold and measurement attribute criteria for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities. As of December 31, 2013, there are no unrecognized tax benefits included in the consolidated balance sheet that would, if recognized, affect the Company s effective tax rate. The Company has not recognized interest and penalties in the consolidated balance sheets or consolidated statements of operations and comprehensive loss. The Company is subject to U.S. and California taxation. As of December 31, 2013, the Company s tax years beginning 2005 to date are subject to examination by taxing authorities.

Stock-Based Compensation

Stock-based compensation for the Company includes amortization related to all stock option awards granted, based on the grant date fair value estimated in accordance with the applicable accounting guidance. The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model using the assumptions noted in the following table. The expected life of options is based on the simplified method described in the Securities and Exchange Commission (SEC) Staff Accounting Bulletin No. 107. The expected volatility of stock options is based upon the historical volatility of a number of publicly traded companies in similar stages of clinical development. The risk-free interest rate is based on the average yield of five- and seven-year U.S. Treasury Bills as of the valuation date.

	Year Ended December 31,		
Assumptions	**2013**	**2012**	**2011**
Risk-free interest rate	0.95% 1.81%	0.78% 1.41%	1.18% 2.71%
Expected dividend yield	0%	0%	0%
Expected volatility	69% 79%	69% 70%	70% 72%
Expected term (in years)	6.0 6.1	6.1	6.1

The Company recorded stock-based compensation of $257,451, $144,024, $159,690 and $654,833 for the years ended December 31, 2013, 2012 and 2011, and for the period from July 13, 2005 (inception) to December 31, 2013, respectively. Unrecognized compensation expense at December 31, 2013 was $1,567,510, which is expected to be recognized over a weighted-average vesting term of 2.9 years.

Convertible Preferred Stock Warrant Liability

The Company has issued freestanding warrants exercisable to purchase shares of its Series A and Series B convertible preferred stock. These warrants were classified as a liability in the accompanying consolidated balance sheets prior to the completion of the IPO, as the terms for redemption of the underlying security were outside the Company s control. The Series A convertible preferred stock warrants were recorded at fair value using the Black-Scholes option pricing model. The Series B convertible preferred stock warrants were recorded at fair value using a Monte Carlo model. The fair value of all warrants, except as noted below, was remeasured at each financial reporting date using the Black-Scholes option pricing model with any changes in fair value being recognized in other financing (expense) income, a component of other (expense) income, in the accompanying consolidated statements of operations and comprehensive loss. The Company ceased the remeasurement of the fair value upon exercise of the Series A warrants and the Series B warrants becoming exercisable for shares of common stock, immediately prior to the completion of the Company s IPO in July 2013.

Comprehensive Loss

The Company is required to report all components of comprehensive loss, including net loss, in the consolidated financial statements in the period in which they are recognized. Comprehensive loss is defined as

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the change in equity during a period from transactions and other events and circumstances from nonowner sources, including unrealized gains and losses on investments. Comprehensive gains (losses) have been reflected in the consolidated statements of operations and comprehensive loss for all periods presented.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. To date, the Company has viewed its operations and managed its business as one segment operating primarily in the United States.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common shares and common share equivalents outstanding for the period. Common stock equivalents are only included when their effect is dilutive. The Company s potentially dilutive securities, which include convertible preferred stock, warrants and outstanding stock options under the stock option plan, have been excluded from the computation of diluted net loss per share in the periods in which they would be anti-dilutive. For all periods presented, there is no difference in the number of shares used to compute basic and diluted shares outstanding due to the Company s net loss position.

The following table sets forth the computation of basic and diluted earnings per share:

	December 31,		
	2013	**2012**	**2011**
Numerator:			
Net loss attributable to common stockholders	$ (4,600,010)	$ (8,749,239)	$ (11,996,580)
Denominator for basic and diluted net loss per share:			
Weighted average common shares outstanding, basic and diluted	7,358,201	1,016,951	1,011,649
Net loss per share applicable to common stockholders:			
Basic	$ (0.63)	$ (8.60)	$ (11.86)
Diluted	$ (0.63)	$ (8.60)	$ (11.86)

The following table sets forth the outstanding potentially dilutive securities that have been excluded in the calculation of diluted net loss per share because to do so would be anti-dilutive.

	December 31,		
	2013	**2012**	**2011**
Convertible preferred stock		9,565,021	9,565,021
Warrants to purchase preferred stock		280,675	280,675
Warrants to purchase common stock.	149,704		
Common stock options	790,590	690,223	760,373

Common stock subject to repurchase	233,337	154,480	
Total	1,173,631	10,690,399	10,606,069

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3. Fair Value Measurements

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Includes financial instruments for which quoted market prices for identical instruments are available in active markets.

Level 2: Includes financial instruments for which there are inputs other than quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets with insufficient volume or infrequent transaction (less active markets) or model-driven valuations in which significant inputs are observable or can be derived principally from, or corroborated by, observable market data.

Level 3: Includes financial instruments for which fair value is derived from valuation techniques in which one or more significant inputs are unobservable, including management s own assumptions.

Below is a summary of assets and liabilities measured at fair value as of December 31, 2013 and 2012.

