UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2016

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 001-36183

Eiger BioPharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**33-0971591**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
350 Cambridge Avenue, Suite 350, Palo Alto, CA	**94306**
(Address of principal executive offices)	**(Zip Code)**

(650) 272 6138

(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 $0.001 per share	**The NASDAQ Global Market**

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of 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	☐ (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 Act). Yes ☐ No ☒

The aggregate market value of voting and non-voting common stock held by non-affiliates of the registrant as of June 30, 2016 totaled approximately $72,484,515 based on the closing price of $19.82 as reported by the NASDAQ Global Market.

The number of outstanding shares of the registrant's common stock, par value $0.0001 per share, as of March 16, 2017 was 8,361,196.

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PART I

Forward-Looking Statements

This Annual Report on Form 10-K, including the sections entitled “Business,” “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” may contain “forward-looking statements.” We may, in some cases, use words such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes, to identify these forward-looking statements. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. Forward-looking statements in this Annual Report include, but are not limited to, statements about:

- the success, cost and timing of our product development activities and clinical trials;
- our ability and the time required to obtain and maintain regulatory approval for lonafarnib, lambda, exendin 9-39 and ubenimex, and any of our future product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- our ability to obtain funding for our operations, including funding necessary to complete all clinical trials that may potentially be required to file a new drug application, or NDA, and a Marketing Authorization Application, or MAA, for our product candidates;
- the commercialization of our product candidates, if approved;
- our plans to research, develop and commercialize our product candidates;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- the rate and degree of market acceptance of our product candidates;
- regulatory developments in the United States and foreign countries;
- the performance of our third-party suppliers and manufacturers;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- our expectations regarding the period during which we qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act; and
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates.

These forward-looking statements reflect our management’s beliefs and views with respect to future events and are based on estimates and assumptions as of the filing date of this Annual Report and are subject to risks and uncertainties. We discuss many of these risks in greater detail under “Risk Factors.” Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

ITEM 1. Business

Merger of Celladon Corporation and Eiger BioPharmaceuticals, Inc.

On March 22, 2016, Celladon Corporation, or Celladon, and privately-held Eiger BioPharmaceuticals, Inc., or Private Eiger, completed a business combination in accordance with the terms of the Agreement and Plan of Merger and Reorganization, or the Merger Agreement, dated as of November 18, 2015, by and among Celladon, Celladon Merger Sub, Inc., a wholly-owned subsidiary of Celladon, or Merger Sub, and Private Eiger, pursuant to which Merger Sub merged with and into Private Eiger, with Private Eiger surviving as a wholly-owned subsidiary of Celladon. This transaction is referred to herein as "the Merger." Immediately following the Merger, Celladon changed its name to "Eiger BioPharmaceuticals, Inc." In connection with the closing of the Merger, our common stock began trading on The NASDAQ Global Market under the ticker symbol "EIGR" on March 23, 2016.

Overview

We are a clinical stage biopharmaceutical company focused on bringing to market novel product candidates for the treatment of orphan diseases. Since our founding in 2008, we have worked with investigators at Stanford University and evaluated a number of potential development candidates from pharmaceutical companies to comprise a pipeline of novel product candidates. Our resulting pipeline includes five Phase 2 development programs addressing four distinct orphan diseases. The programs have several aspects in common: the disease targets represent conditions of high medical need which are inadequately treated by current standard of care; the therapeutic approaches are supported by an understanding of disease biology and mechanism as elucidated by our academic research relationships; prior clinical experience with the product candidates guides an understanding of safety; and the development paths leverage the experience and capabilities of our experienced, commercially focused management team. The pipeline includes lonafarnib for Hepatitis Delta Virus, or HDV, PEG-interferon lambda-1a (lambda) for HDV, exendin 9-39 for Post-Bariatric Hypoglycemia, or PBH and ubenimex for Pulmonary Arterial Hypertension, or PAH and lymphedema. We plan to deliver data from all ongoing Phase 2 clinical trials over the course of the next eighteen months.

Our current project timelines, planned development and regulatory pathways are illustrated below. As discussed above, prior clinical experience by our licensors with the product candidates has supported and guided our understanding of safety in advancing these products in our clinical development programs. Specifically, we in-licensed lonafarnib from Merck Sharp & Dohme Corp, or Merck, in 2010; licensed ubenimex from Nippon Kayaku Co., Ltd., or Nippon Kayaku, in 2015; and licensed lambda from Bristol-Myers Squibb, or BMS, in April 2016. We have relied upon Merck's, Nippon Kayaku's and BMS's prior Phase 1/2/3 clinical data, manufacturing and experience with these three molecules to proceed directly into Phase 2 clinical trials following authorization by the U.S. Food and Drug Administration.

Pipeline Timeline

Note: All dates represent our current expectations. Actual timing may vary.

Our product candidate pipeline includes five Phase 2 programs:

1. Lonafarnib (LNF)

Lonafarnib, or LNF, is an orally bioavailable, small molecule in Phase 2 clinical trials for HDV infection and is our most advanced program. HDV is the most severe form of viral hepatitis for which there is currently no approved therapy. Chronic HDV infection can lead to a rapid progression to liver cirrhosis, a greater likelihood of developing liver cancer, and has the highest fatality rate of all the chronic hepatitis infections.

We in-licensed LNF from Merck in 2010. LNF blocks the production of HDV virus particles by inhibiting a key step, called prenylation, in the virus life cycle. To date, over 100 HDV infected patients have been dosed with LNF across international Phase 2 clinical trials. LNF has demonstrated dose-related activity in reducing HDV viral load both as a monotherapy and in combination with other agents. LNF boosted with ritonavir, or RTV, has demonstrated a mean viral load reduction in HDV-RNA of 1.15 logs, with some patients achieving HDV-RNA PCR-negativity in twenty-four weeks. LNF boosted with RTV and combined with pegylated interferon alfa, or PEG-IFN-alfa, has demonstrated a mean viral load reduction in HDV-RNA of 5.57 logs, with some patients achieving HDV-RNA PCR-negativity in twenty-four weeks. Multiple Phase 2 studies of LNF are ongoing with endpoints of clearance of HDV virus (sustained virologic response, or SVR). HDV-RNA PCR-negativity is defined as 0 IU/mL. The most common adverse events experienced with LNF to date are gastrointestinal-related and include anorexia, nausea, vomiting, diarrhea and weight loss.

LNF for the treatment of HDV infection has been granted orphan drug designation by the U.S. Food and Drug Administration, or the FDA, and European Medicines Agency, or EMA. The potential market for HDV therapies in the United States and Western Europe is growing due to increased migration from regions where the disease is endemic, primarily from Eastern Europe, the Middle East and Asia.

2. Lambda

Lambda is our second Phase 2 program treating HDV. Lambda is a well-characterized, late-stage, first in class, type III interferon, or IFN, that stimulates immune responses that are critical for the development of host protection during viral infections. Lambda targets type III IFN receptors which are distinct from the type I IFN, receptors targeted by PEG, or pegylated, IFN-alfa. These type III receptors are highly expressed on hepatocytes with limited expression on hematopoietic and central nervous system cells, which has been demonstrated to reduce the off-target effects associated with other IFNs and improve the tolerability of lambda. Although lambda does not use the IFN-alfa receptor, signaling through either the IFN-lambda or IFN-alfa receptor complexes results in the activation of the same Jak-STAT signal transduction cascade.

We licensed worldwide rights to lambda from BMS in April 2016. Lambda has been administered in clinical trials involving over 3,000 patients infected with the Hepatitis B Virus, or HBV, or Hepatitis C Virus, or HCV. Lambda has not been approved for any indication. We plan to evaluate lambda as both a monotherapy and in a combination therapy with lonafarnib. Currently, we are conducting a Phase 2 monotherapy study using lambda to treat HDV and are recruiting and dosing at four international sites. We currently plan to file a US IND for lambda in HDV in April 2017.

3. Exendin 9-39

Exendin 9-39 is the third Phase 2 program and we are developing this candidate as a treatment for PBH. PBH is a debilitating and potentially life-threatening condition for which there is currently no approved therapy. This disorder occurs often in a subset of bariatric surgeries called Roux-en-Y gastric bypass, or RYGB, where affected patients experience frequent symptomatic hypoglycemia, with blood glucose concentrations often low enough to cause seizures, altered mental status, loss of consciousness and even death. Gastric bypass procedures are widely performed and are increasing in frequency for medically complicated obesity.

To date, research at Stanford has generated results demonstrating clinical proof of concept in 29 patients suffering from PBH indicating that exendin 9-39 can potentially prevent post-prandial hypoglycemia in affected patients. Exendin 9-39 is a glucagon-like peptide-1, or GLP-1, receptor antagonist that competes with endogenous GLP-1 and has the potential to prevent the excessive post-prandial insulin release that characterizes this disorder. These data were generated using both intravenous and subcutaneous, or SC, formulation delivery developed by Stanford. Pharmacokinetics from this Phase 2 SC study indicate that the SC formulation could enable once or twice a day pre-prandial dosing. We developed a proprietary SC formulation and plan to initiate a Phase 1 dose-ranging pharmacokinetics trial in healthy humans and a Phase 2 28-day trial in affected patients with our exendin 9-39 SC formulation in 2017.

In December 2016, Eiger filed an Investigational New Drug application for exendin 9-39 in the United States. Exendin 9-39 for the treatment of hyperinsulinemic hypoglycemia has been granted orphan drug designation by the FDA and EMA.

4. Ubenimex PAH

Our fourth Phase 2 program is ubenimex for the treatment of Pulmonary Arterial Hypertension or PAH. PAH is a life-threatening disease characterized by increased pulmonary vascular resistance, heart failure and premature death.

Ubenimex is a well-characterized, oral, small-molecule inhibitor of leukotriene A4 hydrolase, or LTA4H, the enzyme responsible for converting the inflammatory mediator leukotriene A4, or LTA4, to leukotriene B4, or LTB4. Results of a preclinical study published in Science Translational Medicine (Tian, W. et al. “Blocking Macrophage Leukotriene B4 Prevents Endothelial Injury and Reverses Pulmonary Hypertension,” Sci Transl Med, 2013; 5:1) by Stanford researchers have demonstrated that both LTB4 and LTA4H are elevated in animal models of PAH and human PAH disease. In that study, elevated LTB4 caused inflammation resulting in arteriole occlusion and hypertension in animal models of PAH. Targeted pharmacologic inhibition of LTB4, including ubenimex, reversed PAH disease in treated rat animal models; obstructed arterioles opened, cardiac function improved, and the animals survived. Based on the findings in these models that pathological inflammation may be important in the etiology of PAH, we believe that ubenimex is an attractive candidate for clinical development. Ubenimex was granted orphan

drug designation by the FDA and EMA. In addition, we were granted U.S. patent allowances for claims in PAH in September 2015. We are currently conducting a Phase 2 clinical trial of ubenimex in patients with PAH, referred to herein as "the LIBERTY Study," and expect recruiting to be completed in the first half of 2017. We anticipate the completion of dosing in the LIBERTY Study by end of 2017 with data in early 2018.

Ubenimex was licensed from Nippon Kayaku, and we have exclusive rights in the United States, Europe and certain other countries to develop ubenimex for PAH as well as other inflammatory diseases involving LTB4. Ubenimex has been marketed in Japan and other countries outside of our licensed territories by Nippon Kayaku for over 25 years for a different indication.

5. Ubenimex lymphedema

Our fifth Phase 2 program involves clinical development of ubenimex in lymphedema, which is a state of vascular functional insufficiency in which decreased clearance of interstitial fluid through the lymphatic vasculature leads to edema formation and to progressive, debilitating architectural alterations in skin and supporting tissues. There is no approved pharmacologic therapy. The current standard of therapy involves compression garments.

Researchers at Stanford have demonstrated for the first time that LTB4 is elevated in both animal models of lymphedema as well as human lymphedema and that elevated LTB4 is associated with tissue inflammation and impaired lymphatic function. In that research, applying inhibitors of LTB4 promoted physiologic lymphatic repair and reversed lymphedema in treated animals. We are seeking orphan drug designation for ubenimex in lymphedema. We are currently conducting a Phase 2 clinical trial (ULTRA Study) treating subjects with lyphedema with ubenimex. We intend to complete enrollment of the ULTRA Study in the fourth quarter of 2017 and expect results from this Phase 2 clinical trial in the first half of 2018.

We believe that our approach to clinical development enables achievement of early clinical signals of efficacy and safety in our Phase 2 programs and potentially reduces clinical risks and costs inherent in the drug discovery and development process. We have a highly experienced management team whose members have, in the course of their prior employment, participated in bringing more than 20 product candidates through regulatory approval and into commercialization. We plan to leverage our management team's breadth and depth of experience in clinical and regulatory drug development as well as market development and commercialization to identify potentially promising product candidates to address unmet medical needs.

Our current product candidate pipeline has been obtained by in-licensing from pharmaceutical companies. With our focus on orphan diseases, our strategy is to acquire and retain some or all commercialization rights to our products in significant territories to diversify risk, identify a rapid regulatory pathway to approval and minimize the development investment in order to maximize long-term value for our stockholders. Over time, depending upon the data and potential market opportunity, we expect to establish a commercial organization, which we believe can be targeted and cost effective for selected, promising orphan disease designated programs. We plan to balance these interests with opportunities to out-license assets from our portfolio enhance stockholder value through partnerships and other strategic relationships.

Business Model and Management Team

We plan to continue evaluating in-licensing opportunities in order to enhance our pipeline and leverage our business development, clinical development, regulatory and commercial expertise. We believe our management team has the capability and experience to continue to execute this model. Our management team has worked in other private and public biotechnology companies such as Prestwick Pharmaceuticals, New River Pharmaceuticals, Clinical Data Inc., CoTherix and InterMune, each of which was acquired by a larger pharmaceutical industry company. Our management also has previous work experience, in some cases working together, at pharmaceutical companies, including The Upjohn Company, Glaxo, Glaxo Wellcome, Glaxo Smith Kline, Arena Pharmaceuticals, Alza (Johnson and Johnson), Halozyme, Clinical Data Inc., New River Pharmaceuticals, Dynavax, Covance, Genentech and Gilead Sciences.

Our Strategy

Our mission is to identify, develop, and, directly or through collaborations, bring to market novel products that receive orphan drug designation for the treatment of rare diseases or conditions. We currently have a diverse portfolio of well-characterized product candidates with the potential to address diseases for which the unmet medical need is high, the biology for treatment is believed to be understood, and for which an effective therapy is not available. Our goal is to be a leader in the development and commercialization of novel therapeutics for serious unmet medical needs in orphan diseases. Our focus to achieve this goal will be to utilize our experience and capabilities to:

- Advance our existing product candidates through late-stage clinical trials, generating meaningful clinical results;
- Work with U.S. and international regulatory authorities for expeditious, efficient development pathways toward registration;
- Prepare for commercialization of each program;
- Use our industry relationships and experience to source, evaluate and in-license well-characterized product candidates to continue pipeline development; and
- Identify potential commercial or distribution partners for our products in relevant territories.

Our Product Candidates

Lonafarnib in HDV

Lonafarnib (LNF) is a small molecule that we in-licensed from Merck in 2010 that we are advancing for the treatment of HDV infection. LNF is a well-characterized, orally active inhibitor of farnesyl transferase, an enzyme involved in modification of proteins through a process called prenylation. HDV uses this prenylation process inside host liver cells to complete a key step in its life cycle. LNF inhibits the prenylation step of HDV replication inside liver cells and blocks the virus life cycle at the stage of assembly. Since prenylation is carried out by a host enzyme, there is a higher barrier to develop viral resistance mutations to LNF therapy. We have generated clinical results in over 100 HDV-infected patients in Phase 2 trials, across international study sites, demonstrating rapid decreases in HDV viral loads and no resistance. We intend to initiate additional Phase 2 trials of longer duration using LNF in combination with RTV and possibly other antiviral therapies with a goal of addressing chronic HDV infection.

Lambda in HDV

Lambda is a well-characterized, late-stage, first in class, type III interferon (IFN) that we in-licensed from BMS in April 2016 for the treatment of HDV. Lambda stimulates immune responses that are critical for the development of host protection during viral infections. Lambda targets type III IFN receptors which are distinct from the type I IFN receptors targeted by IFN-alfa. These type III receptors are highly expressed on hepatocytes with limited expression on hematopoietic and central nervous system cells, which in BMS's clinical trials has demonstrated to reduce the off-target effects associated with other IFNs and improve the tolerability of lambda. Although lambda does not use the IFN-alfa receptor, signaling through either the lambda or IFN-alfa receptor complexes results in the activation of the same Jak-STAT signal transduction cascade. Lambda has not been approved for any indication. We plan to evaluate lambda as both a monotherapy and in a combination therapy with lonafarnib. Currently, we are conducting a Phase 2 monotherapy study using lambda to treat HDV and are recruiting patients and dosing at four international sites.

Hepatitis Delta Virus Overview

About Hepatitis Delta Virus

Hepatitis delta infection is caused by HDV, a small circular ribonucleic acid, or RNA, that expresses only one protein, the hepatitis delta antigen, or HDAg. There are two forms of HDAg; small and large. Together, these two forms of HDAg and the single-stranded RNA genome are surrounded by a lipid envelope, which is embedded with Hepatitis B Virus, or HBV surface antigen, or HBsAg, proteins. HDV does not encode its own envelope proteins

and must acquire them from HBV during the final steps of replication. Hence, natural HDV infections always occur in the presence of a co-existing HBV infection. HBsAg is the only element of HBV relied upon by HDV. HDV replication can occur independently of HBV replication.

HDV is the most severe form of viral hepatitis. HDV can be acquired either by co-infection (a simultaneous co-infection with HDV and HBV) or by super-infection (HDV infection of someone already harboring a chronic HBV infection). Both co-infection and super-infection with HDV result in more severe complications compared to infection with HBV alone. These complications include a greater likelihood of experiencing liver failure in acute infections and a rapid progression to liver cirrhosis, with an increased chance of developing liver cancer in chronic infections. HDV has the highest fatality rate of all the hepatitis infections at up to 20%. Although HDV/HBV simultaneous co-infection in adults usually resolves completely, in some cases it can become fulminant hepatitis, which carries a very high mortality rate. In the case of super-infections, the predominant form of HDV, HDV super-infection leads to a more severe form of disease than chronic HBV mono-infection. In a study published in 1987 in the Journal of Infectious Diseases (Fattovich, G. et al. “Influence of Hepatitis Delta Virus Infection on Progression to Cirrhosis in Chronic Hepatitis Type B,” J Infect Dis, 1987; 155:931), histological liver deterioration was observed in 77% of HBV patients co-infected with HDV over a 15-year follow-up period, versus 30% of patients infected with HBV alone ($p<0.01$). In a 2013 study of chronic HBV patients published in the Journal of Gastroenterology and Hepatology (Gish, R. et al. “Coinfection with hepatitis B and D: epidemiology, prevalence and disease in patients in Northern California,” J Gastroenterol Hepatol, 2013; 28(9):1521), cirrhosis was present in 73% of HBV patients co-infected with HDV, compared to only 22% of those infected with HBV alone. Patients co-infected with HDV are more than twice-as-likely to develop liver-related complications, cirrhosis, or require liver transplants than matched patients infected with HBV alone.

HDV is generally spread through exchange of body fluids either sexually or through contact with infected blood. Globally, it is estimated that between 4.3% and 5.7% of the 240 million worldwide chronic HBV population, or 15 to 20 million people, are infected with HDV. The prevalence of HDV in patients infected with chronic HBV is even higher in certain regions, including certain parts of Mongolia, China, Russia, Central Asia, Pakistan, Turkey, Africa and South America, with an HDV prevalence as high as 60% being reported in HBV-infected patients in Mongolia and Pakistan. The prevalence of HDV has recently begun to increase in Western Europe and the United States due to migration from countries with high infection rates.

The Role of HDV Screening in Identifying Patients Who May Benefit From LNF and/or Lambda

There are diagnostic tests in use today in clinical laboratories to detect anti-HDV antibodies in serum. These tests are currently able to detect acute HDV infections after four weeks, but they are poor tests for active HDV infections. Active HDV infections are best detected by reverse transcriptase-polymerase chain reaction, or RT-PCR, assays for genomic RNA. These assays yield a quantitative assessment of the number of viral particles, or viral load, in serum. A commercial assay for quantitative HDV RNA is currently available in Europe. A commercial assay for quantitative HDV RNA was made available in the United States in October 2016.

Prior to the availability of a commercial HDV RNA quantitative assay in the United States, we had developed an HDV RNA quantitative assay that has been calibrated using the World Health Organization HDV standard provided by the Paul Erhlich Institute in Germany. We have used this assay to quantitate HDV RNA in some of our Phase 2 trials.

Our initial discussions with payers have indicated that they would be willing to reimburse healthcare providers for HDV RNA quantitative assays that are carried out following a positive HBsAg test for HBV. We have recently transferred our HDV RNA quantitative assay into a commercial laboratory in the United States. This assay is now commercially available and is the first HDV RNA quantitative assay in the United States. A commercially available assay will increase the number of assays performed and increase the number of identified patients who can potentially benefit from an HDV therapy such as LNF.

Current Therapy for HDV

Currently, there is no FDA approved therapy for hepatitis delta infection. The American Association for the Study of Liver Diseases, or the AASLD, guidelines suggest treatment of chronic hepatitis delta infections with IFN-alfa. In clinical trials of IFN-alfa or PEG-IFN-alfa, between 25% and 33% of HDV infected patients were able to clear their infections after a minimum of 48 weeks of therapy, with some requiring two years of therapy. However, long-term therapy with IFN-alfa is known to be associated with numerous adverse events and tolerability is a significant problem for some of these patients. HBV nucleoside analogs that inhibit HBV genome replication are ineffective against HDV since they are ineffective in suppressing the expression HBsAg. Other antiviral therapies have been tested including our ongoing Phase 2 study using lambda to treat HDV, but none have yet shown to be effective against HDV infection.

HDV Replication and Prenylation

After HDV enters a target cell hepatocyte, the genome is translocated to the nucleus where genome replication occurs and the two forms of HDAg small delta antigen, or SHDAg, and large delta antigen, or LHDAg, are produced. The newly formed HDV genome and the small and large delta antigen must acquire a lipid envelope from HBV to complete the assembly process. An important interaction between HDV and HBV proteins has been shown to depend on the presence of the last four amino acids of the large delta antigen, comprising a CXXX box motif, where C represents cysteine and X denotes any other amino acid. This amino acid sequence is required for LHDAg to be prenylated by a host enzyme which covalently attaches a 15-carbon prenyl lipid (farnesyl-moiety) to the cysteine of the CXXX box. Prenylation of the large delta antigen renders it more lipophilic, promotes its association with HBsAg and is essential for initiating the HDV particle formation process. Our approach involves targeting this host process called prenylation, or protein farnesylation, which has been shown to be essential for the last steps in HDV replication, the assembly and release of new virus progeny.

In the 1980s farnesyltransferase inhibitors were developed by multiple pharmaceutical companies for oncology indications. Addition of a farnesyl or prenyl lipid group to the Ras protein, or Ras, a well-known and important regulator of cellular proliferation, allows for membrane association. Once membrane bound, Ras may then be activated. The importance of activated Ras in tumor development was demonstrated by sequence analyses of tumors from patients where up to 30% have mutations involving Ras. Several prenylation inhibitors were developed in oncology and taken into the clinic and in some cases through late-stage clinical development. However, these programs did not lead to approvals, due to a lack of compelling efficacy. The class-related, dose-limiting toxicity has been gastrointestinal side effects including nausea, vomiting, diarrhea and weight loss.

Published studies conducted by Stanford researchers demonstrated that farnesyltransferase inhibitors block HDV viral production both in cellular experiments and in HDV transgenic mice. Targeting prenylation or farnesyl transferase, a host target, significantly reduces the likelihood of HDV developing resistance to escape effects of antiviral therapy. Viruses mutate quickly and there is a higher rate of mutations in viral replication compared to mammalian cell division. However, no matter how much HDV may mutate, these changes are unlikely to alter the host process of prenylation which HDV requires to complete packaging. Thus, targeting a host prenylation process provides what we believe to be a higher barrier to resistance. Identification of clinic-ready farnesylation inhibitors has allowed us to move rapidly into proof-of-concept studies in humans.

Our Solution: LNF for HDV

LNF is a well-characterized, orally active inhibitor of farnesyl transferase. LNF inhibits the prenylation step of HDV replication inside liver cells and blocks the ability of the virus to multiply. Since prenylation is a host process, not under control of HDV, and LNF inhibits prenylation, we believe that there is also a potentially higher barrier to resistance with LNF therapy. LNF for the treatment of HDV infection has been granted orphan drug designation in Europe and the United States, and LNF in combination with RTV has been granted Fast Track designation from FDA for the treatment of chronic HDV infections. We have completed three Phase 2 clinical trials including Proof of Concept (NIH), LOWR HDV – 3 (NIH) and LOWR HDV – 4 (Hannover, Germany), and are in the final stages of completing a Phase 2 clinical trial LOWR HDV – 1 and LOWR HDV - 2 study (Ankara, Turkey). The LOWR HDV – 1 and LOWR HDV – 2 study are not yet complete and therefore, efficacy and safety may not be well-characterized at this time. In addition, we intend to initiate the LOWR HDV–5 clinical study to examine multiple LNF dose levels and examine long term dosing regimens (Ulaanbaatar, Mongolia). LNF has never been approved or commercialized for any indication.

LNF Clinical Data

We in-licensed LNF from Merck in 2010, and have relied upon Merck's prior Phase 1, 2 and 3 clinical experience with LNF to understand safety and pharmacokinetics.

Merck conducted four Phase 1 studies in 85 healthy volunteers to study food effect (study P00042), absorption, metabolism and excretion (study P00260), ketoconazole drug interaction (study P00393), and the effect of age and gender (study P02673) of LNF.

In study P00042, administration of LNF with food decreased the rate and extent of LNF absorption in healthy subjects when administered as a single 100 mg dose of LNF. The relative oral bioavailability of LNF for subjects that ate prior to receiving LNF compared to those that fasted prior to receiving lonafarnib was 48% based on measuring the maximum serum concentration, or Cmax, and 77% based measuring the concentration of the LNF in the blood plasma over time, or AUC. However, administration of LNF with food did not have a significant effect on LNF bioavailability in subjects following multiple-dose administration. In addition, inter-subject variability was lower (~16%) following multiple-dose administration with food. Given the apparent lower incidence of gastrointestinal side effects and the lower inter-subject variability, it is currently recommended to dose LNF with food.

Study P00260 was an absorption, metabolism and excretion study conducted in healthy volunteers following single-dose administration of LNF. Drug-derived radioactivity was primarily excreted via the feces. Mean cumulative excretion of radioactivity was 61% in feces and less than 1% in urine up to 24 hours post-dose. Metabolite profiles in plasma, urine, and feces showed that LNF was metabolized extensively. The common metabolic pathways included oxidation, dehydrogenation, and combinations of these two processes. The results of *in vivo* metabolic profiling and *in vitro* metabolism studies indicate that no human-specific LNF metabolites are formed.

Study P00393 was a two-way crossover study that was conducted in 16 healthy volunteers exploring the interaction of LNF with ketoconazole, an anti-fungal medication and a CYP3A4 inhibitor. LNF is extensively metabolized by CYP3A4. Co-administration of single-dose LNF (50 mg) and multiple doses of ketoconazole (200 mg BID for 5 days) resulted in an approximately five-fold increase in LNF exposures, and an increase in the mean elimination half-life from 2.7 hours to 4 hours. Administration of LNF with ketoconazole was also associated with lower inter-subject variability than when LNF was administered with a placebo.

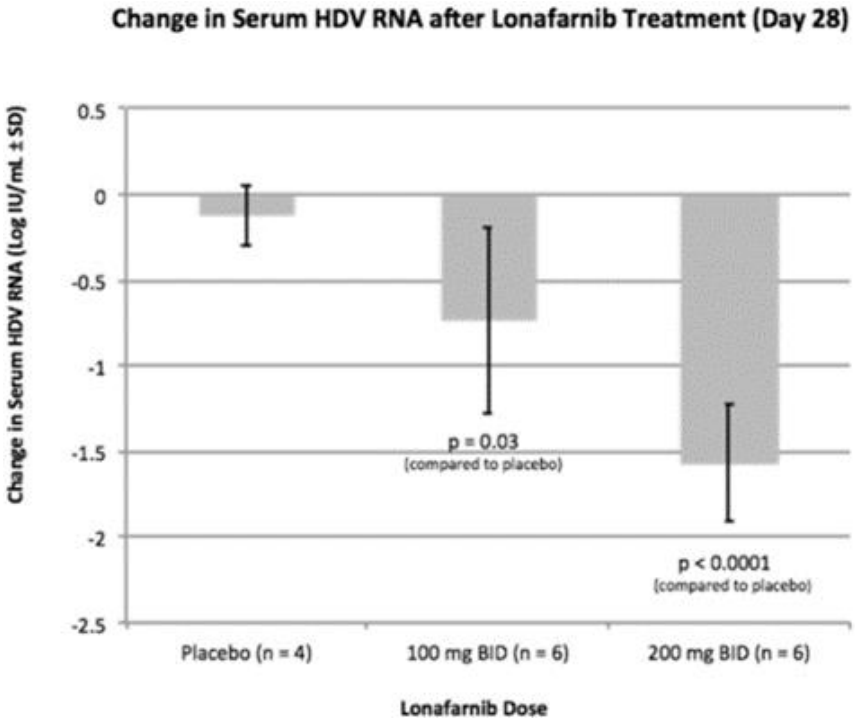
Study P02673 was a single-center, single-dose study conducted in 48 healthy volunteers (24 males and 24 females). Twenty-four of the subjects were between the ages of 18 and 45 and the other 24 subjects were 65 years old or older. Each subject received a single 100 mg dose of LNF in the morning after a standardized meal. PK data suggested that LNF exposures were higher in female subjects (44% higher) as compared to male subjects. Additionally, LNF exposures in subjects 65 years old or older were approximately 59% higher as compared to the younger healthy subject population. Young male subjects had the lowest LNF systemic exposures; AUC values in male subjects between the ages of 18 and 45 were approximately 50% lower than female and elderly subjects.

We conducted a Phase 1 study with goals including: evaluating the effects of multiple-dosing of an antacid (proton pump inhibitor or H2-receptor antagonist) on the systemic absorption of a single dose of LNF, and evaluating the effects of multiple-dosing of LNF on the inhibition potential of the cytochrome P450 enzyme, CYP2C19. The Phase 1 study results demonstrated a weak effect on systemic absorption of LNF following administration of an antacid, which we believe reduces the risk for the use of an antacid by patients treated with LNF to manage possible dyspepsia during treatment. These Phase 1 study results also demonstrated a weak inhibitory activity of LNF on CYP2C19, which we further believe reduces the risk for the use of concomitant medications that are metabolized by CYP2C19 by patients treated with LNF.

In addition to the above Phase 1 studies, under our direction, LNF has been tested in five Phase 2 trials (POC, LOWR HDV – 1, LOWR HDV – 2, LOWR HDV – 3, LOWR HDV – 4) in over 100 HDV-infected patients.

National Institutes of Health (NIH) Clinical Proof-of-Concept Phase 2a Study in HDV

The National Institutes of Health, or the NIH, conducted a 14 patient, double blind, placebo-controlled, proof of concept study, which was the first ever to evaluate LNF in patients infected with HDV. Patients either received LNF 100 mg (group 1) or LNF 200 mg (group 2) twice daily, or BID, for 28 days with six months of follow-up. Both groups enrolled six treatment participants and two placebo participants. The two placebo patients from group 1 later received open-label LNF as group 2 participants. Doses of 100 mg and 200 mg of LNF administered BID demonstrated a dose dependent decrease in viral loads of 0.73 and 1.54 log decline, respectively, in 28 days. The results were published in The Lancet Infectious Diseases Journal in 2015.



As shown in the table above, statistically significant decreases in HDV RNA viral load were demonstrated by both the 100 mg of LNF BID (p=0.03) and 200 mg of LNF BID (p<0.0001) active groups versus the placebo. A statistically significant correlation between increasing LNF serum levels and decreasing HDV RNA viral loads was also demonstrated. The 100 mg twice daily dose was well-tolerated with less frequent GI AEs such as nausea and diarrhea experienced in the 200 mg twice daily dose. No resistant variants were identified from population-based sequencing of HDV infected patients after 28 days of treatment with LNF.

A p-value is a statistical measure of the probability that the difference in two values could have occurred by chance. The smaller the p-value, the greater the statistical significance and confidence in the result. Typically, results are considered statistically significant if they have a p-value less than 0.05, meaning that there is less than a one-in-20 likelihood that the observed results occurred by chance. The FDA requires that sponsors demonstrate the effectiveness and safety of their product candidates through the conduct of adequate and well-controlled studies in order to obtain marketing approval. Typically, the FDA requires a p-value of less than 0.05 to establish the statistical significance of a clinical trial, although there are no laws or regulations requiring that clinical data be statistically significant, or that require a specific p-value, in order for the FDA to grant approval.

In 2014, we initiated the LOWR HDV (LOnafarnib With Ritonavir in HDV) Phase 2 Program. The objective of this program is to identify dose(s) and regimen(s) for registration. To date, over 100 HDV subjects have been dosed with LNF in multiple studies including:

- LOWR HDV – 1 Study (Combination: LNF with RTV or PEG IFN-α)
- LOWR HDV – 2 Study (Dose Finding: LNF + RTV ± PEG IFN-α)
- LOWR HDV – 3 Study (QD Dosing: LNF + RTV)
- LOWR HDV – 4 Study (Dose-Escalation: LNF + RTV)
- LOWR HDV – 5 Study (All-oral Bridging Study to Registration: LNF + RTV)

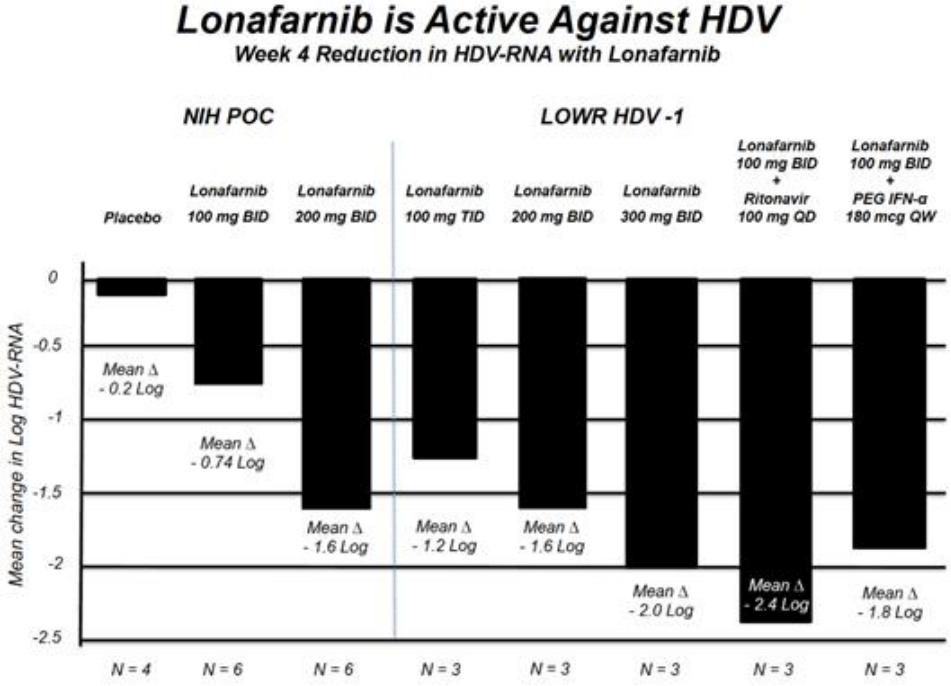
LOWR HDV—1 (LOnafarnib With and without Ritonavir in HDV - 1) Phase 2 Study

The LOWR HDV—1 trial studied LNF in 21 subjects who were enrolled into one of seven groups for durations of 4-12 weeks (three patients in each group): LNF 200 mg BID (12 weeks), LNF 300 mg BID (12 weeks), LNF 100 mg TID (4 weeks), LNF 100 mg BID + RTV 100 mg QD (8 weeks), LNF 100 mg BID + PEG-IFN-alfa 180 mcg QW (8 weeks), LNF 200 mg BID + PEG-IFN-alfa 180 mcg QW (8 weeks) and LNF 300 mg BID + PEG-IFN-alfa 180 mcg QW (8 weeks).

In LNF monotherapy treatment groups, increasing the dosage of LNF from 100 mg three times a day to 200 mg twice a day to 300 mg twice a day led to greater reductions in viral loads at Week 4 (1.2 logs versus 1.6 logs versus 2.0 logs). However, increasing the dosage of LNF also led to increasing gastrointestinal, or GI, intolerability and was not considered for longer term dosing.

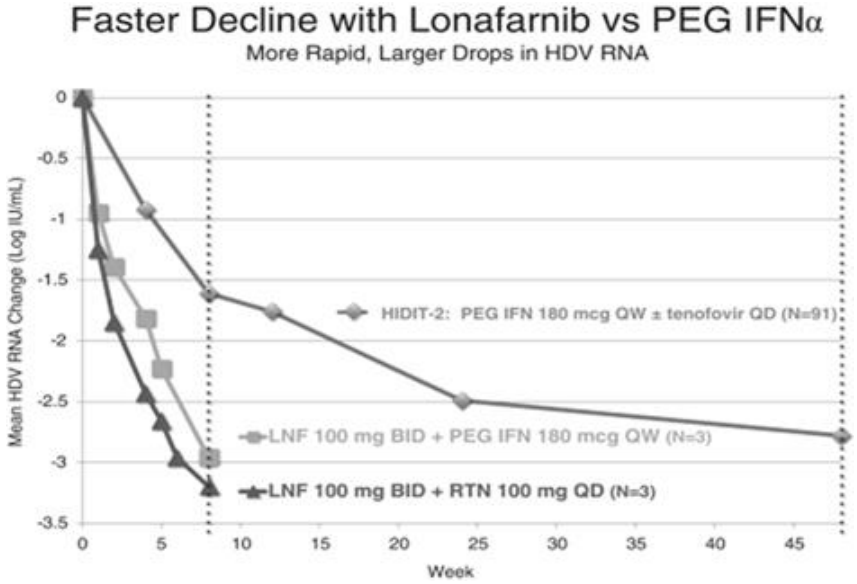
In the LNF-RTV combination arm of LOWR HDV—1, 100 mg of LNF BID was combined with 100 mg of RTV once daily. RTV is a pharmacokinetic, or PK, enhancer known to inhibit the metabolism of LNF, allowing lower doses of LNF to be administered, while resulting in higher systemic concentrations of LNF.