		Fair Value Measurements Using		
	December 31, 2013	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Money market funds	$ 3,832,902	$ 3,832,902	$	$
Municipal bonds	255,000		255,000	
Corporate debt securities	50,438,149		50,438,149	
Debt securities in government sponsored entities	1,500,885		1,500,885	
Total assets	$ 56,026,936	$ 3,832,902	$ 52,194,034	$

		Fair Value Measurements Using		
	December 31, 2012	Quoted Prices in Active Markets for	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)

		Identical Assets (Level 1)		
Assets				
Money market funds	$ 3,874,153	$ 3,874,153	$	$
Municipal bonds	260,000		260,000	
Corporate debt securities	3,729,473		3,729,473	
Total assets	$ 7,863,626	$ 3,874,153	$ 3,989,473	$
Liabilities				
Convertible preferred stock warrant liability	$ 160,345	$	$	$ 160,345
Total liabilities	$ 160,345	$	$	$ 160,345

The Company s marketable securities, consisting principally of debt securities, are classified as available-for-sale, are stated at fair value and consist of Level 2 financial instruments in the fair value hierarchy. The Company determines the fair value of its debt security holdings based on pricing from a service provider. The

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service provider values the securities based on using market prices from a variety of industry-standard independent data providers. Such market prices may be quoted prices in active markets for identical assets (Level 1 inputs) or pricing determined using inputs other than quoted prices that are observable either directly or indirectly (Level 2 inputs), such as, yield curve, volatility factors, credit spreads, default rates, loss severity, current market and contractual prices for the underlying instruments or debt, broker and dealer quotes, as well as other relevant economic measures.

The fair value of the convertible preferred stock warrant liability was determined based on Level 3 inputs and utilized the Black-Scholes option pricing model for the Series A convertible preferred stock warrants. The Series B convertible preferred stock warrants utilized a Monte Carlo model. The warrant liabilities were marked to market before converting to equity at the IPO. The following table presents activity for the convertible preferred stock warrant liability measured at fair value using significant unobservable Level 3 inputs during the years ended December 31, 2012 and 2013.

	Fair Value Measurements at Reporting Date Using Significant Unobservable Inputs (Level 3)
Balance at December 31, 2011	$ 68,786
Changes in fair value reflected as other financing expense	91,559
Balance at December 31, 2012	160,345
Issuance of preferred stock warrants	625,679
Changes in fair value reflected as other financing expense	3,457,184
Conversion to equity at IPO	(4,243,208)
Balance at December 31, 2013	$

The fair value of the convertible promissory notes was determined based on Level 3 inputs and valued the notes utilizing an estimated cost of debt from publicly available information on issuances of high yield fixed income securities issued by comparable companies. The Company concluded that a 15% discount rate was appropriate, resulting in an initial fair value for the notes of approximately $970,000. The discount was accreted to interest expense through the Company s IPO and was accreted completely at IPO as the notes plus accrued interest converted to common stock at IPO. The following table presents activity for the convertible promissory notes measured at fair value using significant unobservable Level 3 inputs during the year ended December 31, 2013.

	Fair Value Measurements at Reporting Date Using

	Significant Unobservable Inputs (Level 3)
Balance at December 31, 2012	$
Issuance of convertible promissory notes	970,000
Accretion of debt discount to interest expense	31,439
Conversion to equity at IPO	(1,001,439)
Balance at December 31, 2013	$

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4. Investments

The Company invests its excess cash in money market funds and debt instruments of financial institutions, corporations, government sponsored entities and municipalities. The following tables summarize the Company s marketable securities:

As of December 31, 2013	Maturity (in years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Corporate debt securities	1 or less	$ 47,172,466	$ 11,148	$	$ 47,183,614
Corporate debt securities	1 2	3,254,329	206		3,254,535
Debt securities in government sponsored entities	1 2	1,500,742	143		1,500,885
Municipal bonds	1 or less	255,000			255,000
Total		$ 52,182,537	$ 11,497	$	$ 52,194,034

As of December 31, 2012	Maturity (in years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Corporate debt securities	1 or less	$ 3,728,922	$ 551	$	$ 3,729,473
Municipal bonds	1 or less	260,000			260,000
Total		$ 3,988,922	$ 551	$	$ 3,989,473

5. Property and Equipment

Property and equipment consist of the following:

	Useful Life in Years	December 31, 2013	December 31, 2012
Furniture and fixtures	4	$ 115,417	$ 112,876
Computer equipment and office equipment	4	96,569	95,199
Leasehold improvements	4	3,645	3,645
		215,631	211,720
Less accumulated depreciation and amortization		(192,563)	(182,116)
		$ 23,068	$ 29,604

Depreciation expense related to property and equipment amounted to $10,446, $9,066, $10,951 and $209,712 for the years ended December 31, 2013, 2012 and 2011, and for the period from July 13, 2005 (inception) to December 31, 2013, respectively.

6. Note Payable

In July 2010, the Company entered into a $1,000,000 promissory note payable to Pfizer Inc. (Pfizer). The note bears interest at 7% per annum which is paid quarterly and matures on July 29, 2020. The note payable prohibits the Company from paying cash dividends and is subject to acceleration upon specified events of default as defined in the agreement including the failure to notify Pfizer of certain material adverse events. In July 2013, the note payable to Pfizer was amended to become convertible into shares of the Company s common stock following the completion of the IPO, at the option of the holder, at a price per share equal to the fair market value of the common stock on the date of conversion.