The addition of 100 mg of RTV once daily to 100 mg LNF BID led to a four- to five-fold increase in the serum concentration of LNF in treated patients compared to LNF 100 mg BID alone. This dose combination led to a mean viral load decrease of 2.4 logs after 28 days of treatment, which is a greater than three-fold reduction in viral load compared to the NIH data of a mean viral load decrease of 0.74 logs after 28 days of monotherapy treatment of 100 mg LNF BID. Extending dosing to Week 8 resulted in a 3.2 viral load decline. Importantly, when therapy was discontinued the viral loads rebounded, which we believe indicates that LNF treatment was eliciting an antiviral effect. The addition of 180 mcg of PEG-IFN-alfa once weekly to 100 mg LNF BID was also more active in reducing HDV RNA versus studies with either agent alone. This dose combination led to a greater reduction in viral load, compared to the NIH results on monotherapy treatment with 100 mg LNF BID, with a mean decrease of 0.74 logs versus 1.8 logs after four weeks. Extending dosing to eight weeks resulted in a 3.0 logs viral load decline. Importantly, when therapy was discontinued the viral loads rebounded. The mean change in HDV RNA for the patients receiving eight weeks of treatment of 100 mg LNF BID in combination with RTV and 100 mg LNF BID in combination with PEG-IFN-alfa is shown below. Viral loads for LNF 200 mg and 300 mg BID in combination with PEG-IFN-alfa was not shown since these dosages were intolerable (all patients discontinued) for future development. LOWR HDV-1 did not include a placebo arm and, as such, statistical significance could not be determined.



Liver enzymes are often elevated during infections with viral hepatitis, a sign of damage being done to liver cells. In both LNF combination cohorts, all HDV patients enrolled had elevated alanine aminotransferase, or ALT, a liver enzyme that is a surrogate marker of inflammation, prior to receiving any treatment. By the end of eight weeks of combination therapy with LNF and RTV or LNF and PEG-IFN-alfa, all patients' ALT liver enzymes normalized or trended toward normal while on therapy.

In the three patients receiving LNF in combination with RTV and the three patients receiving LNF in combination with PEG-IFN-alfa, we observed decreases in HDV RNA viral load of approximately 3.2 logs and 3.0 logs after eight weeks of treatment, respectively. For comparison, and as shown in the figure below, published data from the HIDIT-2 trial of PEG-IFN-alfa in 91 HDV infected patients demonstrated a mean decline in HDV RNA of approximately 1.6 logs and 2.7 logs after 8 weeks and 48 weeks, respectively. The HIDIT-2 (Hep-Net International Delta Hepatitis International Trial-II) was a multicenter randomized trial studying effects of PEG-IFN-alfa plus tenofovir in chronic HDV patients, and is the largest clinical study to date in HDV. The HIDIT-2 trial was conducted on 91 patients, whereas the LOWR HDV—1 study was conducted on an aggregate of 21 patients, with three patients per treatment arm. If the LOWR HDV—1 trial was conducted on a larger group of patients, the mean HDV RNA decline may differ from the 3.2 log and 3.0 log declines after eight weeks of treatment observed in the three patient arms receiving LNF combination treatment in the LOWR HDV—1 trial. However, based on clinical results to date, we expect all patients who are treated with LNF to show a viral load response. The LOWR HDV – 1 study (combined with LOWR HDV – 2, collectively EIG-300) is not yet complete and we have identified and continue to assess certain good clinical practice violations at one site that may impact certain data and information that we plan to submit to the FDA.



LOWR HDV—2 (LOnafarnib With Ritonavir in HDV - 2) Phase 2 Study

LOWR HDV – 2 is a dose-finding Phase 2 study of multiple doses of LNF boosted by RTV with and without PEG-IFN-alfa in 58 subjects for 24-48 weeks of treatment with 24 weeks of follow-up, with the aim to identify regimen(s) with improved tolerability for the longer-term registration studies. LOWR HDV – 2 (conducted as an extension of LOWR HDV – 1, collectively EIG-300) was conducted at Ankara University in Turkey and we have identified and continue to assess certain good clinical practice violations at this site that may impact certain data and information that we plan to submit to the FDA.

Fifty-eight subjects were enrolled into one of ten groups of different LNF with RTV and/or PEG-IFN-alfa combinations for 12 or 24 or 48 weeks as follows: Group 1: LNF 100 mg BID + RTV 50 mg BID; Group 2: LNF 100 mg BID + RTV 100 mg QD; Group 3: LNF 150 mg QD + RTV 100 mg QD; Group 4: LNF 100 mg QD + RTV 100 mg QD; Group 5: LNF 75 mg BID + RTV 100 mg BID with PEG-IFN-alfa 180 mcg QW added at week 12; Group 6: LNF 50 mg BID + RTV 100 mg BID; Group 7: LNF 50 mg BID + RTV 100 mg BID with PEG-IFN-alfa 180 mcg QW added at week 12; Group 8: LNF 50 mg BID + RTV 100 mg BID + PEG-IFN-alfa 180 mcg QW; Group 9: LNF 25 mg BID + RTV 100 mg BID; and Group 10: LNF 25 mg BID + RTV 100 mg BID + PEG-IFN-alfa 180 mcg QW.

Twenty-four-week post-treatment data from LOWR HDV—2 will be presented at the EASL Conference in April 2017. The LOWR HDV – 1 and LOWR HDV – 2 study is not yet complete and we have identified and continue to assess certain good clinical practice violations at one site that may impact certain data and information that we plan to submit to the FDA.

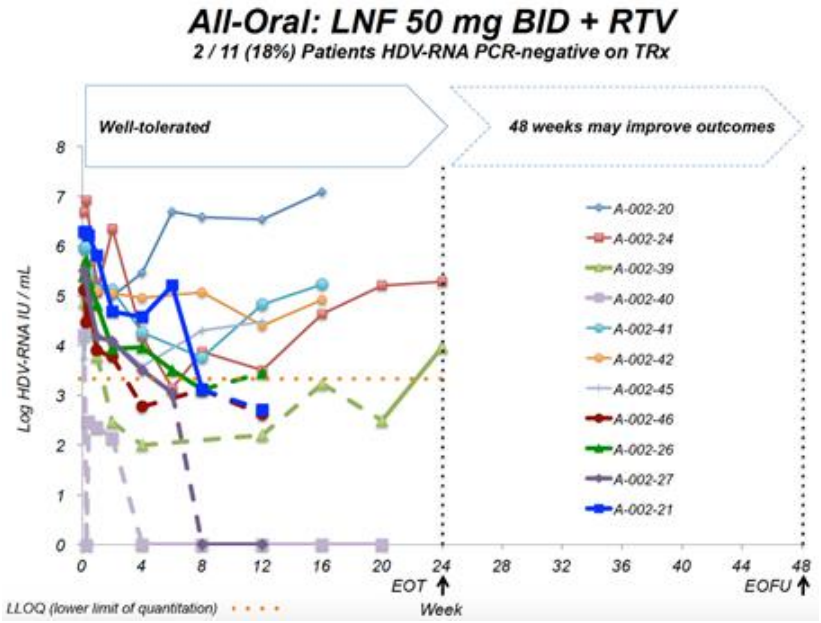
LOWR HDV—3 (LOnafarnib With Ritonavir in HDV - 3) Phase 2 Study

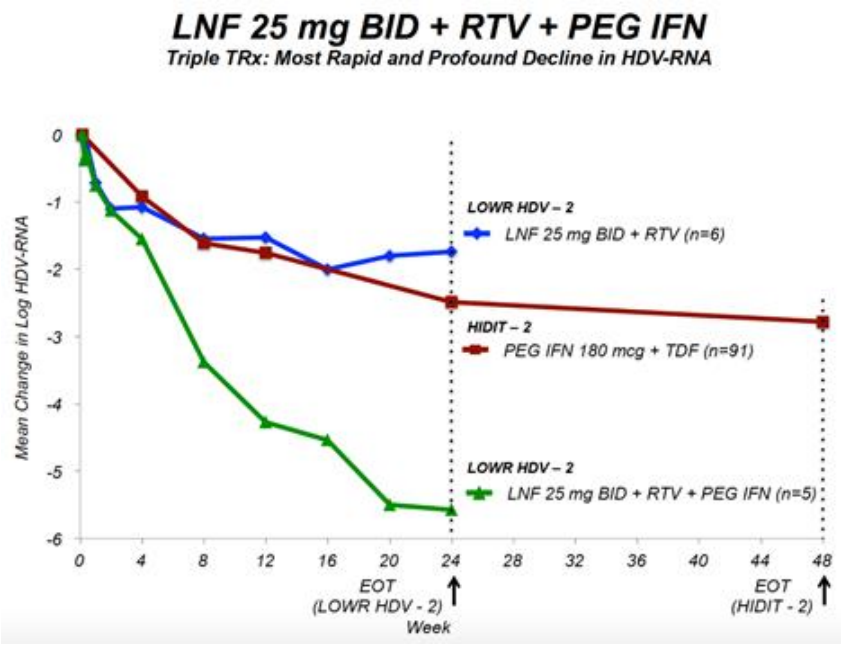
In November 2015, we initiated LOWR HDV – 3, a double-blind, randomized, placebo-controlled study designed to evaluate the efficacy and tolerability of once-daily doses of LNF – 50 mg, 75 mg and 100 mg – each combined with RTV 100 mg once daily for 12 (N=9) or 24 (N=12) weeks. Twenty-one patients with chronic hepatitis delta were randomized into one of six treatment groups. LOWR HDV – 3 is being conducted at the National Institutes of Health (NIH) Bethesda, MD, and dosing has completed.

LOWR HDV—4 (LOnafarnib With Ritonavir in HDV - 4) Phase 2 Study

LOWR HDV – 4 is an open-label study to evaluate the efficacy and tolerability of dose-escalation of LNF combined with RTV administered twice daily for dosing durations of 24 weeks. Fifteen patients were initiated at LNF 50 mg and RTV 100 mg twice daily, and dose-escalated up to LNF 100 mg twice daily at the discretion of the investigator and patient tolerability. LOWR HDV – 4 is being conducted at Hannover Medical School in Hannover, Germany, and dosing has completed.

Week 24 data from LOWR HDV – 2, – 3 and – 4 were presented at AASLD 2016 in Boston, MA. Key findings from the LOWR HDV Program demonstrate that LNF (all-oral) can achieve HDV-RNA negativity on-treatment, and that the most robust HDV-RNA on-treatment on-anti-viral activity is observed in LNF triple therapy with PEG-IFN-alfa. Findings demonstrate that LNF-based regimens can normalize ALTs in 60% of patients. With dosing regimens of LNF 25 and 50 mg BID identified with predominantly grade 1 GI AEs amongst per-protocol treated patients, 48 week dosing may be possible and expected to improve outcomes. Early data also indicate that LNF-based regimens can also induce post-treatment HDV-RNA clearance in a subset of patients, suggesting immune reactivation as a potential second mechanism to achieve HDV-RNA PCR-negativity. Post-treatment follow up on all patients will be reported at EASL 2017. Bridging studies to registration are planned.





LOWR HDV—5 (LOnafarnib With Ritonavir in HDV - 5) Phase 2 Study

In the LOWR HDV – 2 clinical trial, per-protocol patients treated with LNF 25 mg BID + RTV 100 mg BID achieved a mean HDV-RNA decline of 1.8 logs after 24 weeks of treatment and per-protocol patients treated with LNF 50 mg BID + RTV 100 mg BID achieved HDV-RNA PCR-negativity after 24 weeks of treatment. Fewer dose reductions support improved GI tolerability of both of these doses compared to higher LNF doses, and support longer dosing durations of 48 weeks. The LOWR HDV – 1 and LOWR HDV – 2 study is not yet complete we have identified and continue to assess certain good clinical practice violations at one site that may impact certain data and information that we plan to submit to the FDA. We believe dosing for 48 weeks may increase the number of patients achieving HDV-RNA PCR-negativity and/or provide suppression of HDV-RNA for sufficient duration to observe clinical, histological benefit.

LOWR HDV – 5 is a planned, open-label study to evaluate the safety, efficacy and tolerability of all-oral regimens including LNF 25 mg and 50 mg combined with RTV 100 mg administered twice daily for dosing duration of 48 weeks. Planned endpoints are safety/tolerability, change in HDV-RNA, and change in ALT and liver histology. LOWR HDV – 5 is a bridging study, with a goal to be supportive of a future registration study. We are awaiting comments from FDA on the LOWR HDV – 5 protocol before beginning this study. We plan to initiate enrollment for LOWR HDV – 5 in Ulaanbaatar, Mongolia as early as the second quarter of 2017.

Our Second HDV Solution: Lambda for HDV

Lambda is a well-characterized, late-stage, first in class, type III interferon (IFN) that we in-licensed from Bristol-Myers Squibb in April 2016 for the treatment of HDV infection. Lambda stimulates immune responses that are critical for the development of host protection during viral infections. Lambda targets type III IFN receptors which are distinct from the type I IFN receptors targeted by IFN-alfa. These type III receptors are highly expressed on hepatocytes with limited expression on hematopoietic and central nervous system cells, which has been demonstrated to reduce the off-target effects associated with other IFNs and improve the tolerability of lambda (Chan 2016). Although lambda does not use the IFN-alfa receptor, signaling through either the IFN-lambda or IFN-alfa receptor complexes results in the activation of the same Jak-STAT signal transduction cascade.

In clinical trials of IFN-alfa or PEG-IFN-alfa, between 25% and 33% of HDV-infected patients were able to clear their infections after a minimum of 48 weeks of therapy, with some requiring two years of therapy. However, long-term therapy with IFN-alfa is known to be associated with numerous adverse events and tolerability is a significant problem for some of these patients. We believe lambda will be a safer and better tolerated pegylated interferon compared to PEG-IFN-alfa. We are currently enrolling our LIMT HDV (Lambda MonoTherapy) Phase 2 clinical trial in New Zealand, Israel and Pakistan. Lambda has never been approved or commercialized for any indication.

Lambda Clinical Data

A head-to-head study comparing the safety and efficacy of lambda versus PEG-IFN-alfa was reported in 2016 by Chan et al. In this study, HBeAg(+) patients were treated with either Lambda (n=80) or PEG-IFN-alfa (n=83) for 48 weeks. A subset of on-treatment safety data is summarized in the table below. Lambda is generally better-tolerated when compared to PEG-IFN-alfa. Lower rates of flu-like symptoms and musculoskeletal symptoms were observed with lambda versus PEG-IFN-alfa.

Adverse Events	Lambda 180 µg % (N = 80)	Alfa 180 µg % (N = 83)
Fatigue	32.5	28.9
Headache	13.8	28.9
Myalgia	3.8	21.7
Pyrexia	10.0	45.8
Pruritus	8.8	15.7
Neutropenia	2.5	20.7
Musculoskeletal	6.3	27.7
Neurological	22.5	36.1
Flu-like	16.3	54.2

LIMT HDV Monotherapy Phase 2 Clinical Trial

The LIMT HDV Phase 2 Clinical Trial is a 1:1 randomized, open-label study of Lambda 120 or 180 microgram subcutaneous injections administered weekly for 48 weeks in approximately 30 patients with chronic HDV. End of treatment will be followed by a treatment-free 24-week observation period. The primary objective of the Phase 2 Clinical Trial is to evaluate the safety, tolerability, and efficacy of treatment with two dose levels of Lambda monotherapy in patients with chronic HDV infection. All patients will also be administered an anti-HBV nucleos(t)ide analog throughout the study. The trial will be conducted at international sites including New Zealand, Israel and Pakistan.

Potential for Registration in HDV for LNF and Lambda

Our goal in developing LNF and lambda is to reduce viral load in such a manner as to achieve durable clearance of the virus (sustained virologic response), the point where, upon withdrawal of the therapy, the infection does not return. Evidence that academic investigators have gathered suggests that combinations of LNF and lambda with other antiviral agents may hold promise for longer duration treatment and sustained, long-term reduction of viral load.

We also believe that treatment with LNF and lambda in combination with other antiviral agents may contribute to long-term benefit for patients, which may represent an alternative path to regulatory approval. In a study published in Plos One in 2014 (Romeo, R. et al. “High Serum Levels of HDV RNA Are Predictors of Cirrhosis and Liver Cancer in Patients with Chronic Hepatitis Delta,” Plos One, 2014; 9:1), high serum levels of HDV were found to be

a predictor of cirrhosis and liver cancer development. In a study published in Gastroenterology in 2004 (Farci, P. et al. “Long-Term Benefit of Interferon Therapy of Chronic Hepatitis D: Regression of Advanced Hepatic Fibrosis,” Gastroenterol, 2004; 126:1740), researchers demonstrated that lower frequencies of clinical events, leading to improvements in overall liver health and reductions in the rates of developing hepatic complications, could be achieved in HDV infected patients who were treated with high dose IFN-alfa and who experienced biochemical response and sometimes as little as 2 log declines in viral load. A 2014 Hepatology study by Heidrich suggests that transient suppression of HDV replication in patients treated with PEG-IFN-alfa improves the clinical long-term outcome, as not a single patient in their study with a post-treatment week 24 HDV RNA response experienced a clinical event, including those patients who experienced viral rebound. We believe that these studies suggest that eradication of HDV RNA may not be necessary in patients treated with IFNs to achieve a substantial clinical benefit and improve long-term outcomes.

Exendin 9-39 for Post-Bariatric Hypoglycemia

Exendin 9-39 is the second most advanced product candidate in our pipeline. Exendin 9-39 is a glucagon-like peptide-1, or GLP-1, receptor antagonist. GLP-1 is a gut-derived incretin hormone released by intestinal “L” cells after meals. Incretin hormones, such as GLP-1, enhance the secretion of insulin from pancreatic beta cells in a glucose-dependent manner, thereby lowering blood glucose levels after meals. Exendin 9-39 blocks GLP-1 from binding to the GLP-1 receptor, inhibiting the GLP-1-mediated incretin effect. We are developing exendin 9-39 as a treatment for PBH, which is characterized by an exaggerated incretin response, with patients exhibiting low levels of glucose and excessively high levels of insulin in the blood after meals. This form of hypoglycemia is a debilitating and potentially life-threatening condition. Gastric bypass procedures are widely performed and are increasing in frequency for medically complicated obesity. There is no approved therapy for PBH and the unmet medical need is high.

Stanford researchers have demonstrated clinical proof of concept in 29 patients suffering from PBH that exendin 9-39 can prevent an exaggerated fall in blood sugar following a meal, or post-prandial hypoglycemia, in affected patients. Data has been generated using both intravenous delivery and SC delivery. Pharmacokinetics indicate that the SC delivery could enable once or twice a day pre-prandial dosing. Stanford initiated a Phase 2 multi-day dosing trial in affected patients with our exendin 9-39 SC formulation in 2016. We have developed a novel liquid formulation for SC injection. We plan to initiate a Phase 1 PK study in healthy volunteers and a Phase 2 study in affected patients using of the new SC formulation in 2017.

Post-Bariatric Hypoglycemia Overview

As the use of bariatric surgical procedures has increased worldwide, a new post-surgical complication, hypoglycemia associated with bariatric surgery, has been increasingly diagnosed and reported in the procedures that involve reducing the size of the stomach with a vertical sleeve gastrectomy or by resecting and re-routing the small intestine to a small stomach pouch (Roux-en-Y gastric bypass). This disorder leads to frequent symptomatic hypoglycemia, often resulting in glucose concentrations low enough to cause seizures, altered mental status, loss of consciousness, cognitive dysfunction, disability and death. Quality of life can be severely diminished, and many patients cannot care for themselves or others, work, drive, or be left alone. There is no approved treatment for this condition. Severe cases have historically been surgically managed with near-total to total pancreatectomy, which results in insulin dependent diabetes and is associated with a greater than 6% surgical mortality risk.

Research suggests that elevated GLP-1 may play an important role in mediating the glucose-lowering effect associated with bariatric surgery. Surgically-altered nutrient transit, such as a Roux-en-Y procedure, causes early nutrient sensing by the intestinal “L” cells, resulting in enhanced secretion of GLP-1 leading to elevated insulin secretion. This effect may play a primary role in the early resolution of Type 2 diabetes after surgery. A number of synthetic analogs of GLP-1, or agonists, have been approved for the treatment of Type 2 diabetes including Byetta™ (exenatide), Victoza™ (liraglutide), and Trulicity™ (dulaglutide). These drugs, all agonists, bind to the GLP-1 receptor and enhance the release of insulin in a glucose-dependent manner. In patients with PBH, excessive secretion of GLP-1 and/or exaggerated sensitivity to GLP-1 results in dysfunctional insulin release, leading to severe, debilitating hypoglycemia. GLP-1 receptor antagonists compete with endogenous GLP-1 and has the potential to prevent dysfunctional insulin release and resultant symptomatic hypoglycemia.

Approximately 150,000 to 200,000 bariatric surgical procedures are performed each year in the United States, and another 125,000 are performed each year in Europe. Approximately 30% of these bariatric surgeries are Roux-en-Y gastric bypass procedures.

Our Solution: Exendin 9-39 to Treat Post-Bariatric Hypoglycemia

Exendin 9-39 is a well-characterized, competitive antagonist of GLP-1 at its receptor. Exendin 9-39 is a 31 amino acid fragment of exenatide, a commercially available GLP-1 agonist, brand named Byetta™ used in the treatment of type 2 diabetes. Exendin 9-39 blocks the GLP-1 receptor and leads to reduced post-prandial levels of insulin secreted by the pancreas. While exenatide has been approved for the treatment of type 2 diabetes, exendin 9-39, as a new molecular entity, has never been approved or commercialized for any indication.

Clinical Data to Date

Stanford researchers have demonstrated in two clinical studies with exendin 9-39 that pharmacologic blockade of the GLP-1 receptor can prevent hypoglycemia in affected patients and mitigate symptoms of hypoglycemia. A phase 2 multi-ascending dose trial is currently underway at Stanford. We believe that exendin 9-39 may represent the first targeted medical treatment for patients with PBH. In the two completed single-dose studies, there were no adverse drug reactions attributed to exendin 9-39. These single-dose Phase 1 studies were conducted under two investigator INDs for the study of exendin 9-39 for PBH at Stanford.

The first exendin 9-39 study conducted at Stanford was a Phase 1, double-blinded crossover study wherein eight patients with PBH were randomly assigned to receive IV infusion of exendin 9-39 or placebo during an oral glucose tolerance test, or OGTT (Craig et al, Diabetologia 2016). The trial assessed patient blood glucose and insulin levels and the presence and severity of symptoms of hypoglycemia. Hypoglycemia was defined as glucose levels falling to or below 50 mg/dL.

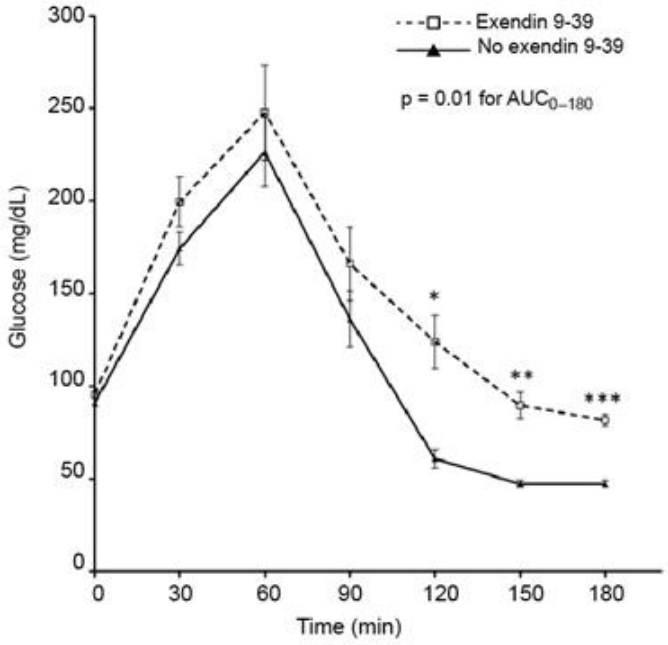
In this trial, IV infusion of exendin 9-39 raised the postprandial glucose nadir by over 70% and lowered the area under the curve insulin by 57%, normalizing both parameters relative to healthy nonsurgical controls, and preventing hypoglycemia in all eight participants. In contrast, during placebo infusion every patient became hypoglycemic, requiring investigator intervention with administration of IV dextrose when patient plasma glucose fell to a level of 50 mg/dL or less.

To assess for the presence and severity of symptoms of hypoglycemia during IV infusion of exendin 9-39 versus placebo, patients completed severity-grade questionnaires every 30 minutes during each 180 minute OGTT period. The severity-grade questionnaires showed that, on average patients experienced fewer and less severe hypoglycemic symptoms during IV infusion of exendin 9-39 as compared to during IV infusion of placebo ($p<0.001$). While symptoms reported by subjects during the glucose rise (from T=0 to peak glucose) were unchanged by exendin 9-39 infusion, both autonomic ($p=0.002$) and neuroglycopenic ($p=0.001$) symptoms reported during the glucose fall period (from peak to nadir glucose) were reduced.

The second clinical proof of concept study, a Phase 2 clinical trial, was a single ascending dose, or SAD. In this investigator-initiated study, conducted at Stanford University School of Medicine, exendin 9-39 was administered subcutaneously in eight patients with PBH. This was the first investigation involving the SC administration of exendin 9-39 in human subjects and was designed to examine the PK, PD, and local tolerability of SC exendin 9-39 in patients with PBH. After metabolic and symptomatic responses to a baseline 75 g OGTT were evaluated, patients returned for a repeat OGTT with administration of a single exendin 9-39 dose, ranging from approximately 10–30 mg (0.13–0.38 mg/kg).

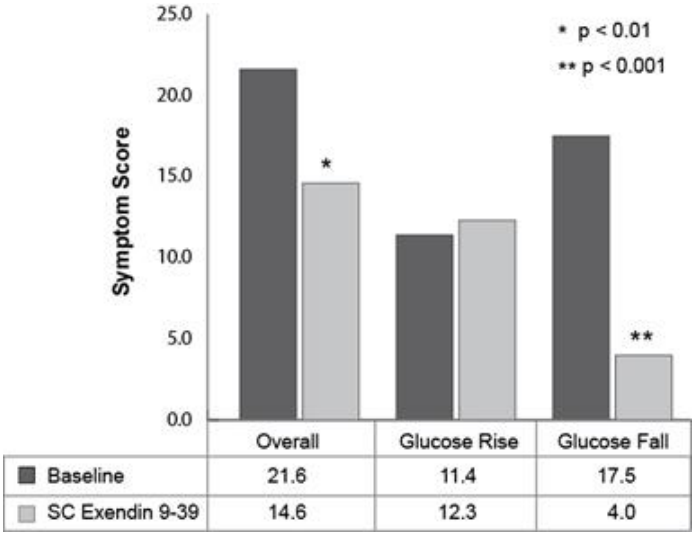
In all eight patients undergoing the OGTT, exendin 9-39 administration prevented hypoglycemia and reduced symptoms of hypoglycemia. The baseline OGTT resulted in a high peak in plasma glucose concentration for all eight patients, followed by a rapid, steep decline, with all patients requiring rescue with IV dextrose at a plasma glucose concentration of 50 mg/dL. In contrast, prevention of hypoglycemia occurred at all dose levels of SC exendin 9-39 tested, with all patients completing the 180-minute OGTT without requiring intervention with IV dextrose. While early glycemic responses (fasting plasma glucose, peak postprandial glucose, time to peak glucose, and AUC glucose from 0–60 minutes postmeal) were unchanged by administration of SC exendin 9-39, late glycemic responses (nadir glucose, time to nadir glucose, AUC glucose from 0–180 minutes) were significantly improved. The average nadir glucose was increased by 61%, as shown in the figure below.

Exendin 9-39 SC Injection SAD Study Results



*p < 0.01, **p < 0.001, and ***p < 0.0001for PBH patients with SC exendin 9-39 injection vs no injection.
Source: Craig et al, ADA 2016.

Symptoms of PBH were assessed using the Edinburgh Hypoglycemia Symptom Scale, which was completed by patients every 30 minutes during each 180-minute OGTT. Patients used the scale to report the presence and severity of autonomic or neuroglycopenic symptoms or symptoms of malaise. SC exendin 9-39 reduced symptoms of PBH overall and during the glucose fall period without altering symptoms during the glucose rise period. While symptoms associated with PBH were observed during this study, no adverse reactions attributed to exendin 9-39 were identified, and no injection site reactions were reported in any patients in this study.

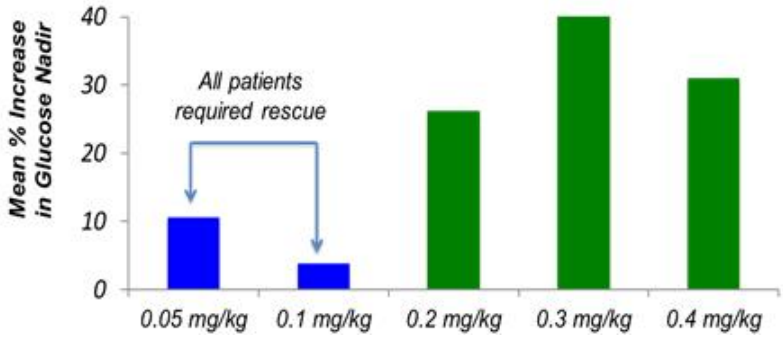


	Overall	Glucose Rise	Glucose Fall
Baseline	21.6	11.4	17.5
SC Exendin 9-39	14.6	12.3	4.0

P-value by paired two-tailed Student's t-test.
Source: Craig et al, ADA, 2016b.

A third trial conducted at Stanford under an investigator IND is currently underway. This is a Phase 2 trial evaluating the safety, efficacy, and PK profile of multiple ascending doses of subcutaneously administered exendin 9-39 in patients with PBH. Interim data from 11 patients participating in this trial as shown below have demonstrated a therapeutic increase in glucose nadir for patients who received doses ≥ 0.2 mg/kg during an OGTT on the final day of dosing as compared to during a baseline OGTT. While all dose levels resulted in an improved mean percent increase in postprandial glucose nadir, patients who received doses < 0.2 mg/kg required rescue with IV dextrose, whereas patients receiving doses ≥ 0.2 mg/kg did not require rescue with IV dextrose.

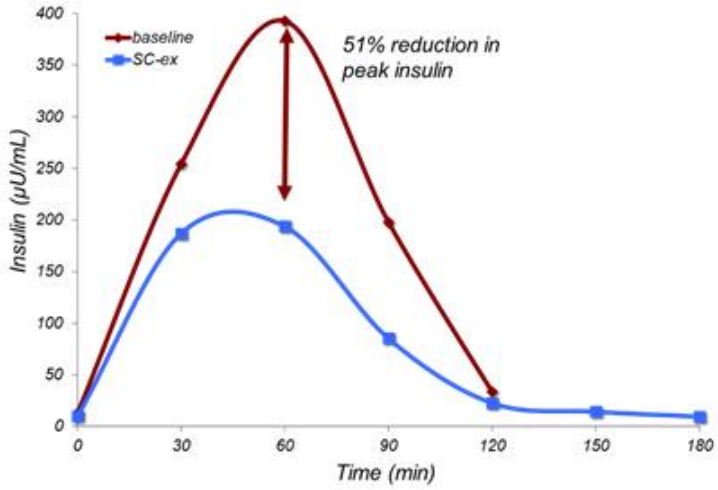
Exendin 9-39 SC Injection MAD Study Interim Glycemic Results



Source: Craig et al KOL/Analyst meeting, Dec 2016.

The mean postprandial insulin peak was reduced by 51%, while fasting insulin was not raised, in patients who received doses of ≥ 0.2 mg/kg.

Exendin 9-39 SC Injection MAD Study Interim Insulin Results



Source: Craig et al KOL/Analyst meeting, Dec 2016.

Ubenimex for Pulmonary Arterial Hypertension

Ubenimex is a well-characterized, oral, small-molecule inhibitor of leukotriene A4 hydrolase, or LTA4H, the enzyme responsible for converting leukotriene A4, or LTA4, to leukotriene B4, or LTB4. LTB4 is a naturally occurring molecule involved in inflammation. Ubenimex has been marketed in Japan by Nippon Kayaku for over 25 years as an adjunct to chemotherapy agents to extend survival and to maintain remission after treatment for acute non-lymphocytic leukemia in adults.

Results of a preclinical study published in Science Translational Medicine (Tian, W. et al. “Blocking Macrophage Leukotriene B4 Prevents Endothelial Injury and Reverses Pulmonary Hypertension,” Sci Transl Med, 2013; 5:1) by Stanford researchers demonstrated that both LTB4 and LTA4H are elevated in animal models of PAH and human PAH disease. Macrophages, a type of white blood cell that ingests foreign materials, accumulate around small arterioles of the lungs and synthesize excess LTB4. This causes programmed cell death, or apoptosis, of cells that line the interior surface of the pulmonary artery, pulmonary artery endothelial cells. Additionally, this causes proliferation and an increase in volume, or hypertrophy, of pulmonary arterial smooth muscle cells. Elevated LTB4 causes inflammation resulting in blockage of the arteries, or arteriole occlusion, and hypertension in animal models of PAH. Targeted pharmacologic inhibition of LTB4, including ubenimex, reversed PAH disease in all treated animals; obstructed arterioles opened, cardiac function improved, and the animals survived. We therefore believe that ubenimex is a potential therapeutic candidate for treatment of PAH where pathological inflammation is believed to be important in the etiology of the disease.

All currently approved agents for PAH were originally developed as vasodilators, drugs that dilate blood vessels. Inflammation is now recognized as a primary component of PAH disease, which can lead to obstructed arterioles, vasoconstriction, and worsening cardiac function. Work published by Stanford researchers in Science Translational Medicine (Tian, W. et al. “Blocking Macrophage Leukotriene B4 Prevents Endothelial Injury and Reverses Pulmonary Hypertension,” Sci Transl Med, 2013; 5:1) discusses a potentially novel therapeutic approach to PAH that may address the inflammatory component of PAH with the potential for disease modification. We are currently conducting a Phase 2 clinical trial of ubenimex in patients with PAH, the LIBERTY Study, and expect recruitment to be completed in the first half of 2017. We anticipate the completion of dosing in the LIBERTY Study by end of 2017 with data in early 2018.

Pulmonary Arterial Hypertension Overview

About Pulmonary Arterial Hypertension Disease

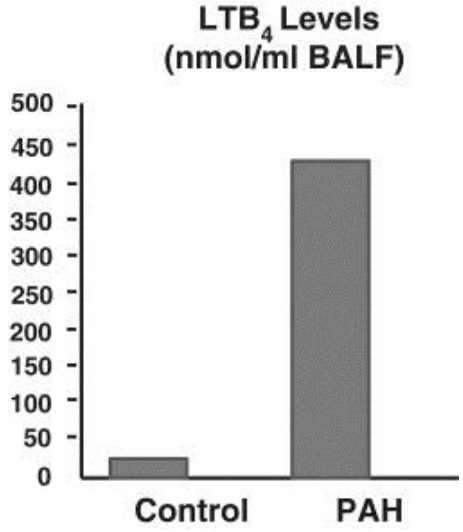
PAH is a type of high blood pressure that affects the arteries in the lungs and the right side of the heart. PAH begins when tiny arteries in the lungs, called pulmonary arterioles, become narrowed, blocked or destroyed. This makes it harder for blood to flow through the lungs, and raises pressure within the arteries in the lungs. As the pressure builds, the heart’s lower right chamber, or right ventricle, must work harder to pump blood through the lungs, causing the heart muscle to weaken and eventually fail. PAH is a progressive, life-threatening illness that meets criteria for orphan drug designation in the United States, European Union, and Japan.

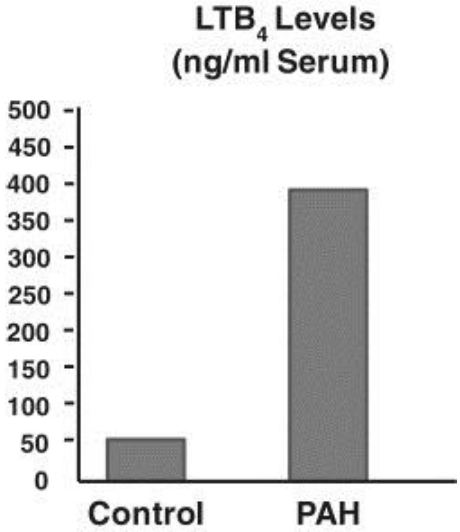
Current Treatments for PAH

Initial treatments developed and used for PAH focus on reduction of hypertension with agents such as diuretics, calcium channel blockers, increasing cardiac output with agents such as digoxin, and various anticoagulation therapies. These therapies are all generic agents. A number of therapies specifically approved for PAH, such as prostacyclin agonists, phosphodiesterase 5, or PDE5, inhibitors, guanylate cyclase stimulators, and endothelin receptor antagonists, target mechanisms that induce vasodilation. These therapies together represent approximately a $4 billion market in the United States and Europe. Prostanoids such as epoprostenol, treprostinil and iloprost are stable versions of vasodilators that are naturally produced by the body and help compensate for low levels of prostacyclin production in some patients. PDE5 inhibitors such as sildenafil and tadalafil also work as vasodilators by increased signaling through the nitric oxide pathway. Other stimulators of this pathway include guanylate cyclase stimulators such as riociguat. Endothelin is a natural vasoconstrictor which binds to the endothelin receptors to elicit vasoconstriction. Antagonists of the endothelin receptor such as ambrisentan, bosentan, and macitentan have been approved for the treatment of PAH. Despite their premium pricing, these drugs are all considered to be palliative and not disease-modifying. Specifically, these drugs do not address the underlying causes of the disease, especially in PAH patients with connective tissue diseases, or CTD, or PAH patients with inflammation, highlighting the need for novel therapeutic approaches. An estimated 30,000 PAH patients and 15,000 PAH patients receive pharmacologic therapy in the United States and Europe, respectively.

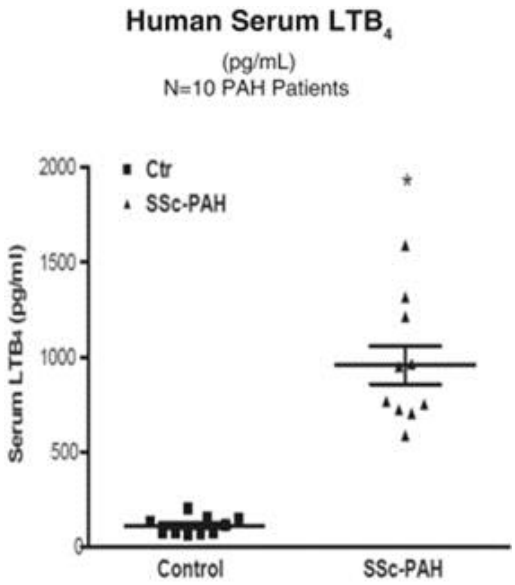
Preclinical LTB4 Data in PAH

In animal models of PAH, LTB4 was significantly elevated in both broncho-alveolar lavage fluid and in serum, suggesting that LTB4 may play a key role in development of the pathology associated with PAH.