In May 2013, the Company entered into a note and warrant purchase agreement with certain existing investors pursuant to which it sold, in a private placement, an aggregate of $1.0 million of convertible promissory notes (the 2013 Notes), and issued warrants exercisable to purchase 1,124,026 shares of Series B Preferred Stock (the 2013 Warrants). The 2013 Notes accrued interest at a rate of 6% per annum and were due and payable on the

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earlier of (1) any date after November 30, 2013 upon which holders of 75% of the outstanding principal amount of all such 2013 Notes demand repayment, or (2) the occurrence of a change of control of the Company, subject in each case to their earlier conversion in the event the Company completed a qualified initial public offering or private placement of debt and/or equity. The 2013 Notes did not provide for any potential adjustments to the stated conversion rates other than in the event of stock splits, stock dividends and recapitalizations. The conversion of the 2013 Notes in the event of a qualified initial public offering or private placement of equity was deemed to be the predominant settlement mechanism. As this predominant settlement mechanism provided for the settlement of a fixed monetary amount in a variable number of equity instruments, the Company concluded that it was appropriate to recognize the 2013 Notes at fair value. The Company valued the 2013 Notes utilizing an estimated cost of debt from publicly available information on issuances of high yield fixed income securities issued by comparable companies. The Company concluded that a 15% discount rate was appropriate, resulting in an initial fair value for the 2013 Notes of approximately $970,000. Upon completion of the IPO, the 2013 Notes plus accrued interest automatically converted into 91,948 shares of common stock.

The 2013 Warrants were exercisable for an aggregate of 1,124,026 shares of Series B Preferred Stock at an exercise price of $0.90 per share. Upon completion of the IPO, the 2013 Warrants became exercisable for an aggregate of 136,236 shares of common stock at an exercise price of $7.43 per share. The 2013 Warrants will expire on May 30, 2018. The 2013 Warrants were initially accounted for as liabilities with changes in fair value recognized within the consolidated statements of operations and comprehensive loss. The Company determined that the initial value of the 2013 Warrants was $506,000. The 2013 Warrants were valued utilizing a Monte Carlo simulation of various weighted scenarios. Following the IPO, the 2013 Warrants were reclassified into equity at their fair value at the time of the completion of the IPO.

The valuation at the issuance of the 2013 Notes and 2013 Warrants resulted in a deemed distribution in the amount of $474,561 accounted for as a reduction in net income attributable to common stockholders.

In July 2013, the Company entered into a loan and security agreement, (the Credit Facility) with Oxford Finance LLC and Silicon Valley Bank (the Lenders). The Credit Facility provided funding for an aggregate principal amount of up to $15.0 million. The first term loan of the Credit Facility was funded in July 2013 in the amount of $1.0 million. On September 25, 2013, the Company prepaid the outstanding advances under the Credit Facility. Accordingly, the Credit Facility was terminated on September 25, 2013. In connection with the funding of the first term loan under the Credit Facility, the Company issued warrants to the Lenders to purchase up to an aggregate of 111,112 shares of Series B convertible preferred stock at an exercise price of $0.90 per share (Lender Warrants). The Lender Warrants will expire on July 3, 2023. The Lender Warrants were initially accounted for as liabilities with the changes in fair value recognized within the consolidated statements of operations and comprehensive loss.

The Lender Warrants were initially valued at $119,679, and such amount was recognized as additional expense. Upon completion of the IPO, the Lender Warrants became exercisable for an aggregate of 13,468 shares of common stock at an exercise price of $7.43 per share. Following the IPO, the Lender Warrants were reclassified into equity at their fair value at the time of the completion of the IPO.

7. Convertible Preferred Stock and Stockholders Equity (Deficit)

Common Stock

During 2005, the Company sold 727,273 shares of common stock to founders for approximately $6,000. During 2006, the Company sold 181,818 shares of common stock to founders for approximately $45,000, subject to certain

restrictions that have since been released.

In July 2013, the Company implemented a 1-for-8.25 reverse stock split of its outstanding common stock. The accompanying consolidated financial statements give effect to the reverse split for all periods presented.

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In July 2013, the Company completed the IPO of 6,000,000 shares of common stock at an offering price of $11.00 per share. The Company received net proceeds of approximately $58.6 million, after deducting underwriting discounts and commissions and offering-related transaction costs.

Convertible Preferred Stock

Between August 2005 and July 2006, the Company borrowed from certain officers and investors an aggregate principal amount of $1,200,000 under convertible promissory notes. The convertible promissory notes had an annual interest rate of 8% and a conversion premium on principal and accrued interest of 15%. The principal, accrued interest and conversion premium under the convertible promissory notes converted into shares of Series A convertible preferred stock (Series A Preferred Stock) in October 2006, in connection with the initial closing of the Series A Preferred Stock financing.

During 2006, the Company entered into agreements with the founding officers and several investors who collectively purchased 10,160,885 shares of Series A Preferred Stock at $0.75 per share for $5,500,000 in cash, the conversion of the bridge financing noted above, plus related accrued interest and conversion premium of $261,439, and the issuance of preferred stock to employees of approximately $659,224 for services (Initial Closing). Additionally, the Company issued 333,333 shares of the Series A Preferred Stock in satisfaction of its initial license payment to Roche Palo Alto LLC and F. Hoffman-La Roche Ltd. (collectively, Roche).