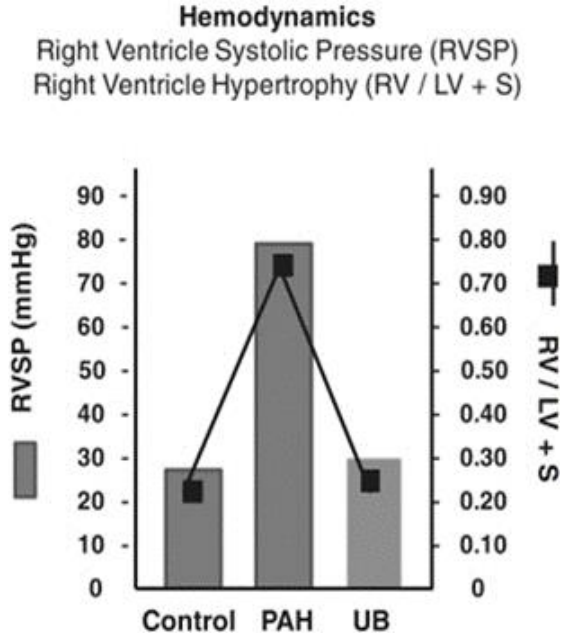




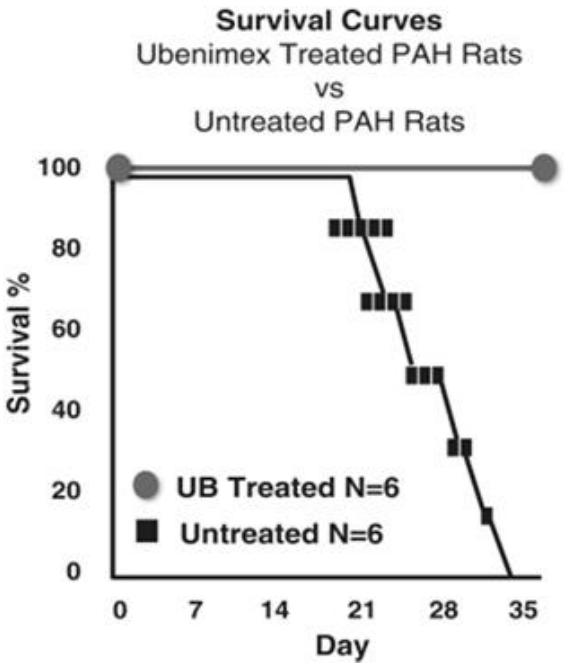
Significantly elevated levels of LTB4 were also observed in serum from PAH patients, with the highest levels in patients with systemic sclerosis-related PAH, or SSc-PAH, identifying a link between the pathology of the animal model of PAH disease and human PAH disease.



In animal models of PAH, right ventricular systolic pressure is greatly elevated and there is hypertrophy of the right ventricle 21 days after induction of the disease. Treatment with ubenimex for 14 days reversed these effects, normalizing ventricular pressure and right ventricular size.



The activity of ubenimex in this PAH animal model is more pronounced when overall survival is examined. All of the animals tested in this model that received ubenimex survived until at least day 35, whereas none of the untreated animals survived.



Improvements in pressures and survival with ubenimex were seen in three distinct animal models of PAH disease: SU5416 induced-PAH in athymic rats, SU5416-induced PAH in hypoxia-induced PAH, and monocrotaline-induced PAH. Activity of ubenimex in treated animals correlated with LTB4 levels in the model.

Our Planned Solution: Ubenimex for PAH

Ubenimex is a well-characterized, oral, small-molecule, dual-inhibitor of aminopeptidase and LTA4H, the enzyme responsible for catalyzing the committed step in the formation of the proinflammatory mediator LTB4. Ubenimex is approved in Japan as an adjuvant to chemotherapy agents to extend survival and to maintain remission after treatment for acute non-lymphocytic leukemia in adults. Ubenimex has been used for over 25 years in Japan and remains commercially available through Nippon Kayaku. The FDA and EMA granted orphan drug designation to ubenimex for the treatment of PAH in the United States and Europe, respectively. Ubenimex is not approved for any indication in the United States or Europe.

Clinical Data to Date and Clinical Development Plan

We in-licensed ubenimex from Nippon Kayaku in 2015 and have relied on Nippon Kayaku's prior Phase 1 clinical data and experience with ubenimex to understand safety. Nippon Kayaku conducted four Phase 1 studies in healthy subjects and cancer patients to study metabolite determination, metabolism and excretion, drug absorption, and a pharmacokinetic study in lymphoma patients.

In the metabolite determination study, ubenimex was rapidly absorbed following oral administration of single doses ranging from 10 mg to 200 mg, reaching a maximum serum level between 30 minutes and three hours after dosing. Mean peak concentrations after 30 mg, 100 mg and 200 mg were 2.2 µg/mL at one hour, 2.5 µg/mL at three hours, and 7.4 µg/mL at two hours, respectively.

In the metabolism and excretion study, 84% to 94% of the administered doses of ubenimex was recovered in urine within 24 hours of dosing.

In the absorption study, prolonged administration of ubenimex to cancer patients showed rapid absorption of the drug and maximum peak levels which ranged from 30 minutes to three hours in most patients. In a small study of eight patients receiving 30 mg of ubenimex daily, delayed α-phase decrease, an initial phase of rapid decrease of concentration of the drug in the plasma, was observed in patients with renal cancer compared to patients with bladder cancer, suggesting that clearance of ubenimex may be slower in patients with impaired renal function. The pharmacokinetics did not appear to change over time with repeated administration of ubenimex.

In a Phase 1b study performed in bone marrow transplant lymphoma patients in the United States, PK evaluation was performed in groups of ten patients receiving 10 mg of ubenimex QD, 30 mg of ubenimex QD, 30 mg of ubenimex three times a day, or TID, or 60 mg of ubenimex TID, in each case for up to 60 days. The mean AUC and Cmax increased with increasing doses of 10 mg, 30 mg, 90 mg or 180 mg ubenimex daily. At all doses, no accumulation was apparent over the six days.

We completed a pre-IND meeting at FDA in May 2014 where we discussed both Phase 2 and Phase 3 clinical development plans for ubenimex in patients with PAH. We subsequently filed an IND with FDA which became effective in September 2015. Our Phase 2 trial for ubenimex in PAH is called LIBERTY (A Randomized, Double-BLInd, Placebo-Controlled Study of uBEnimex in Patients with PulmonaRy ArTerial HYpertension) and is planned to enroll a total of approximately 45 patients with PAH in multiple centers. The trial will assess activity of ubenimex combined with standard of care treatment for PAH versus placebo combined with standard of care treatment for PAH. The primary endpoint will be a measure of change in pulmonary vascular resistance, or PVR, with secondary endpoints based on hemodynamic changes and exercise tolerance tests, including a six minute walk. Based on the proposed mechanism of action of ubenimex as a potential anti-proliferative, anti-inflammatory and disease modifying agent, dosing in the LIBERTY trial will be six months, which we believe will be sufficient time to demonstrate activity. First patient was dosed in LIBERTY in July 2016. We anticipate 6 months dosing to be completed by end of 2017.

Ubenimex for Lymphedema

A study conducted at Stanford demonstrated that LTB4 is elevated in both animal models of lymphedema and human lymphedema. Elevated LTB4 is associated with tissue inflammation and impaired lymphatic function. Targeted pharmacologic inhibition of LTB4 promotes physiologic lymphatic repair and reverses lymphedema disease in treated animals.

Researchers at Stanford demonstrated a novel function of LTB4 in the pathogenesis of lymphedema suggesting that blocking the effects of LTB4 may be a promising and potentially safe new therapeutic strategy for this disease. We intend to conduct a clinical study to explore if blocking the effects of LTB4 may be useful as a new treatment for lymphedema.

Lymphedema Disease Overview

About Lymphedema

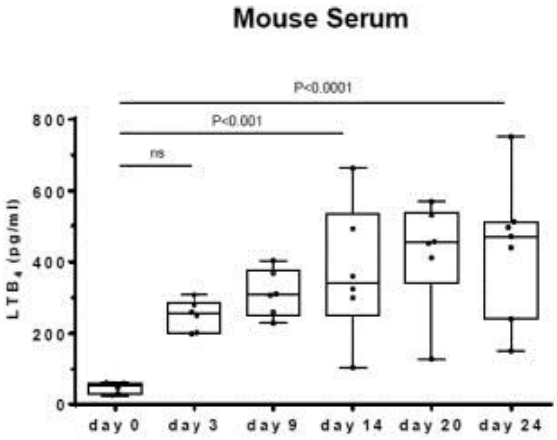
Lymphedema is the build-up of fluid in soft body tissues when the lymph system has been damaged or blocked. It is characterized by swelling due to abnormal transport of lymphatic fluid and thickening or hardening of the skin in affected areas. As fluid builds up, swelling occurs, usually in an arm or a leg, but can also affect other parts of the body. Lymphedema often causes long-term physical, psychological and social problems for patients and significantly impacts quality of life. There are currently no approved pharmacological treatments for lymphedema and the unmet medical need is high.

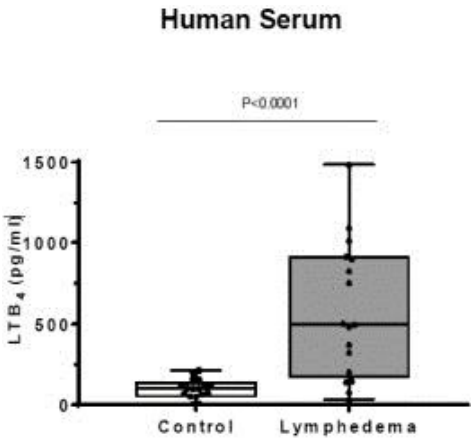
Lymphedema can be either primary, meaning it is congenital or occurs on its own, or secondary, meaning it is caused by another disease or condition. Primary lymphedema is caused by the absence of certain lymph vessels at birth or by abnormalities in the lymphatic vessels. It can be divided into three forms, depending on age of onset. The prevalence of primary lymphedema is less than 200,000 in the United States and less than 5 in 10,000 in the European Union, and expected to be eligible for orphan drug designation by regulatory authorities. Secondary lymphedema usually develops as a result of a blockage or interruption that alters the flow of lymph through the lymphatic system and can develop from an infection, malignancy, surgery, scar tissue formation, trauma, radiation, or other cancer treatment.

Primary lymphedema and secondary lymphedema can both be debilitating disorders with negative impact on quality of life and a large unmet medical need exists for an effective therapy. There is no approved pharmacologic treatment for lymphedema. Available treatments include compression garments, massage and exercise. Several agents such as coumarin have been tested in investigator-initiated clinical trials but have shown no clinical efficacy.

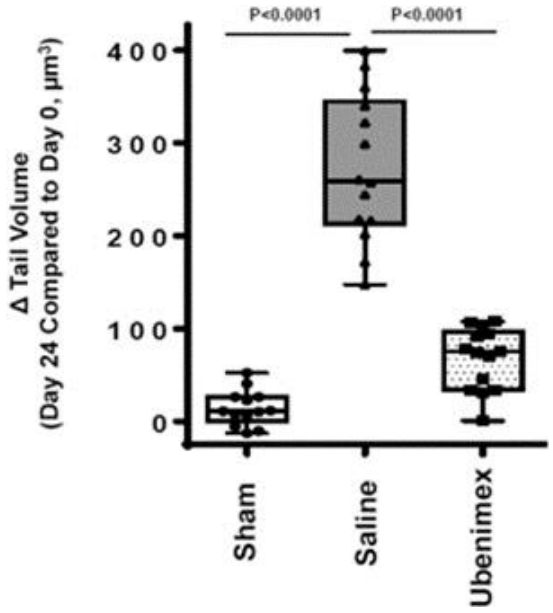
Preclinical LTB4 Data in Lymphedema

An animal model of lymphedema was used to mimic the physiological changes seen in lymphedema patients. In this model, acquired lymphedema was surgically induced in the tails of mice through the ablation of lymphatic trunks. As the tail volume increases, there is an accumulation of fibroblasts, fat cells and skin cells in the tail, and poor clearance of immune cells from the tail. As lymphedema is established in this model, the levels of LTB4 in serum rise significantly. For surgical controls (sham animals), skin incision alone was performed without lymphatic cautery. Normal controls did not go under any surgical manipulation. When serum from human lymphedema patients was examined, the LTB4 levels were also significantly ($p<0.0001$) elevated compared to normal controls (control n=18, lymphedema patients n=8).

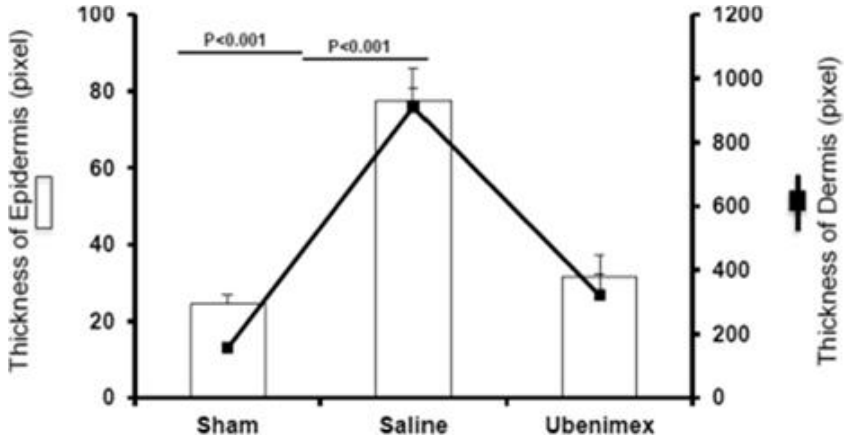




In animal models, ubenimex significantly reduced tail volume ($p<0.0001$, sham n=13, saline n=14, ubenimex n=14). Sham surgery (placebo surgery) is a faked surgical intervention that omits the step thought to be therapeutically necessary. In clinical trials of surgical interventions, sham surgery is an important scientific control. This is because it isolates the specific effects of the treatment as opposed to the incidental effects caused by anesthesia, the incisional trauma, pre- and postoperative care, and the patient's perception of having had a regular operation. Thus, sham surgery serves an analogous purpose to placebo drugs, neutralizing biases such as the placebo effect.



Ubenimex reversed lymphedema-induced tissue remodeling in animal models. Thickness of both the epidermis and dermis were reduced.



Our Planned Solution: Ubenimex for Lymphedema

Clinical Plan

We in-licensed ubenimex from Nippon Kayaku in 2015 and have relied on Nippon Kayaku's prior Phase 1 clinical data and experience with ubenimex to understand safety. We submitted a U.S. IND in January 2016 for ubenimex in lymphedema. We filed an additional IND for ubenimex in lymphedema with FDA in December 2015. Our Phase 2 clinical proof of concept trial for ubenimex in lymphedema is called ULTRA (Ubenimex Lymphedema Trial to Restore Activity). The trial is expected to enroll approximately 40 patients at Stanford with a goal to assess activity of ubenimex versus placebo. The primary endpoint is a measure of change in skin fold thickness from baseline. Secondary endpoints include change in limb volume from baseline and patient reported outcomes, including quality of life. Based on the proposed mechanism of action of ubenimex, as a potential anti-proliferative and a potential disease modifying agent, dosing in the planned trial is expected to be six months, which we believe represents sufficient time to demonstrate activity. First patient was dosed in July 2016. We plan to complete enrollment during the second half of 2017.

Manufacturing

We currently contract with third parties for the manufacturing of all of our product candidates for preclinical and clinical studies and intend to do so in the future. We do not own or operate manufacturing facilities for the production of clinical trial quantities of our product candidates and have no plans to build our own clinical or commercial scale manufacturing capabilities. We believe that the use of contracted manufacturing organizations, or CMOs, eliminates the need for us to directly invest in manufacturing facilities and equipment and additional staff. Although we rely on contract manufacturers, our personnel and consultants have extensive manufacturing experience overseeing our CMOs.

To date, our third-party manufacturers have met the manufacturing requirements for the product candidates. We expect third-party manufacturers to be capable of providing sufficient quantities of our product candidates to meet anticipated full scale commercial demands but have not assessed these capabilities beyond the supply of clinical material. We plan to identify commercial contract manufacturers as we move our product candidates to Phase 3 clinical trials. We believe there are alternate sources of manufacturing that could be identified and enabled to satisfy our clinical and commercial requirements, however, we cannot be certain that identifying and establishing alternative relationships with such sources can be successful, cost effective, or completed on a timely basis without significant delay in the development or commercialization of our product candidates.

Lonafarnib (LNF)

The drug product for completed LNF Phase 2 clinical studies for the treatment of HDV was manufactured by Merck. We have successfully completed the technology transfer for manufacture of the LNF drug substance and the LNF drug product to our third-party manufacturers. All future clinical trials will be conducted with product manufactured by these CMOs.

PEGylated Interferon Lambda (Lambda)

We have completed the technology transfer from the licensor, BMS for our PEGylated Interferon Lambda product. As part of the license agreement, sufficient inventory of drug substance and drug product was obtained to complete our Phase 2 and initiate our Phase 3 clinical trials. We have initiated start-up activities at a new drug product facility and expect to complete the first GMP campaign in 2017. The drug substance CMO remains the same CMO contracted by BMS and no changes are anticipated for the drug substance manufacturing process.

Exendin 9-39

The drug product for exendin 9-39 for the treatment of PBH for Phase 2 clinical studies is manufactured by a third-party CMO.

Ubenimex

Nippon Kayaku manufactures the drug substance and drug product for ubenimex Phase 2 clinical studies for the treatment of PAH and lymphedema. We are in the process of transferring the drug substance process from Nippon Kayaku to our CMO. We have successfully manufactured a new formulation for the drug product which is intended to improve dosing compliance and reduce capsule burden. This new formulation will be introduced into our Phase 2 Open Label Extension for PAH and ultimately the Phase 3 clinical trial and commercial materials.

Intellectual Property

We strive to protect those proprietary technologies we believe are important to our business. We seek and maintain, where available, patent protection for our product candidates including: composition of matter, method(s) of use, and process patents covering manufacture and/or formulation. We have also licensed patents and patent applications that cover certain of our product candidates and/or their manufacture, use, or formulation.

We also rely, or plan to rely, on regulatory exclusivity, including orphan drug designation and New Chemical Entity (NCE) and Biologic License Application (BLA) exclusivities, as well as trade secrets and carefully monitor our proprietary information to protect all aspects of our business.

We plan to continue to expand our intellectual property portfolio by filing patent applications on new dosage forms, methods of treatment, and compositions of matter for our product candidates. We file and prosecute patent applications in the United States and Europe, and when appropriate, additional countries, including Japan, Korea and China.

Our success will depend significantly upon our ability to: (i) obtain and maintain patents and other exclusivity protections for commercially important technology, inventions and know-how related to our business; (ii) prosecute our patent applications to issue as patents and defend and enforce our patents; (iii) maintain our licenses to use intellectual property owned by others; (iv) preserve the confidentiality of our trade secrets, and (v) operate without infringing the valid and enforceable patents and other proprietary rights of others. In addition to maintaining our existing proprietary assets, we seek to strengthen our proprietary positions when economically reasonable to do so. Our ability to augment our proprietary position relies on its: (i) know-how; (ii) ability to access technological innovations, and (iii) ability to in-license technology when appropriate.

The patent positions of pharmaceutical/biotechnology companies like us are generally uncertain and involve complex legal, scientific, and factual issues. In addition, the scope claimed in a patent application can be significantly reduced during the patent prosecution process before any patent issues. After issuance of a patent, if the

issued patent is challenged, then the courts can redefine the scope of the patent, including by invalidating some or all of the patent claims, or rendering the patent unenforceable in its entirety. Consequently, we do not know with certainty whether patents will issue in each country where we or our licensors file patent applications, or if those patent applications, if ever issued, will issue with claims that cover our product candidates, or, even if they do issue, whether the patent or its relevant claims will remain enforceable upon challenge. Accordingly, we cannot predict with certainty whether the patent applications we are currently pursuing will issue as patents in a particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from potential competitors to make any of our products commercially successful. Any of our patents, including already issued in-licensed patents or any patents that may issue to us or our licensors in the future, could be challenged, narrowed, circumvented, or invalidated by third parties. Newly filed patent applications in the United States Patent and Trademark Office, or the USPTO, and certain other patent offices are maintained in secrecy for a minimum of 18 months, and publications of discoveries in the scientific or patent literature often lag far behind the actual discoveries themselves. Further, the date of an invention is typically not publicly disclosed. For these reasons, we cannot be certain that inventions claimed in pending patent applications were not invented by another party prior to our invention, or claimed in a patent application filed before the effective filing date of our applications, in either of which case the claims may not be patentable to us. For certain applications with an effective filing date prior to March 13, 2013, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention. Also, while we are not currently participating in any interferences or post-grant challenge proceedings, such as patent oppositions, post-grant reexamination proceedings, inter parties review proceedings and patent litigation, that seek to invalidate claims of pending patent applications or issued patents, we may have to participate in such proceedings in the future. Such proceedings could result in substantial cost, even if the eventual outcome is favorable to us.