In May 2007, the Company closed the second round of its Series A Preferred Stock financing, providing the Company with $22,000,000 in gross proceeds from the issuance of an additional 29,333,334 shares of Series A Preferred Stock (Second Closing). Additionally, the Company s Board of Directors determined that the Company had obtained satisfactory completion of certain preclinical studies of its product candidate, which was licensed from Roche, which triggered an additional $3,500,000 payment in cash and $2,000,000, in the form of the issuance of an additional 2,666,666 shares of Series A Preferred Stock to Roche.

The holders of the Series A Preferred Stock were entitled to receive noncumulative dividends at a rate of $0.06 per share per annum. The Series A Preferred Stock dividends were payable when and if declared by the Company s Board of Directors. As of December 31, 2013, the Company s Board of Directors had not declared any dividends. The Series A Preferred Stock dividends were payable in preference and in priority to any dividends on common stock.

Included in the terms of the Series A Preferred Stock agreement were certain rights granted to the holders of the Series A Preferred Stock issued in the Initial Closing which obligated the Company to deliver additional shares of Series A Preferred Stock at a specified price in the future at the potential Second Closing based on the achievement of a milestone or at the option of the holders of the Series A Preferred Stock (the Tranche Right). The Series A Preferred Stock, based on its deemed liquidation terms, was classified outside of stockholder s deficit. Accordingly, the Tranche Right to purchase additional shares was valued and classified as a liability in 2006 and 2007. The carrying value was adjusted at each reporting date for any material changes in its estimated fair value. The estimated fair value was determined using a valuation model which considered the probability of achieving a milestone, if any, the entity s cost of capital, the estimated time period the Tranche Right would be outstanding, consideration received for the instrument with the Tranche Right, the number of shares to be issued to satisfy the Tranche Right, and at what price and any changes in the fair value of the underlying instrument to the Tranche Right. At December 31, 2006, the change in fair value of the Tranche Right was immaterial. In 2007, the change in fair value of the Tranche Right of $530,977 was recorded as other financing expense and the adjusted carrying value of the Tranche Right of $1,827,784 was reclassified to convertible preferred stock on the balance sheet upon the Second Closing in May 2007.

In February 2011, the Company closed the first round of its Series B convertible preferred stock (Series B Preferred Stock) financing, providing the Company with $20,000,000 in gross proceeds from the issuance of 22,222,223 shares of Series B Preferred Stock. Upon the first closing, 5,861,667 shares of Series B Preferred

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Stock were issued upon the conversion of convertible bridge notes and related accrued interest under the terms of the convertible bridge financing agreement. In March 2011, the Company completed an additional closing to a new investor of its Series B Preferred Stock financing, providing the Company with $7,500,000 in gross proceeds from the issuance of an additional 8,333,334 shares of Series B Preferred Stock.

The holders of the Series B Preferred Stock were entitled to receive noncumulative dividends at a rate of $0.072 per share per annum. The Series B Preferred Stock dividends were payable when and if declared by the Company s Board of Directors. As of December 31, 2013, the Company s Board of Directors had not declared any dividends. The Series B Preferred Stock dividends were payable in preference and in priority to any dividends on common stock and Series A Preferred Stock.

The Series B Preferred Stock, based on its deemed liquidation terms, was classified outside of stockholders deficit.

On May 30, 2013, 15,576,789 shares of the Company s convertible preferred stock were converted into 1,557,678 shares of common stock (188,808 shares on a post-reverse split basis) as a result of one preferred stock investor not purchasing a pro rata share of the 2013 Notes. As a result of this transaction, a gain on the extinguishment of preferred stock was recognized as income applicable to common stockholders and an addition to additional paid-in capital in the amount of $11,491,043, which represented the difference between the carrying value of the 15,576,789 shares of convertible preferred stock and the fair value of the 188,808 shares of common stock.

In connection with the IPO in July 2013, all 63,334,653 outstanding shares of convertible preferred stock converted into an aggregate of 7,676,914 shares of common stock.

Warrants

The Company issued warrants to purchase a total of 2,333,320 shares of Series A Preferred Stock in conjunction with a convertible bridge financing in 2010 and issued the 2013 Warrants and Lender Warrants in conjunction with a convertible bridge financing and Credit Facility funding in 2013. The Company initially accounted for the warrants as liabilities because they were exercisable for shares of preferred stock that was classified outside of permanent equity. The convertible preferred stock warrant liability was required to be recorded at fair value at the grant date of the warrants and the carrying value adjusted at each reporting date. The Company revalued the warrants at July 30, 2013 (date of IPO closing) and December 31, 2012 and 2011. The Company recorded the change in the value of the warrants of $3,457,184 for the year ended December 31, 2013, $91,559 for the year ended December 31, 2012, as other financing expense, and $1,665,758 for the year ended December 31, 2011, as other financing income. The Series A warrants converted to 280,675 shares of common stock as a result of the net exercise of such warrants at the IPO. Upon the completion of the IPO, the 2013 Warrants and the Lender Warrants became exercisable for an aggregate of 149,704 shares of common stock at an exercise price of $7.43 per share. Following the IPO, the 2013 Warrants and Lender Warrants were reclassified into equity at their fair value at the time of the completion of the IPO.

Stock Options

The Company adopted an Equity Incentive Plan in 2006 (the 2006 Plan) under which 1,030,303 shares of common stock were reserved for issuance to employees, nonemployee directors and consultants of the Company. The Company adopted an Equity Incentive Award Plan in July 2013 (the 2013 Plan) under which 1,000,000 shares of common stock were reserved for issuance to employees, nonemployee directors and consultants of the Company at December 31, 2013. Shares that remain available, that expire or otherwise terminate without having been exercised in full, and unvested shares that are forfeited to or repurchased by us under the 2006 Plan will roll into the 2013 Plan. The 2013 Plan provides for the grant of incentive stock options, nonstatutory stock options, rights to purchase restricted stock,

stock appreciation rights, dividend equivalents, stock payments and restricted

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stock units to eligible recipients. Recipients of incentive stock options shall be eligible to purchase shares of the Company s common stock at an exercise price equal to no less than the estimated fair market value of such stock on the date of grant. The maximum term of options granted under the 2013 Plan is ten years. The options generally vest 25% on the first anniversary of the original vesting date, with the balance vesting monthly over the remaining three years. As of December 31, 2013, 767,278 options remain available for future grant under the 2013 Plan.

The following table summarizes stock option transactions since the Company s inception:

Weighted- Average Exercise

	Total Options	Weighted-Average Exercise Price
Balance at July 13, 2005 (inception) and December 31, 2005		$
Granted	75,755	0.09
Exercised	(72,725)	0.09
Balance at December 31, 2006	3,030	0.09
Granted	48,482	0.37
Exercised	(30,301)	0.44
Balance at December 31, 2007	21,211	0.23
Granted	124,267	1.24
Cancelled	(6,060)	1.24
Balance at December 31, 2008	139,418	1.09
Granted	29,997	1.24
Balance at December 31, 2009	169,415	1.11
Cancelled	(18,181)	1.24
Balance at December 31, 2010	151,234	1.10
Granted	609,139	0.75
Balance at December 31, 2011	760,373	0.82
Granted	199,597	0.09
Exercised	(194,962)	0.09
Cancelled	(74,785)	0.94
Balance at December 31, 2012	690,223	0.80
Granted	316,935	9.44
Exercised	(174,447)	0.24
Cancelled	(42,121)	7.86
Balance at December 31, 2013	790,590	4.01

Vested at December 31, 2013	528,654	1.02

The weighted-average fair value of options granted for the years ended December 31, 2013, 2012 and 2011, and for the period from July 13, 2005 (inception) to December 31, 2013 were $6.31, $0.08, $0.50 and $1.75, respectively. At December 31, 2013, there were options outstanding to purchase 790,590 shares and 537,290 of these shares were exercisable. The intrinsic value of options outstanding at December 31, 2013 was $2,913,083.

The total intrinsic value of stock options exercised during the years ended December 31, 2013 and 2012 were $1,082,574 and $0, respectively. There were no stock option exercises in 2011.

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Unvested shares from the early exercise of options are subject to repurchase by the Company at the lower of the original issue price or fair value. Options granted under the 2006 Plan and 2013 Plan will vest according to the respective option agreement. There were 174,447 shares exercised during the year ended December 31, 2013 with 233,337 shares subject to repurchase at December 31, 2013.

The Company recorded a related liability totaling $47,909 and $12,480 at December 31, 2013 and December 31, 2012, respectively, which is included in accrued compensation on the consolidated balance sheets.

Common Stock Reserved for Future Issuance

	December 31, 2013	December 31, 2012
Conversion of preferred stock		9,565,021
Convertible preferred stock warrants		282,826
Convertible common stock warrants	149,704	
Stock options issued and outstanding	790,590	690,223
Authorized for future option grants	767,278	11,757
	1,707,572	10,549,827

8. License Agreements

In November 2006, the Company entered into a research, development and commercialization agreement with Roche, in which the Company obtained a sole and exclusive license to develop, make, use and sell a novel, clinical-stage product candidate. The Company intended to develop the product candidate for liver disease. An initial payment of $250,000 was made in November 2006, in the form of the issuance of 333,333 shares of Series A Preferred Stock. In 2007, the Company s Board of Directors determined that the preclinical studies were satisfactorily completed, and the Company was obligated to make another payment consisting of $3,500,000 in cash. In addition, an aggregate of $2,000,000 in payments were due under the agreement in 2011 and 2012 in the form of the issuance of an additional 2,666,666 shares of Series A Preferred Stock. In late 2011, the Company ceased clinical development of this product candidate and in early 2012 the rights to the product candidate reverted to Roche. The Company has no further obligations under the agreement.

9. Income Taxes

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by the federal and state jurisdictions where applicable. There are currently no pending income tax examinations. The Company s tax years for 2005 and forward are subject to examination by the federal and California tax authorities due to the carryforward of unutilized net operating losses and research and development credits.