The term of individual patents depends upon the legal term of the patents in the countries where they are issued. In most countries, the standard patent term for inventions relating to human drugs and their formulation and use is 20 years from the date of filing the first non-provisional patent or international application under the Patent Cooperation Treaty of 1970, or the PCT.

Patent Protection of Our Product Candidates

Our product candidates and/or their uses in one or more indications of interest to us are covered by in-licensed patents and patent applications and by our own patent applications.

Lonafarnib (LNF). We have in-licensed from Merck a portfolio of patents covering the compound, formulations of the compound, and synthesis, but these expire before the anticipated launch date of the LNF product candidate. We have a PCT application that claims the use of LNF in combination with RTV and/or optionally other drugs for the treatment of HDV infection that has matured into patent applications in at least the United States, the European Patent Office, or the EPO, Japan, Korea and China. Any patents that issue from this these applications will expire in 2035, but a patent term extension (as described below) of up to 5 years is available in the United States, and we expect LNF to be eligible for this additional protection. In addition, we expect LNF to be eligible for NCE status, and LNF has been granted orphan drug designation by the FDA and the EMA in this indication, which respectively provide five, seven and ten years of regulatory exclusivity.

We have filed two additional PCT applications, one relating to methods for treating HDV with LNF in combination with Ritonavir and the other for the combination drug products useful in such methods. The PCT is an international patent law treaty that provides a single PCT application can be converted into a patent application in any of the more than 145 PCT contracting states, providing a cost-effective means for seeking patent protection in numerous regions or countries. Conversion of a PCT application into an application in any of the contracting states typically occurs about 30 months after a priority application is filed, or about 18 months after the PCT application filing date. An applicant must undertake prosecution within the allotted time in the patent offices of any, or a combination, of the contracting states or in a regional patent office it determines to undertake patent issuance in protection in such country or territory. We have not yet determined the countries in which we will pursue potential patent protection from this PCT application, but even if we determine to make such filings, our efforts may not result in the issuance of patents as a result.

Pegylated interferon-lambda (Lambda). We have in-licensed from BMS a portfolio of patents relating to the manufacture, use, and compositions of interferon Lambda modified by polyethylene glycol derivatization (Lambda). The key United States composition of matter patent in this portfolio expires in 2025, but we expect to be eligible for the full 5 years of patent term extension for that patent. In addition, we expect Lambda to be filed under a BLA and so Lambda would be eligible for 12 years reference product exclusivity (4 years in filing exclusivity; 12 years for data), as well as orphan drug exclusivity in this indication. We also filed a PCT application relating to the use of Lambda in HDV.

Exendin 9-39. We have in-licensed from Stanford two PCT applications that claim the use of exendin 9-39 and other agents in the treatment of hypoglycemia associated with bariatric surgery, including in PBH. Any patents that issue from these PCT applications will expire in 2036 without extension and will be eligible for patent term extension of up to 5 years is available in the United States. Exendin 9-39 to be eligible for orphan drug designation exclusivity in this indication, which as noted above provides seven years and twelve years of regulatory exclusivity in the United States and Europe, respectively.

Ubenimex.

PAH. We have in-licensed from Stanford issued U.S. Patent No. 9,233,089 and a corresponding pending EPO application that claim the use of ubenimex and other agents in the treatment of PAH; a continuation application of the U.S. patent is also pending. We have also in-licensed from Nippon Kayaku the exclusive right outside Asia to access its regulatory dossier for ubenimex, which we believe to be a significant competitive advantage. U.S. Patent No. 9,233,089 (and from any patent that issues in the EPO or from any U.S. continuation) will expire in 2033. The U.S. patent may be eligible for patent extension of up to 5 years in the United States. Ubenimex is eligible for orphan drug designation exclusivity in this indication.

Lymphedema. We have also in-licensed from Stanford a PCT application that claims the use of ubenimex and other agents in the treatment of lymphedema. This PCT is not due for nationalization until 2017, and if nationalized and issued, any patents that result from this PCT filing would expire in 2036. Any US patent may be eligible for patent extension of up to 5 years in the United States.

Regulatory Exclusivity and Patent Term Extension. If ubenimex is approved in any indication, it would be entitled to NCE exclusivity, which would provide for five years of regulatory exclusivity for the approved product. In addition, the FDA has granted orphan drug designation to ubenimex for the treatment of PAH, and we are seeking orphan drug designation for ubenimex for the treatment of lymphedema. Orphan drug designation, if obtained, may provide seven years of regulatory exclusivity for each indication upon NDA approval. However, patent term extension, as described below, will be available only for the first of the two indications to be approved.

Patent Term

In the United States, the patent term for an FDA-approved drug may be eligible for a patent term extension, or a PTE. The Hatch-Waxman Act of 1984 permits restoration of a portion of the patent term of a U.S. patent as compensation for the patent term lost during product development and the FDA regulatory review process if approval of the application for the product is the first permitted commercial marketing of a drug or biological product containing the active ingredient. The length of the PTE is based on the length of time it takes for the drug to complete the pre-market regulatory approval requirements. The time required for approval of a NDA or BLA and 50% of the time spent in testing phase, reduced by any periods of lack of diligence, are credited up to a maximum five year extension. The PTE cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent per approved drug may be extended and a patent can only be extended once; thus, even if a single patent is applicable to multiple products, it can only be extended based on one product.

Similar provisions to extend the term of a patent that covers an approved drug may be available in certain other foreign jurisdictions. For example, in Europe, a supplementary protection certificate (SPC), if granted, may extend certain patent rights for up to 5 years. In addition, in Europe, marketing approval obtained through the European Medicines Agency (EMA) may provide a period of ten years of regulatory data exclusivity from the time of approval. When possible, depending upon the length of clinical trials and other factors involved in the filing of NDAs and BLAs for our products, we expect to apply for patent term extension for patents covering our product candidates and their methods of use both in the United States and any foreign jurisdiction where available. There is no guarantee, however, that the applicable authorities will agree to grant extensions, and if granted, what the length of those extensions will be.

Other Proprietary Rights and Processes

We also rely on trade secret protection for some of our confidential and proprietary information. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business, scientific, development or financial affairs that are either developed or made known to the individual during the course of the individual's relationship with us are to be kept confidential and not disclosed to third parties except in specific circumstances. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets and disclose our technology. If these events happen, we may not be able to meaningfully protect our trade secrets.

Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or based on the employee's use of our confidential information are our exclusive property or that we have an exclusive royalty free license to use such technology.

Competition

The biopharmaceutical industry is highly competitive. We face competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Given the significant unmet medical need for novel therapies to treat chronic hepatitis delta infection, post-bariatric surgery-induced hypoglycemia associated with bariatric surgery, PAH and lymphedema, these conditions are where various treatments from many companies are used and where many public and private universities and research organizations are actively engaged in the discovery, research and development of product candidates. As a result, there are and will likely continue to be extensive resources invested in the discovery and development of new products to treat these unmet medical needs. We anticipate facing intense and increasing competition as new products enter the market and advanced technologies become available.

In addition, there are numerous multinational pharmaceutical companies and large biotechnology companies currently marketing or pursuing the development of products or product candidates targeting the same indications as our product candidates. Many of our competitors, either alone or with strategic partners, have or will have substantially greater financial, technical and human resources than us. Accordingly, our competitors may be more successful than us in developing or marketing products and technologies that are more effective, safer or less costly. Additionally, our competitors may obtain regulatory approval for their products more rapidly and may achieve more widespread market acceptance. Accelerated mergers and acquisitions activity in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These companies also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical study sites and patient registration for clinical studies and acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our potential competitors and the related stage of development of their product candidates in target indications is as follows:

- Hepatitis delta virus: Replicor, Inc. (Phase 2), Hepatera Ltd (Phase 2) and Alnylam Pharmaceutical, Inc. (preclinical);
- Hypoglycemia associated with bariatric surgery: Xoma Corporation (Phase 2);
- Pulmonary arterial hypertension: Reata Pharmaceuticals, Inc. (Phase 2), Arena Pharmaceuticals (Phase 2), and United Therapeutics Corporation (Phase 1);
- Lymphedema: Novartis (Phase 2).

There are other therapies that are used or may be used for our targeted indications, however, we do not believe that these therapies are potentially curative for our targeted indications. For example, there are a number of therapies used for symptomatic relief of PAH such as calcium channel blockers and diuretics as well as vasodilators. Other

products in clinical development or marketed for other indications may be used in competition with our product candidates if we are able to identify potential market opportunities of interest. For example, HDV has not been generally identified as a target for development compared to hepatitis B or hepatitis C, and products on the market or in development for those indications may potentially be tested in HDV as the understanding of the potential medical need for therapies in this indication become more widely understood.

We believe that the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety and tolerability profile, convenience in dosing, product labeling, cost-effectiveness, price, the level of generic competition and the availability of reimbursement from the government and other third-parties. Our commercial opportunity could be reduced or eliminated for any of our products if our competitors have products that are approved earlier than our product candidates or are superior compared to our product candidates or if our product candidates do not result in an improvement in condition compared to those other products.

License and Asset Purchase Agreements

License Agreement with Merck

In September 2010, we entered into an exclusive license agreement with Schering Corporation, subsequently acquired by Merck & Co., Inc., or Merck, which provides us with the exclusive right to develop and commercialize lonafarnib. As consideration for such exclusive right, we issued Private Eiger convertible preferred stock with a fair value of $0.5 million when the agreement was executed in September 2010. This preferred stock was converted to 27,350 shares of common stock upon the Merger. In addition, we are obligated to pay Merck up to an aggregate of $27.0 million in development milestones and will be required to pay tiered royalties based on aggregate annual net sales of all licensed products ranging from mid-single to low double-digit royalties on net sales. Our obligation to pay royalties to Merck expires on a country-by-country and product-by-product basis on the later of the expiration of the last to expire patent assigned to us under the agreement, which is estimated to be in December 2016; or on the tenth anniversary of the first commercial sale of the product. In May 2015, the first regulatory milestone was achieved and we paid the related milestone payment of $1.0 million to Merck. The amount was recorded as a charge to research and development expense during the year ended December 31, 2015. No additional charges were recorded during the year ended December 31, 2016.

The Merck License will continue for so long as we owe royalty payments to Merck under the agreement. Each party has the right to terminate the Merck License Agreement for the other party’s uncured material breach or bankruptcy. Merck also has the right to terminate the agreement if we discontinue development and commercialization of LNF for a specified period of time. In addition, we have the right to terminate the agreement, with notice, for any reason.

Asset Purchase Agreement with Eiger Group International, Inc.

In December 2010, we entered into an Asset Purchase Agreement with Eiger Group International, Inc., or EGI, dated December 8, 2010, or the EGI APA. Dr. Jeffrey Glenn is the sole owner of EGI.

Under the EGI APA, we purchased all the assets including intellectual property rights related to the use of farnesyl transferase inhibitors as anti-viral agents and methods to treat viral infection with those inhibitors. We also purchased all assets including intellectual property rights related to the use of inhibitors of prenylation, prenyl cysteine methyltransferase, and a specified protease as anti-viral agents and methods to treat viral infection with those inhibitors. We are obligated to use commercially reasonable efforts to develop and commercialize the licensed products in major markets.

Under the EGI APA, we paid EGI an upfront payment of $0.4 million. Additionally, we are obligated to pay EGI a low single-digit royalty based on aggregate annual net sales of products developed using the intellectual property. Within the first ten years after commercialization, we may make a one-time payment of $0.5 million for each contract for the three types of product related to such intellectual property that would reduce the payment term for the three products to the tenth anniversary of the first commercial sale. The obligation to pay royalties expires on a country-by-country and product-by-product basis on the later of either when the product is no longer sold in any country or the earliest of the tenth anniversary of the first commercial sale of the product.

The term of the EGI APA extends until expiration of all payment obligations, and we may terminate the agreement upon notice to EGI. EGI may terminate the EGI APA if we fail to use commercially reasonable efforts to develop and commercialize licensed products. In addition, each party may terminate the EGI APA for the other party's uncured material breach or bankruptcy. In the event of any termination, other than termination by us for EGI's breach, we will assign the purchased assets back to EGI.

In November 2012, we entered into an agreement with EGI whereby we sold all of the assets related to the compound clemizole, including any related intellectual property. EGI is obligated to pay to us a high single-digit royalty on future aggregate annual net sales, subject to certain reductions and exceptions. EGI's obligation to pay royalties expires on a country-by-country and product-by-product basis on the later of either expiration of the last to expire patent sold to EGI under the agreement or the earliest of the tenth anniversary of the first commercial sale of the product.

License Agreement with Janssen Pharmaceutica NV

In December 2014, we, through our wholly-owned subsidiary EB Pharma, LLC, or EBP, entered a License Agreement, or the Janssen License Agreement, with Janssen Pharmaceutica NV, or Janssen, dated December 19, 2014.

Under the Janssen License Agreement, Janssen granted us an exclusive, worldwide, license to develop, manufacture, and sell products containing the compound tipifarnib for all therapeutic and diagnostic uses in humans, including any such uses for human virology diseases, but excluding oncology diseases.

We are responsible for the development of at least one product in a major market country and for commercialization of products in all countries where necessary authorization is obtained, both at our cost and expense. We may manufacture, develop, and commercialize the products itself or we may grant one or more sublicenses for such purposes. However, for a period of time following completion of the proof of concept trial, Janssen has a first right of negotiation for an exclusive license back from us to develop and commercialize tipifarnib in any country in the world.

Under the Janssen License Agreement, we are obligated to make development milestone payments in aggregate of up to $38.0 million, sales milestone payments in aggregate of up to $65.8 million, and pay a tiered royalty, ranging from the mid single to low double digits, based on aggregate annual net sales of all licensed products. If we grant a sublicense, we are obligated to pay Janssen a portion of the sublicensing income received. As of December 31, 2016, the product has not reached commercialization and no milestones have been paid.

The Janssen License Agreement will continue for so long as we owe royalty payments to Janssen under the agreement or for so long as there is a valid patent claim under the agreement, whichever is longer. Both parties have the right to terminate the agreement for the other party's uncured material breach of the agreement or for the other party's bankruptcy. Janssen also has the right to terminate the agreement if we fail to meet certain specified diligence obligations. In addition, we have the right to terminate the agreement without cause at any time.

License Agreement with Nippon Kayaku Co., Ltd.

In May 2015, Eiccose, LLC, or Eiccose, and Nippon Kayaku Co., Ltd, or NK, entered into a License Agreement, or NK License, dated May 1, 2015 pursuant to which NK granted Eiccose an exclusive license to develop, manufacture, and sell ubenimex outside certain identified Asia countries, including Japan, for the treatment of PAH and other inflammatory disease involving leukotriene B4. Eiccose assigned the NK License to us as part of the Eiccose asset purchase described below.

Under the NK License, we are responsible for the development and commercialization of ubenimex in our territory at our cost and expense. We will purchase ubenimex for development and commercial use from NK at agreed transfer prices under a separate supply agreement, but we have the option to manufacture and supply the product for Phase 3 studies and/or commercial use. If we exercise the manufacturing option, NK will transfer the manufacture of the product to us or our contract manufacturer, at our cost and expense, and we will pay NK a running, mid single-digit royalty on the net sales of ubenimex sold in our territory or, if the parties agree, a lump-sum payment, for the use of NK's manufacturing know-how.

Under the NK License, we also granted back to NK an exclusive license to develop, manufacture, and sell ubenimex for the treatment of PAH and other inflammatory disease involving leukotriene B4 in the Asia countries comprising the NK territory. NK is responsible for the development and commercialization of ubenimex in the licensed indications in its territory at its own cost and expense. NK will pay us a running, mid single-digit royalty on net sales of ubenimex in the specified indications in NK's territory.

The NK License Agreement will continue for so long as the parties and their sublicensees continue to develop and commercialize ubenimex for the treatment of PAH and other inflammatory disease involving leukotriene B4. Both parties have the right to terminate the agreement for the other party's uncured material breach, and NK also has the right to terminate the agreement if we fail to meet certain specified diligence obligations. In addition, the parties may terminate the agreement if further development of the product is commercially, financially, or otherwise not advisable.

Asset Purchase Agreement with Tracey McLaughlin and Colleen Craig

In September 2015, we entered into an Asset Purchase Agreement with two individuals, Dr. Tracey McLaughlin and Dr. Colleen Craig, or the Sellers, dated September 25, 2015, or the Exendin APA. We also entered into a consulting agreement with the Sellers as part of the agreement.

Under the Exendin APA, we purchased all the assets and the intellectual property rights related to the compound exendin 9-39 from the Sellers, including an assignment of a license agreement with Stanford which covered exclusive rights with respect to the compound exendin 9-39. Under the assigned Stanford exclusive license agreement, we are obligated to pay Stanford a low, single-digit royalty on net sales after the first commercial sale of any product developed based on exendin 9-39.

Under the Exendin APA, we are obligated to pay a development milestone payments in aggregate up to $1.0 million to each of the Sellers and a low, single-digit royalty based on aggregate annual net sales of all products developed based on exendin 9-39 subject to certain reductions and exceptions. Our obligation to pay royalties expires on the expiration of the last to expire patent assigned to us under the agreement. We also agreed to retain each of the Sellers pursuant to a consulting agreement with a term of one year, subject to annual renewal. The consulting agreement with Dr. Tracey McLaughlin was extended during the year ended December 31, 2016. The consulting agreement with Dr. Colleen Craig was not extended during the year ended December 31, 2016. As of December 31, 2016, the product has not reached commercialization and no milestones have been paid.

Asset Purchase Agreement with Eiccose, LLC

In October 2015, we entered into an asset purchase agreement with Eiccose, LLC., or Eiccose, whereby Eiccose sold all of the assets related to the treatment of pulmonary arterial hypertension, or PAH, treatment of lymphedema and products containing ubenimex for the treatment of disorders involving LTB4, and any related intellectual property to us (the "Eiccose APA"). David Cory, the President, Chief Executive Officer and director of ours, is the sole managing member and significant equity interest holder of Eiccose. We made a payment to Eiccose of $0.1 million representing reimbursement of certain previously incurred expenses, including payments and accrued amounts owed to Stanford in connection with the license agreement for the treatment of Lymphedema and the license agreement for the treatment of PAH. The Eiccose APA also provided that, upon a next round of financing pursuant to which we sold shares of capital stock resulting in gross proceeds of at least $25.0 million, we would issue to Eiccose fully vested shares of our common stock equal to 1.75% of the total number of our outstanding capital stock, before Merger. In October 2015, we recorded $1.5 million in research and development expenses and a corresponding liability representing the fair value of our obligation to issue common stock to Eiccose.

On March 22, 2016, we issued to Eiccose 96,300 fully vested shares of common stock pursuant to the terms of the Eiccose APA. In connection with this transaction we remeasured the fair value of the obligation to issue common stock at the settlement date and the change in fair value of $0.2 million was recognized within other expense, net in the consolidated statement of operations during the year ended December 31, 2016. Upon the settlement of the obligation with the issuance of shares on March 22, 2016, the liability was reclassified to common stock and additional paid-in capital within stockholders' equity.

We are also obligated to pay to Eiccose an aggregate of up to a maximum of $10.0 million of commercial milestones in connection with future sales of the product and royalties in the low single-digits based on aggregate annual net sales following the first commercial sale of any product. As of December 31, 2016, the product has not reached commercialization and no milestones have been paid.