Pursuant to Internal Revenue Code (IRC) Sections 382 and 383, annual use of the Company s net operating loss and research and development credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. The Company has not completed an IRC Section 382/383 analysis

regarding the limitation of net operating loss and research and development credit carryforwards. The Company does not expect this analysis to be completed within the next 12 months. Due to the existence of the valuation allowance, future changes in the Company s unrecognized tax benefits will not impact the Company s effective tax rate.

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Significant components of the Company s deferred tax assets at December 31, 2013 and 2012, are shown below:

	December 31,	
	2013	2012
Deferred tax assets		
Net operating loss carryovers	$ 17,179,000	$ 20,772,000
Research and development tax credits	1,617,000	1,755,000
Intangibles	1,345,000	1,466,000
Compensation	483,000	101,000
Other	115,000	35,000
Total gross deferred tax assets	20,739,000	24,129,000
Less valuation allowance	(20,739,000)	(24,129,000)
Net deferred tax assets	$	$

A reconciliation of the statutory tax rates and the effective tax rates for the years ended December 31, 2013, 2012 and 2011 is as follows:

	December 31,		
	2013	2012	2011
Statutory rate	34.00%	34.00%	34.00%
State tax, net of federal benefit	5.83%	5.83%	5.83%
Valuation allowance	(7.75)%	(39.50)%	(39.59)%
Gain on distribution of subsidiary	(24.49)%	0.00%	0.00%
Nondeductible interest	(9.08)%	(0.42)%	(3.65)%
Other	1.49%	0.09%	3.41%
Effective tax rate	%	%	%

At December 31, 2013, the Company has federal and state net operating loss carryforwards of approximately $43.2 million and $42.6 million, respectively. The federal and state loss carryforwards begin to expire in 2025 and 2015, respectively, unless previously utilized. The Company also has federal and state research credit carryforwards of approximately $1.5 million and $0.8 million, respectively. The federal research credit carryforwards will begin expiring in 2026 unless previously utilized. The state research credit will carry forward indefinitely. The change in the valuation allowance is a decrease of $3.4 million and an increase of $3.5 million for the years ended December 31, 2013 and 2012. The Company removed the net operating losses and research credits attributable to their subsidiary, Idun. The stock of Idun was distributed to the Company s stockholders in January 2013.

The Company accounts for income taxes in accordance with Accounting Standards Codification 740-10, Accounting for Uncertainty in Income Tax. The impact of an uncertain income tax position is recognized at the largest amount that is more likely than not to be sustained upon audit by the relevant taxing authority. An uncertain tax position will not be recognized if it has less than a 50% likelihood of being sustained.

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The following table summarized the activity related to our unrecognized tax benefits:

	2013	2012	2011
Balance at beginning of year	$	$	$
Additions based on tax positions related to the current year	97,412		
Additions for tax positions of prior years	359,694		
Reductions for tax positions of prior years			
Settlement of tax audits			
Reductions due to lapsed statute of limitations			
Balance at end of year	**$ 457,106**	**$**	**$**

The Company does not expect that the unrecognized tax benefits will change within 12 months of this reporting date. Due to the existence of the valuation allowance, future changes in the Company s unrecognized tax benefits will not impact the Company s effective tax rate. The Company s policy is to recognize interest and penalties related to income tax matters in income tax expense. Interest of $0 has been recognized as of and for the period ended December 31, 2013.

10. Employee Benefits

Effective December 4, 2006, the Company has a defined contribution 401(k) plan for its employees. Employees are eligible to participate in the plan beginning on the first day of employment. Under the terms of the plan, employees may make voluntary contributions as a percent of compensation. Effective January 1, 2007, the Company instituted a safe harbor matching contribution program. Contributions to the matching program totaled $120,750, $107,564, $89,755 and $658,458 for the years ended December 31, 2013, 2012 and 2011, and for the period from July 13, 2005 (inception) to December 31, 2013, respectively.

11. Commitments

The Company leases certain office space under a noncancelable operating lease with terms through June 30, 2013. The rent expense for 2013, 2012, 2011, and the period from July 13, 2005 (inception) to December 31, 2013, totaled $167,998, $152,448, $155,723 and $1,387,953, respectively. Future minimum payments under the aforementioned noncancelable operating lease total $89,766 at December 31, 2013.

In July 2010, the Company entered into a stock purchase agreement with Pfizer, pursuant to which the Company acquired all of the outstanding stock of Idun. Under the agreement, the Company may be required to make payments to Pfizer totaling $18.0 million upon the achievement of specified regulatory milestones.

12. Spin-off of Idun Pharmaceuticals, Inc.

In January 2013, the Company spun off its subsidiary Idun to the Company s stockholders. Prior to the spin-off, rights relating to emricasan were distributed to the Company by Idun pursuant to a distribution agreement. The spin-off was conducted as a dividend of all of the outstanding capital stock of Idun to the Company s stockholders. As a result, the Company no longer held any capital stock of Idun.

In connection with the spin-off, the Company contributed $500,000 to Idun to provide for Idun s initial working capital requirements. The assets remaining in Idun at the time of the spin-off consisted of cash, intellectual property rights and license and collaboration agreements unrelated to emricasan. Other than the cash of $500,000, none of the assets held by Idun had any historical carrying value at the time of the spin-off. As a result, the Company recognized a reduction in equity as a result of the spin-off of $500,000, representing the carrying value of Idun in the Company s consolidated financial statements at the time of the spin-off.

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Conatus Pharmaceuticals Inc.

(a development stage company)

Notes to Consolidated Financial Statements

13. Quarterly Financial Data (unaudited)

The following table summarizes the unaudited quarterly financial data for the last two fiscal years.

	2013				
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
Operating expenses:					
Research and development	$ 967,778	$ 1,117,096	$ 1,885,567	$ 2,976,998	$ 6,947,439
General and administrative	748,796	670,430	1,107,668	2,123,913	4,650,807
Total operating expenses	1,716,574	1,787,526	2,993,235	5,100,911	11,598,246
Other (expense) income:					
Interest income	132		7,788	14,224	22,144
Interest expense	(17,500)	(196,244)	(203,917)	(44,909)	(462,570)
Other (expense) income	(15,677)	726	7,911	5,970	(1,070)
Other financing expense income	(547,164)	(2,890,258)	(139,328)		(3,576,750)
Total other (expense) income	(580,209)	(3,085,776)	(327,546)	(24,715)	(4,018,246)
Net loss	(2,296,783)	(4,873,302)	(3,320,781)	(5,125,626)	(15,616,492)
Gain on extinguishment of convertible preferred stock		11,491,043			11,491,043
Deemed distribution from promissory note issuance		(474,561)			(474,561)
Net income applicable to participating securities		(5,919,404)			
Net (loss) income applicable to common stockholders	$ (2,296,783)	$ 223,776	$ (3,320,781)	$ (5,125,626)	$ (4,600,010)
Net (loss) income per share applicable to common stockholders:					
Basic	$ (2.17)	$ 0.20	$ (0.28)	$ (0.33)	
Diluted	$ (2.17)	$ 0.16	$ (0.28)	$ (0.33)	
Weighted average shares outstanding used in computing					

net (loss) income per share applicable to common stockholders:				
Basic	1,060,533	1,138,695	11,664,328	15,352,684
Diluted	1,060,533	1,439,211	11,664,328	15,352,684

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	2012				
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
Operating expenses:					
Research and development	$ 1,128,995	$ 1,119,145	$ 1,774,322	$ 1,505,644	$ 5,528,106
General and administrative	782,795	649,430	737,460	916,794	3,086,479
Total operating expenses	1,911,790	1,768,575	2,511,782	2,422,438	8,614,585
Other income (expense):					
Interest income	8,330	8,292	5,705	3,220	25,547
Interest expense	(17,500)	(17,500)	(17,500)	(17,500)	(70,000)
Other income (expense)	9,254	(4,939)	(4,354)	1,397	1,358
Other financing income (expense)	9,100	(44,193)	(56,700)	234	(91,559)
Total other income (expense)	9,184	(58,340)	(72,849)	(12,649)	(134,654)
Net loss applicable to common stockholders	$ (1,902,606)	$ (1,826,915)	$ (2,584,631)	$ (2,435,087)	$ (8,749,239)
Net loss per share applicable to common stockholders, basic and diluted	$ (1.88)	$ (1.81)	$ (2.55)	$ (2.36)	
Weighted average shares outstanding used in computing net loss per share applicable to common stockholders. basic and diluted	1,012,117	1,012,117	1,012,117	1,031,350	

14. Subsequent Events

On February 28, 2014, the Company executed an agreement with The Point Office Partners, LLC for the lease of approximately 9,954 square feet of office space located in San Diego, California. This operating lease has an initial term of 65 months with a renewal option for an additional five years. The Company will relocate its offices from its present location, which is also located in San Diego, California, to the new facility in June 2014. The Company has outgrown its present office space, and the new facility will accommodate projected growth over the lease term. Management considers the costs associated with the new facility, including rent, maintenance and moving costs, to be reasonable and believes the overall increase in costs will have a minimal impact on operating expenses over the lease term.

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SIGNATURES

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

CONATUS PHARMACEUTICALS INC.

/s/ Steven J. Mento, Ph.D.
Steven J. Mento, Ph.D.

President and Chief Executive Officer

Date: March 28, 2014

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Steven J. Mento, Ph.D. **Steven J. Mento, Ph.D.**	President, Chief Executive Officer and Director (Principal Executive Officer)	March 28, 2014
/s/ Charles J. Cashion **Charles J. Cashion**	Senior Vice President, Finance, Chief Financial Officer and Secretary (Principal Financial Officer and Principal Accounting Officer)	March 28, 2014
/s/ David F. Hale **David F. Hale**	Chairman of the Board	March 28, 2014
/s/ Daniel L. Kisner, M.D. **Daniel L. Kisner, M.D.**	Director	March 28, 2014
/s/ Preston S. Klassen, M.D., M.H.S. **Preston S. Klassen, M.D., M.H.S.**	Director	March 28, 2014
/s/ Paul H. Klingenstein	Director	March 28, 2014

Paul H. Klingenstein		
/s/ Louis Lacasse	Director	March 28, 2014
Louis Lacasse		
/s/ Shahzad Malik, M.D.	Director	March 28, 2014
Shahzad Malik, M.D.		
/s/ James Scopa	Director	March 28, 2014
James Scopa		
/s/ Harold Van Wart, Ph.D.	Director	March 28, 2014
Harold Van Wart, Ph.D.		