Exclusive Agreement with the Board of Trustees of the Leland Stanford Junior University—Lymphedema

In October 2015, as part of the assets we purchased from Eiccose, we acquired and were assigned an Exclusive Agreement, or the Stanford Lymphedema Agreement, between Eiccose and the Board of Trustees of Stanford dated October 27, 2015.

Under the Stanford Lymphedema Agreement, Stanford granted us an exclusive, worldwide license under specified patent rights related to the treatment of lymphedema, to manufacture, use, and sell products covered by the licensed patents for all uses.

We are responsible for the development and commercialization of any products under the license at our cost and expense, and are obligated to use commercially reasonable efforts to achieve certain specified milestones. In consideration of the license, we paid to Stanford a low, single-digit equity interest and are obligated to make development and commercial milestone payments in aggregate of up to $0.5 million as well as a low, single-digit royalty on net sales of any products. As of December 31, 2016, the product has not reached commercialization and no milestones have been paid.

Stanford may terminate the agreement for our uncured material breach or bankruptcy. Stanford also has the right to terminate the agreement if we fail to develop and commercialize products in accordance with certain specified diligence obligations. We have the right to terminate the agreement without cause at any time.

Exclusive Agreement with the Board of Trustees of the Leland Stanford Junior University—PAH

In October 2015, as part of the assets we purchased from Eiccose, we also acquired an Exclusive Agreement between Eiccose and Stanford, dated May 1, 2015, or the Stanford PAH Agreement.

Under the Stanford PAH Agreement, Stanford granted us an exclusive, worldwide license under specified patent rights related to the treatment of PAH and improved right ventricle function, to manufacture, use, and sell products covered by the licensed patents for all uses. Stanford and other non-profit research institutions retain the right to practice under the licensed patents for any non-profit purpose.

We are responsible for the development and commercialization of the products at our cost and expense, and are obligated to use commercially reasonable efforts to achieve certain specified milestones. We may satisfy these requirements our self, through our affiliates, or through granting one or more sublicenses. We are obligated to give Stanford a low, single-digit equity interest, make development and commercial milestone payments in aggregate of up to $0.5 million, and pay a low, single-digit royalty on net sales of the products. If we grant a sublicense, we will pay Stanford a portion of the sublicensing income received.

Stanford may terminate the agreement for our uncured material breach or bankruptcy. Stanford also has the right to terminate the agreement if we fail to develop and commercialize products in accordance with certain specified diligence obligations. We have the right to terminate the agreement, with notice, for any reason.

License Agreement with Bristol-Myers Squibb Company

In April 2016, we entered into a License Agreement, or the BMS License Agreement, and a Common Stock Purchase Agreement, or BMS Purchase Agreement, with Bristol-Myers Squibb Company, or BMS, dated April 20, 2016.

Under the BMS License Agreement, BMS granted us an exclusive, worldwide, license to research, develop, manufacture, and sell products containing the proprietary BMS molecule known as PEG-interferon Lambda-1a, or the Licensed Product, for all therapeutic and diagnostic uses in humans and animals.

We are responsible for the development and commercialization of the Licensed Product at our sole cost and expense. In April 2016, under the BMS License Agreement we paid an upfront payment of $2.0 million in cash and issued 157,587 shares of our common stock to BMS with an aggregate fair value of $3.2 million. The BMS Purchase Agreement grants BMS certain registration rights with respect to the shares of common stock delivered, and BMS has agreed to certain trading and other restrictions with respect to the shares purchased.

Under the BMS License Agreement, we are obligated to make development and regulatory milestone payments totaling $61.0 million and commercial sales milestones of up to $128.0 million after the achievement of specified milestones. We are also obligated to pay BMS annual net sales royalties in the range of mid-single to mid-teens, depending on net sales levels. If we grant a sublicense, we are obligated to pay BMS a portion of the sublicensing income received. As of December 31, 2016, the product has not reached commercialization and no milestones have been paid.

Government Regulations and Product Approvals

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, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import and export of pharmaceutical products such as those we are developing. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

FDA Approval Process

All of our current product candidates are subject to regulation in the United States by the FDA under the Federal Food, Drug, and Cosmetic Act, or FDC Act, and it's implementing regulations. Our Lambda product candidate is additionally subject to regulation as a biologic under the Public Health Service Act. The FDA subjects drugs and biologics to extensive pre and post market regulation. Failure to comply with the FDC Act and other federal and state statutes and regulations may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, BLAs, withdrawal of approvals, clinical holds, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal penalties.

FDA approval is required before any new biologic, drug or dosage form, including a new use of a previously approved drug, can be marketed in the United States. The process required by the FDA before a new drug may be marketed in the United States is long, expensive, and inherently uncertain. Drug development in the United States typically involves completion of preclinical laboratory and animal tests, submission to the FDA of an Investigational New Drug application, or IND, which must become effective before clinical testing may commence, approval by an independent institutional review board, or IRB, at each clinical site before each trial may be initiated, performance of adequate and well controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought, submission to the FDA of an NDA or BLA, satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced, and FDA review and approval of the NDA or BLA. Developing the data to satisfy FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product, disease or indication.

Preclinical tests include laboratory evaluation of the product's chemistry, formulation, and toxicity, as well as animal studies to characterize and assess the potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practice, or GLP, regulations. These preclinical results are submitted to the FDA as part of an IND along with other information, including information about the product's chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long term preclinical studies including reproductive toxicity and carcinogenicity may be initiated or continue after the IND is submitted.

An IND must become effective before United States clinical trials may begin. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the IND automatically becomes effective and the clinical trial proposed in the IND may begin. If the FDA does raise any concerns or questions and places the clinical trial on a clinical hold, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, a submission of an IND may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development.

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations, including good clinical practice, or GCP, requirements for conducting, monitoring, recording and reporting the results of clinical trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials; and (ii) with protocols that detail, among other things, the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to and approved by an IRB at each study site before the study commences at that site and the IRB must monitor the clinical trial until it is completed. An IRB may also require the clinical trial at that site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements or if the drug candidate has been associated with unexpected serious harm to patients, or the IRB may impose other conditions. The study sponsor or the FDA may also suspend or discontinue a clinical trial at any time on various grounds, including a determination that the subjects are being exposed to an unacceptable health risk.

Clinical trials to support an NDA or BLA for marketing approval are typically conducted in three sequential phases, although there is leeway to overlap or combine these phases.

- ***Phase 1***. The drug candidate is initially introduced into healthy human subjects or patients with the target disease or condition, and is tested to assess safety, dosage tolerance, pharmacokinetics and pharmacological activity, and, when possible, to ascertain evidence of efficacy. The drug candidate may also be tested in patients with severe or life-threatening diseases to gain an early indication of its effectiveness.
- ***Phase 2***. The trials are conducted using a limited patient population for the purposes of preliminarily determining the effectiveness of the drug in that particular indication, ascertaining dosage tolerance, discerning the optimal dosage, and identifying possible adverse effects and safety risks.
- **Phase 3**. If a compound demonstrates evidence of efficacy and has an acceptable safety profile in the Phase 2 clinical trials, then Phase 3 clinical trials are undertaken to obtain additional information from an expanded and diverse patient population, at multiple, geographically dispersed clinical trial sites, in randomized controlled studies often with a double-blind design to maximize the reproducibility of the study results. Typically, a minimum of two positive Phase 3 clinical trials are submitted to support the product's marketing application. These Phase 3 clinical trials are intended to provide sufficient data demonstrating evidence of the efficacy and safety of the drug such that the FDA can evaluate the overall benefit-risk of the drug and provide adequate information for the labeling and package insert for the drug. Trials conducted outside of the United States under similar, GCP-compliant conditions in accordance with local applicable laws may also be acceptable to FDA in support of product approval.

Sponsors of clinical trials for investigational drugs must publicly disclose certain clinical trial information, including detailed trial design. These requirements are subject to specific timelines and apply to most Phase 3 clinical trials of FDA-regulated products.

In some cases, FDA may condition approval of an NDA or BLA for a product candidate on the sponsor's agreement to conduct additional clinical trials after approval. In other cases, a sponsor may voluntarily conduct additional clinical trials post approval to gain more information about the drug. Such post approval trials are typically referred to as Phase 4 clinical trials.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. 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 committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the study. Phase 1, Phase 2, Phase 3 and Phase 4 clinical trials may not be completed successfully within any specified period, or at all.

Concurrent with clinical trials, companies usually finalize a process for manufacturing the drug in commercial quantities in accordance with current good manufacturing practice, or cGMP, requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug product. 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.

After completion of the required clinical testing, an NDA or BLA is prepared and submitted to the FDA requesting approval to market the drug or biologic for one or more specified indications. FDA review and approval of the NDA or BLA is required before marketing of the product may begin in the United States. The NDA or BLA must include the results of all preclinical, clinical, and other testing, including negative or ambiguous results as well as positive findings, together with other detailed information including compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The application must also contain extensive manufacturing information. The FDA reviews an NDA or BLA to determine, among other things, whether a product is safe and effective for its intended use. The cost of preparing and submitting an NDA or BLA is substantial. Under federal law, the submission of most NDAs and BLAs is subject to both a substantial application user fee and annual product and establishment user fees. These fees are typically increased annually.

The FDA has 60 days from its receipt of an NDA or BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an application for filing. In this event, the application must be resubmitted with the additional information. Once the submission is accepted for filing, the FDA begins an in-depth review.

Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has agreed to certain performance goals in the review of applications. Standard applications are generally reviewed within ten months of filing, or twelve months from submission. Although FDA often meets its user fee performance goals, the FDA can extend these timelines if necessary, and FDA review may not occur on a timely basis. The FDA usually refers applications for novel drugs, or drugs that present difficult questions of safety or efficacy, to an advisory committee—a panel of independent experts, typically including clinicians and other scientific 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 recommendation of the advisory committee, but it generally follows its recommendations. Before approving an NDA or BLA, the FDA will typically inspect one, or more, clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the product is manufactured. The FDA will not approve an application unless it verifies that compliance with cGMP requirements is satisfactory and that the manufacturing processes and facilities are adequate to assure consistent production of the product within required specifications. The FDA will not approve a product unless the application contains data showing substantial evidence that it is safe and effective in the indication studied.

After the FDA evaluates the application and conducts its inspections, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies contained in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application, including potentially significant, expensive and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. Even if such data are submitted, the FDA may ultimately decide that the NDA or BLA does not

satisfy the criteria for approval. Data from clinical trials are not always conclusive, and the FDA may interpret data differently than we do. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the application, the FDA will typically issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of additional information requested. FDA approval is never guaranteed. The FDA may refuse to approve an application if applicable regulatory criteria are not satisfied.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. The approval for a drug may be significantly more limited than requested in the application, including limitations on the specific diseases and dosages or the indications for use, which could restrict the commercial value of the product. The FDA may also require that certain contraindications, warnings, or precautions be included in the product's package insert, or labeling.

In addition, as a condition of approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guidelines, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing-including dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS or use of a companion diagnostic with a drug can materially affect the potential market and profitability of the drug. Moreover, product approval may require, as a condition of approval, substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. The FDA may also condition approval on, among other things, changes to proposed labeling or development of adequate controls and specifications.

Once granted, product approvals may be withdrawn if compliance with regulatory standards are not maintained or problems are identified following initial marketing. In addition, after approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant an orphan drug designation to products intended to treat a rare disease or condition—generally one that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting the NDA or BLA. After the FDA grants orphan drug designation, the FDA publicly discloses the drug's identity and its intended orphan use. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first active moiety to be approved to treat a disease with FDA's orphan drug designation is entitled to a seven-year period of marketing exclusivity in the United States for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same orphan indication, regardless of patent status, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or if the FDA finds that the holder of the orphan exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different chemical/biological entity for the same disease or condition. An orphan drug designation also does not preclude the same drug from being developed for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research expenses and a waiver of the application user fee.

Advertising and Promotion

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing post-approval regulatory requirements. For instance, the FDA closely regulates the post-approval marketing, labeling, advertising and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Failure to comply with these requirements can result in adverse publicity as well as significant penalties, including the issuance of warning letters directing a company to correct any deviations from the FDA's standards. The FDA may also impose a requirement that future advertising and promotional materials be pre-cleared by the FDA, and the company may face federal and/or state civil and criminal investigations and prosecutions.

Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new application or supplement before the change can be implemented. A supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing supplements as it does in reviewing NDAs or BLAs. Obtaining new indication is an important part of managing the life cycle of the drug.

Adverse Event Reporting and cGMP Compliance

Recordkeeping, adverse event reporting and the submission of periodic reports are required following the FDA's approval of an NDA or BLA. The FDA also may require post-marketing testing or Phase 4 clinical trials, REMS, or surveillance to monitor the effects of an approved drug. In addition, the FDA may place conditions on an approval that could restrict the distribution or use of the product. Furthermore, manufacture, packaging, labeling, storage and distribution procedures must continue to conform to cGMPs after approval. Manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies to assess compliance with ongoing regulatory requirements, including cGMPs. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality control to maintain compliance with cGMPs. Failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, seizure of product, injunctive action or possible civil penalties. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing FDA regulatory requirements. If we or our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, require us to recall a drug from distribution or withdraw approval of the NDA for that drug. Regulatory authorities may also withdraw product approvals, request product recalls, or impose marketing restrictions through labeling changes or product removals upon discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes.

Other Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by federal, state, and local authorities in addition to the FDA. These other agencies include, without limitation, the Centers for Medicare and Medicaid Services, other divisions of the U.S. Department of Health and Human Services, the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, as well as state and local governments. Such agencies enforce a variety of laws, including without limitation, anti-kickback and false claims laws, data privacy and security laws, and physician payment transparency laws.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the Anti-Kickback Statute has been violated.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to or approval by the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus non-reimbursable, uses. In addition, the civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

Also, many states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs.

We may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, including the final Omnibus Rule published on January 25, 2013, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, defined as service providers of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in certain circumstances, many of which differ from HIPAA and each other in significant ways and may not have the same effect, thus complicating compliance efforts.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Physician Payments Sunshine Act imposes, among other things, annual reporting requirements for covered manufacturers for certain payments and "transfers of value" provided to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties of up to an aggregate of $0.2 million per year and up to an aggregate of $1.0 million per year for "knowing failures." Covered manufacturers must submit reports by the 90th day of each calendar year. In addition, certain states require implementation of commercial compliance programs and compliance with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, impose restrictions on marketing practices, and/or tracking and reporting of gifts, compensation and other remuneration or items of value provided to physicians and other healthcare professionals and entities.

If our operations are found to be in violation of any of the health regulatory laws described above or any other laws that apply to it, we may be subject to penalties, including potentially significant criminal, civil and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

International Regulation

In addition to regulations in the United States, a variety of foreign regulations govern clinical trials, commercial sales, and distribution of drugs. Whether or not we obtain FDA approval for a drug, we or our collaborators must obtain approval of the drug by the comparable regulatory authorities of foreign countries before commencing clinical trials or marketing of the drug in those countries. The approval process varies from country to country and the time to approve may be longer or shorter than that required for FDA approval. Further, to the extent that any of our products are sold in a foreign country, we may be subject to additional foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Pharmaceutical Coverage, Pricing and Reimbursement

In the United States and other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Sales of any products for which we receive regulatory approval for commercial sale will therefore depend in part on the availability of reimbursement from third-party payors, including government health administrative authorities, managed care providers, private health insurers, and other organizations.

The process for determining whether a third-party payor will provide coverage for a drug product typically is separate from the process for setting the price of a drug product or for establishing the reimbursement rate that the payor will pay for the drug product once coverage is approved. Third-party payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the FDA-approved drugs for a particular indication. A decision by a third-party payor not to cover our product candidates could reduce physician utilization of our products once approved and have a material adverse effect on our sales, results of operations and financial condition. Moreover, a third-party payor’s decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Additionally, coverage and reimbursement for drug products can differ significantly from payor to payor. One third-party payor’s decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service, or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately and will be a time-consuming process.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost-effectiveness of drug products and medical services, in addition to questioning safety and efficacy. If these third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after FDA approval or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. By way of example, in the United States, the Affordable Care Act, or ACA, contains provisions that may reduce the profitability of drug products. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the ACA. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress also could consider subsequent legislation to replace elements of the ACA that are repealed. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products once approved or additional pricing pressures.

Research and Development Expenses

Our research and development expenses were $33.0 million, $8.1 million and $0.6 million for the years ended December 31, 2016, 2015 and 2014, respectively.

Employees

As of December 31, 2016, we had a total of 20 full-time employees in the United States, thirteen of whom were primarily engaged in research and development activities and seven of whom were engaged in general management and administration. Eight of our employees have either an M.D. or a Ph.D. None of our employees are represented by a labor union or subject to a collective bargaining agreement. We have never experienced any work stoppage and consider our relations with our employees to be good.

Corporate Information

We were originally incorporated in California in December 2000 as Celladon Corporation. In April 2012, we reincorporated in Delaware and had our initial public offering in February of 2014. On March 22, 2016, Private Eiger completed its merger with Celladon in accordance with the terms of the Merger Agreement. Pursuant to the Merger Agreement, Merger Sub merged with and into Private Eiger, with Private Eiger becoming a wholly-owned subsidiary of Celladon and the surviving corporation of the Merger. Immediately following the Merger, Celladon changed its name to “Eiger BioPharmaceuticals, Inc.” In connection with the Merger, our common stock began trading on The NASDAQ Global Market with the ticker symbol “EIGR” on March 23, 2016. Our principal executive offices are located at 350 Cambridge Avenue, Suite 350, Palo Alto, California 94306, and our telephone number is 650-272-6138. Our corporate website address is www.eigerbio.com. The contents of our website are not incorporated into this Annual Report on Form 10-K and our reference to the URL for our website is intended to be an inactive textual reference only.

This Annual Report on Form 10-K contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report on Form 10-K, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies’ trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other company.

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering in February 2014, (b) in which we have total annual gross revenue of at least $1.0 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeded $700.0 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. We refer to the Jumpstart Our Business Startups Act of 2012 in this Annual Report on Form 10-K as the “JOBS Act,” and references to “emerging growth company” have the meaning associated with it in the JOBS Act.

Item 1A. Risk Factors

You should carefully consider the following risk factors, as well as the other information in this report, and in our other public filings. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should consider all of the risk factors described when evaluating our business.

Risks Related to our Financial Condition, Integration and Capital Requirements

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

We are a clinical development-stage biopharmaceutical company with a limited operating history. We have incurred net losses in each year since our inception. For the years ended December 31, 2016, 2015 and 2014, we reported a net loss of $47.1 million, $13.3 million and $1.5 million, respectively. As of December 31, 2016, we had an accumulated deficit of approximately $76.4 million. Our prior losses, combined with expected future losses, have had and may continue to have an adverse effect on our stockholders' equity and working capital.

We believe that the currently available resources will be sufficient to fund our operations for at least the next 12 months following the issuance date of these consolidated financial statements. We will continue to require substantial additional capital to continue our clinical development and potential commercialization activities. Accordingly, we will need to raise substantial additional capital to continue to fund our operations. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on our financial condition and our ability to develop our product candidates.

We have devoted substantially all of our financial resources to identify, acquire, and develop our product candidates, including conducting clinical studies and providing general and administrative support for our operations. To date, we have financed our operations primarily through the sale of equity securities. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings, strategic collaborations, or grants. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We expect losses to increase as we advance five Phase 2 clinical development programs for potentially four indications. While we have not yet commenced pivotal clinical studies for any product candidate and it may be several years, if ever, before we complete pivotal clinical studies and have a product candidate approved for commercialization, we expect to invest significant funds into these clinical candidates to determine the potential to advance these compounds to regulatory approval.