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EXHIBIT INDEX

Exhibit Number	Description
2.1(1)	Distribution Agreement, dated January 10, 2013, by and between Idun Pharmaceuticals, Inc. and the Registrant
3.1(2)	Amended and Restated Certificate of Incorporation
3.2(2)	Amended and Restated Bylaws
4.1(3)	Specimen Common Stock Certificate
4.2(1)	First Amended and Restated Investor Rights Agreement, dated February 9, 2011
4.3(1)	Form of Warrant issued to investors in the Registrant s 2013 bridge financing
4.4(3)	Form of Warrant issued to lenders under the Loan and Security Agreement, dated as of July 3, 2013, by and among the Registrant, Oxford Finance LLC, Silicon Valley Bank and the other lenders party thereto
10.1#(4)	Form of Indemnity Agreement for Directors and Officers
10.2#(1)	2006 Equity Incentive Award Plan, as amended, and form of option agreement thereunder
10.3#(3)	2013 Incentive Award Plan and form of option agreement thereunder
10.4#(3)	2013 Employee Stock Purchase Plan
10.5#(3)	Non-Employee Director Compensation Program
10.6#(3)	Employee Incentive Compensation Plan
10.7#	Amended and Restated Annual Incentive Plan, dated January 1, 2014
10.8#(1)	Employment Agreement, dated December 17, 2008, by and between Steven J. Mento, Ph.D. and the Registrant
10.9#(1)	Employment Agreement, dated December 17, 2008, by and between Alfred P. Spada, Ph.D. and the Registrant
10.10#(1)	Employment Agreement, dated December 17, 2008, by and between Gary C. Burgess, M.B., Ch.B. M.Med and the Registrant
10.11#(3)	Amendment to Employment Agreement, dated July 2, 2013, by and between Steven J. Mento, Ph.D. and the Registrant
10.12#(3)	Amendment to Employment Agreement, dated July 2, 2013, by and between Alfred P. Spada, Ph.D. and the Registrant
10.13#(3)	Amendment to Employment Agreement, dated July 2, 2013, by and between Gary C. Burgess, M.B., Ch.B. M.Med and the Registrant
10.14(5)	Stock Purchase Agreement, dated July 29, 2010, by and between Pfizer Inc. and the Registrant
10.15(1)	Promissory Note, dated July 29, 2010, issued by the Registrant to Pfizer Inc.

10.16[3]	Amendment to Promissory Note, dated July 3, 2013, by and between the Registrant and Pfizer Inc.
10.17[3]	Loan and Security Agreement, dated as of July 3, 2013, by and among the Registrant, Oxford Finance LLC, Silicon Valley Bank and the other lenders party thereto
10.18[1]	Sublicense Agreement, dated March 1, 2013, by and between the Registrant and Idun Pharmaceuticals, Inc.
10.19[1]	Office Lease Agreement, dated April 7, 2006, by and between EOP-Plaza at La Jolla, L.L.C. and the Registrant
10.20[1]	First Amendment to Office Lease Agreement, dated November 30, 2009, by and between EOP-Plaza at La Jolla, L.L.C. and the Registrant
10.21[1]	Second Amendment to Office Lease Agreement, dated May 2, 2011, by and between Pacifica Tower LLC, sucessor in interest to EOP-Plaza at La Jolla, L.L.C., and the Registrant

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Exhibit Number	Description
10.22[(1)]	Third Amendment to Office Lease Agreement, dated March 28, 2012, by and between Pacifica Tower LLC, sucessor in interest to EOP-Plaza at La Jolla, L.L.C., and the Registrant
10.23[(3)]	Fourth Amendment to Office Lease Agreement, dated June 25, 2013, by and between Pacifica Tower LLC, successor in interest to EOP-Plaza at La Jolla, L.L.C., and the Registrant
10.24	Office Lease Agreement, dated February 28, 2014, by and between the Registrant and The Point Office Partners, LLC
23.1	Consent of Ernst & Young LLP, independent registered public accounting firm
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document

(1) Incorporated by reference to the Registrant s Registration Statement on Form S-1 (Registration No. 333- 189305), filed with the SEC on June 14, 2013.
(2) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed with the SEC on August 1, 2013.
(3) Incorporated by reference to Amendment No. 2 to the Registrant s Registration Statement on Form S-1 (Registration No. 333-189305), filed with the SEC on July 8, 2013.
(4) Incorporated by reference to Amendment No. 1 to the Registrant s Registration Statement on Form S-1 (Registration No. 333-189305), filed with the SEC on July 1, 2013.
(5) Incorporated by reference to Amendment No. 3 to the Registrant s Registration Statement on Form S-1 (Registration No. 333-189305), filed with the SEC on July 23, 2013.
Confidential treatment has been granted for portions of this exhibit. These portions have been omitted from the exhibit and filed separately with the SEC.
# Indicates management contract or compensatory plan.
* These certifications are being furnished solely to accompany this annual report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.
** Users of this data are advised that pursuant to Rule 406T of Regulation S-T, this XBRL information is being furnished and not filed herewith for purposes of Section 18 of the Securities Exchange Act of 1934, as amended,

and Sections 11 or 12 of the Securities Act of 1933, as amended, and is not to be incorporated by reference into any filing, or part of any registration statement or prospectus, of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.