If we obtain regulatory approval to market a product candidate, our future revenue will depend upon the size of any markets in which our product candidates may receive approval, and our ability to achieve sufficient market acceptance, pricing, reimbursement from third-party payors, and adequate market share for our product candidates in those markets. Even if we obtain adequate market share for our product candidates, because the potential markets in which our product candidates may ultimately receive regulatory approval could be very small, we may never become profitable despite obtaining such market share and acceptance of our products.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future and our expenses will increase substantially if and as we:

- continue the clinical development of our product candidates;
- in-license or acquire additional product candidates;
- undertake the manufacturing or have manufactured our product candidates;
- advance our programs into larger, more expensive clinical studies;
- initiate additional nonclinical, clinical, or other studies for our product candidates;

- identify, educate and develop potential commercial opportunities, such as hepatitis D virus biology for our LNF product candidate;
- seek regulatory and marketing approvals and reimbursement for our product candidates;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval and market ourselves;
- seek to identify, assess, acquire, and/or develop other product candidates;
- make milestone, royalty or other payments under third-party license agreements;
- seek to maintain, protect, and expand our intellectual property portfolio;
- seek to attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts; and
- experience any delays or encounter issues with the development and potential for regulatory approval of our clinical candidates such as safety issues, clinical trial accrual delays, longer follow-up for planned studies, additional major studies, or supportive studies necessary to support marketing approval.

Further, the net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a representative indication of our future performance.

We have never generated any revenue from product sales and may never be profitable.

We have no products approved for commercialization and have never generated any revenue. Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize, one or more of our product candidates. We do not anticipate generating revenue from product sales for the foreseeable future. Our ability to generate future revenue from product sales depends heavily on our success in many areas, including but not limited to:

- completing research and development of our product candidates;
- obtaining regulatory and marketing approvals for our product candidates;
- manufacturing product candidates and establishing and maintaining supply and manufacturing relationships with third parties that meet regulatory requirements and our supply needs in sufficient quantities to meet market demand for our product candidates, if approved;
- marketing, launching and commercializing product candidates for which we obtain regulatory and marketing approval, either directly or with a collaborator or distributor;
- gaining market acceptance of our product candidates as treatment options;
- addressing any competing products;
- protecting and enforcing our intellectual property rights, including patents, trade secrets, and know-how;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;
- obtaining reimbursement or pricing for our product candidates that supports profitability; and
- attracting, hiring, and retaining qualified personnel.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our current pipeline of product candidates has been in-licensed from third parties and we will have to develop or acquire manufacturing capabilities in order to continue development and potential commercialization of our product candidates. Additionally, if we are not able to generate revenue from the sale of any approved products, we may never become profitable.

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

To the extent that we raise additional capital through the sale of equity, debt or other securities convertible into equity, your ownership interest will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available at all, would likely involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, making additional product acquisitions, or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates or future revenue streams or grant licenses on terms that are not favorable to us. We cannot assure you that we will we will be able to obtain additional funding if and when necessary to fund our entire portfolio of product candidates to meet our projected plans. If we are unable to obtain funding on a timely basis, we may be required to delay or discontinue one or more of our development programs or the commercialization of any product candidates or be unable to expand our operations or otherwise capitalize on potential business opportunities, which could materially affect our business, financial condition, and results of operations.

In March 2016 we completed the Merger with Celladon and the failure to successfully integrate could adversely affect our future results.

Our success will depend, in significant part, on our ability to integrate successfully and to manage successfully the challenges presented by the integration process in the Merger with Celladon that was completed in March 2016. Potential difficulties that may be encountered in the integration process include the following:

- using our cash and assets efficiently to develop our business;
- appropriately managing our liabilities;
- potential unknown or currently unquantifiable liabilities associated with the Merger and our operations;
- difficulties in operating with a new management team as a public company; and
- performance shortfalls as a result of the diversion of the management’s attention caused by integrating the Company’s operation as a public company following the Merger.

Covenants in our loan and security agreement restrict our business and operations in many ways and if we do not effectively manage our covenants, our financial conditions and results of operations could be adversely affected. In addition, we may not meet the milestones required to access the final loan available under the agreement and may also not provide sufficient cash to meet the repayment obligations of our debt incurred under the loan and security agreement.

Our loan and security agreement with Oxford Finance LLC provides for up to $25.0 million in term loans due on July 1, 2021, of which $15.0 million in term loans has been borrowed to date. All of our current and future assets, except for intellectual property, are secured for our borrowings under the loan and security agreement. The loan and security agreement requires that we comply with certain covenants applicable to us, including among other things, covenants restricting dispositions, changes in business, management, ownership or business locations, mergers or acquisitions, indebtedness, encumbrances, distributions, investments, transactions with affiliates and subordinated debt, any of which could restrict our business and operations, particularly our ability to respond to changes in our business or to take specified actions to take advantage of certain business opportunities that may be presented to us.

Our failure to comply with any of the covenants could result in a default under the loan and security agreement, which could permit the lenders to declare all or part of any outstanding borrowings to be immediately due and payable, or to refuse to permit additional borrowings under the loan and security agreement. If we are unable to repay those amounts, the lenders under the loan and security agreement could proceed against the collateral granted to them to secure that debt, which would seriously harm our business. In addition, should we be unable to comply with these covenants or if we default on any portion of our outstanding borrowings, the lenders can also impose a 5.0% penalty and restrict access to additional borrowings under the loan and security agreement. Moreover, our ability to access the final $10.0 million under the loan and security agreement is subject to our ability to achieve certain clinical development milestones, which we may not be able to meet and which and could adversely affect our liquidity. In addition, although we expect to borrow additional funds under the loan and security agreement, before we do so, we must first satisfy ourselves that we will have access to future alternate sources of capital, including cash flow from our own operations, equity capital markets or debt capital markets in order to repay any principal borrowed, which we may be unable to do, in which case, our liquidity and ability to fund our operations may be substantially impaired.

Risks Related to the Development of our Product Candidates

We are heavily dependent on the success of our product candidates, which are in the early stages of clinical development. Certain of our product candidates have produced results in academic settings to date or for other indications than those that we contemplate and we cannot give any assurance that we will generate data for any of our product candidates sufficient to receive regulatory approval in our planned indications, which will be required before they can be commercialized.

To date, we have invested substantially all of our efforts and financial resources to identify, acquire, and develop our portfolio of product candidates. Our future success is dependent on our ability to successfully further develop, obtain regulatory approval for, and commercialize one or more of these product candidates. We currently generate no revenue from sales of any drugs, and we may never be able to develop or commercialize a product candidate.

We currently have five Phase 2 development programs focused on four separate indications. One of our product candidates, exendin 9-39, has only generated data in an academic setting and we may not be able to replicate or develop additional data to satisfy regulatory requirements for approval. For ubenimex, data to date has been developed for use in indications other than those that we have rights to or in which we plan to develop the product candidate. Similarly, some of our lonafarnib results to date rely on laboratory-developed assays that have not been validated or accepted by the FDA to assess the potential efficacy of the product. While we are undertaking confirmation with an European Medical Agency approved assay, there can be no assurance that the data we have seen to date may be replicated in such validated assay. In addition, we would need to verify that any of our clinical trials and results were undertaken and conducted in accordance with good clinical practices in connection with submission of such data and information to regulatory authorities for consideration in the conduct of additional studies or regulatory approval. There can be no assurance that the data that we develop for our product candidates in our planned indications will be sufficient to obtain regulatory approval.

In addition, none of our product candidates have advanced into a pivotal study for our proposed indications and it may be years before such study is initiated and completed, if at all. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. We cannot be certain that any of our product candidates will be successful in clinical studies or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical studies. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

Our business strategy is based upon obtaining orphan drug designation for our product candidates, which is an uncertain process. The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, and inherently unpredictable. If we are unable to obtain orphan drug designation or regulatory approval for our product candidates, our business will be substantially harmed.

Our approach to identifying and developing product candidates depends, in large part, on our ability to obtain orphan drug designation from regulatory authorities in major markets. Without the potential protection of this

regulatory exclusivity upon approval, many of our product candidates would otherwise not justify investment as they are not protected by patents or they are otherwise marketed or generic products. While we assess the potential for obtaining orphan drug designation at the time that we contemplate the acquisition of product candidates and we intend to timely file for such designation, there can be no assurance that we will obtain orphan drug designation or be able to successfully meet the regulatory requirements to maintain that designation with the planned clinical trials for our product candidates. Failure to obtain orphan drug designation would make our product candidates significantly less competitive and potentially not viable investments for further development.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable, typically takes many years following the commencement of clinical studies, and depends upon numerous factors. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. We have not obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design, size or implementation of our clinical studies;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from our development efforts;
- the data collected from clinical studies of our product candidates may not be sufficient or complete or meet the regulatory requirements to support the submission of a new drug application, or NDA, or other submission or to obtain regulatory approval in the United States or foreign jurisdictions. For example, the LOWR HDV – 1 and LOWR HDV – 2 study is not yet complete and we have identified and continue to assess certain good clinical practice violations at one site that may impact certain data and information that we plan to submit to the FDA;
- the FDA or comparable foreign regulatory authorities may find failures in our manufacturing processes, validation procedures and specifications, or facilities of our third-party manufacturers with which we contract for clinical and commercial supplies that may delay or limit our ability to obtain regulatory approval for our product candidates; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our NDA or other submission insufficient for approval.

The lengthy and uncertain regulatory approval process, as well as the unpredictability of the results of clinical studies, may result in our failing to obtain regulatory approval to market any of our product candidates or to be significantly delayed from our expectations for potential approval, which would significantly harm our business, results of operations, and prospects. In addition, although we have obtained orphan drug designation for two of our product candidates in our planned indications to date, there can be no assurance that the FDA will grant our similar status for our other proposed development indications or other product candidates in the future.

Drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies may not be predictive of future study results.

Clinical testing is expensive and generally takes many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the clinical study process. The results of preclinical studies and early clinical studies of our product candidates may not be predictive of the results of larger, later-stage controlled clinical studies. Product candidates that have shown promising results in early-stage clinical studies may still suffer significant setbacks in subsequent clinical studies. Our clinical studies to date have been conducted on a small number of

patients in limited numbers of clinical sites and in academic settings or for other indications. We will have to conduct larger, well-controlled studies in our proposed indications to verify the results obtained to date and to support any regulatory submissions for further clinical development. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical studies due to lack of efficacy or adverse safety profiles despite promising results in earlier, smaller clinical studies. Moreover, clinical data are often susceptible to varying interpretations and analyses. We do not know whether any Phase 2, Phase 3, or other clinical studies we have conducted or may conduct will demonstrate consistent or adequate efficacy and safety with respect to the proposed indication for use sufficient to obtain regulatory approval to receive regulatory approval or market our drug candidates. For example, the LOWR HDV – 1 and LOWR HDV – 2 study is not yet complete and we have identified and continue to assess certain good clinical practice violations at one site that may impact certain data and information that we plan to submit to the FDA.

We may find it difficult to enroll patients in our clinical studies given the limited number of patients who have the diseases for which our product candidates are being studied. Difficulty in enrolling patients could delay or prevent clinical studies of our product candidates.

Identifying and qualifying patients to participate in clinical studies of our product candidates is essential to our success. The timing of our clinical studies depends in part on the rate at which we can recruit patients to participate in clinical trials of our product candidates, and we may experience delays in our clinical studies if we encounter difficulties in enrollment.

The eligibility criteria of our planned clinical studies may further limit the available eligible study participants as we expect to require that patients have specific characteristics that we can measure or meet the criteria to assure their conditions are appropriate for inclusion in our clinical studies. We may not be able to identify, recruit, and enroll a sufficient number of patients to complete our clinical studies in a timely manner because of the perceived risks and benefits of the product candidate under study, the availability and efficacy of competing therapies and clinical studies, and the willingness of physicians to participate in our planned clinical studies. If patients are unwilling to participate in our clinical studies for any reason, the timeline for conducting studies and obtaining regulatory approval of our product candidates may be delayed.

If we experience delays in the completion of, or termination of, any clinical study of our product candidates, the commercial prospects of our product candidates could be harmed, and our ability to generate product revenue from any of these product candidates could be delayed or prevented. In addition, any delays in completing our clinical studies would likely increase our overall costs, impair product candidate development and jeopardize our ability to obtain regulatory approval relative to our current plans. Any of these occurrences may harm our business, financial condition, and prospects significantly.

Clinical studies are costly, time consuming and inherently risky, and we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Clinical development is expensive, time consuming and involves significant risk. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical studies can occur at any stage of development. Events that may prevent successful or timely completion of clinical development include but are not limited to:

- inability to generate satisfactory preclinical, toxicology, or other in vivo or in vitro data or diagnostics to support the initiation or continuation of clinical studies necessary for product approval;
- delays in reaching agreement on acceptable terms with CROs and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays in obtaining required Institutional Review Board, or IRB, approval at each clinical study site;
- failure to permit the conduct of a study by regulatory authorities, after review of an investigational new drug, or IND, or equivalent foreign application or amendment;
- delays in recruiting qualified patients in our clinical studies;

- failure by clinical sites or our CROs or other third parties to adhere to clinical study requirements or report complete findings such as the LOWR HDV – 1 and LOWR HDV – 2 study which is not yet complete and we have identified and continue to assess certain good clinical practice violations at one site that may impact certain data and information that we plan to submit to the FDA;
- failure to perform the clinical studies in accordance with the FDA's good clinical practices requirements, or applicable foreign regulatory guidelines;
- patients dropping out of our clinical studies;
- occurrence of adverse events associated with our product candidates;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- the cost of clinical studies of our product candidates;
- negative or inconclusive results from our clinical trials which may result in our deciding, or regulators requiring us, to conduct additional clinical studies or abandon development programs in other ongoing or planned indications for a product candidate; and
- delays in reaching agreement on acceptable terms with third-party manufacturers and the time for manufacture of sufficient quantities of our product candidates for use in clinical studies.

Any inability to successfully complete clinical development and obtain regulatory approval could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, such as our plan to manufacture a new subcutaneous formulation of exendin 9-39, we may need to conduct additional studies or the results obtained from such new formulation may not be consistent with previous results obtained. Clinical study delays could also shorten any periods during which our products have patent protection and may allow competitors to develop and bring products to market before we do, which could impair our ability to obtain orphan drug designation exclusivity and to successfully commercialize our product candidates and may harm our business and results of operations.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects, including the reporting of potentially incomplete or inadequate safety data from LOWR HDV – 1 and LOWR HDV – 2, caused by our product candidates could cause us or regulatory authorities to interrupt, delay, or terminate or conduct additional or larger clinical studies or even if approved, result in a restrictive label or delay regulatory approval by the FDA or comparable foreign authorities.

In addition, while our LNF product candidate has been studied in thousands of oncology patients and the most common non-hematologic adverse events of any grade were gastrointestinal system disorders (nausea, anorexia, diarrhea and vomiting), weight loss, fatigue and rash, treatment discontinuation across the LNF clinical studies conducted in oncology has been in the range of approximately 19-52% and we may experience comparable or higher rates of discontinuation in testing in our anti-viral, hepatitis D virus studies. There is no guarantee that additional or more severe side effects will not be identified through ongoing clinical studies by other uses of LNF for other indications or our own clinical trials. Additionally, while we have a license to another farnesyltranferase inhibitor compound, tipifarnib, from Janssen Pharmaceutica, N.V., or Janssen, Janssen has granted rights to tipifarnib to Kura Oncology, Inc., or Kura, in oncology and negative results or undesirable side effects from Kura's clinical trials for a compound with a similar mechanism of action may negatively impact the perception of LNF for anti-viral indications. Merck may also grant rights to other anti-viral or potentially other indications to other third parties. Undesirable side effects and negative results for other indications may negatively impact the development and potential for approval of our product candidates for our proposed indications.

Additionally, even if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may withdraw approvals of such products;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a Risk Evaluation and Mitigation Strategy, or REMS, plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements to assure safe use;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of a product candidate, even if approved, and could significantly harm our business, results of operations, and prospects.

Even if we obtain regulatory approval for a product candidate, we will remain subject to ongoing regulatory requirements.

If our product candidates are approved, they will be subject to ongoing regulatory requirements with respect to manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy and other post-approval information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to continuously comply with FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices, or cGMP, regulations and corresponding foreign regulatory manufacturing requirements. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA or marketing authorization application, or MAA.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product candidate may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. We will be required to report certain adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities.

Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. If our original marketing approval for a product candidate was obtained through an accelerated approval pathway, we could be required to conduct a successful post-marketing clinical study in order to confirm the clinical benefit for our products. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing, or labeling of a product, the regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our ongoing clinical studies;

- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- require a product recall.

Any government investigation of alleged violations of law would be expected to require us to expend significant time and resources in response and could generate adverse publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to develop and commercialize our products and the value of us and our operating results would be adversely affected.

We rely on third parties to conduct our clinical studies, manufacture our product candidates and perform other services. If these third parties do not successfully perform and comply with regulatory requirements, we may not be able to successfully complete clinical development, obtain regulatory approval or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon investigators and third-party CROs to conduct, monitor and manage our ongoing clinical programs. We rely on these parties for execution of clinical studies and manage and control only certain aspects of their activities. We remain responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We, our investigators, and our CROs and other vendors are required to comply all applicable laws, regulations and guidelines, including those required by the FDA and comparable foreign regulatory authorities for all of our product candidates in clinical development. If we or any of our investigators, CROs or vendors fail to comply with applicable laws, regulations and guidelines, the results generated in our clinical studies may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional studies before approving our marketing applications. For example, since LOWR HDV – 1 and LOWR HDV – 2 have not yet completed, and we have identified and continue to assess certain good clinical practice violations at one site that may impact certain data and information that we plan to submit to the FDA. We cannot assure you that our CROs and other vendors will meet these requirements, or that upon inspection by any regulatory authority, such regulatory authority will determine that efforts, including any of our clinical studies, comply with applicable requirements. Our failure to comply with these laws, regulations and guidelines may require us to repeat clinical studies or conduct larger additional studies, which would be costly and delay the regulatory approval process.

If any of our relationships with investigators or third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs in a timely manner or do so on commercially reasonable terms. In addition, our CROs may not prioritize our clinical studies relative to those of other customers and any turnover in personnel or delays in the allocation of CRO employees by the CRO may negatively affect our clinical studies. If investigators or CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, our clinical studies may be delayed or terminated and we may not be able to meet our current plans with respect to our product candidates. CROs may also involve higher costs than anticipated, which could negatively affect our financial condition and operations.

In addition, we do not currently have, nor do we plan to establish the capability to manufacture product candidates for use in the conduct of our clinical studies, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale without the use of third-party manufacturers. We plan to rely on third-party manufacturers and their responsibilities will include purchasing from third-party suppliers the materials necessary to produce our product candidates for our clinical studies and regulatory approval. There are expected to be a limited number of suppliers for the active ingredients and other materials that we expect to use to manufacture our product candidates, and we may not be able to identify alternative suppliers to prevent a possible disruption of the manufacture of our product candidates for our clinical studies, and, if approved, ultimately for commercial sale. Although we generally do not expect to begin a clinical study unless we believe we have a sufficient supply of a product candidate to complete the study, any significant delay or discontinuity in the supply of a product candidate, or the active ingredient or other material components in the manufacture of the product candidate, could delay completion of our clinical studies and potential timing for regulatory approval of our product candidates, which would harm our business and results of operations.

With respect to our LNF program, we procured an inventory of product from Merck to supply our initial clinical study needs. In 2016, we have transferred the manufacturing of drug substance and drug product to our third-party contractors. These vendors have successfully made GMP batches for our future clinical studies. With respect to our lambda program, as part of the license agreement, we obtained a substantial inventory of product from BMS sufficient to initiate our clinical trials. We are in the process of transferring the manufacturing technology to our third-party vendors and anticipate GMP manufacturing at those facilities to begin in 2017. With respect to our ubenimex program we have relied on Nippon Kayaku to provide us with product to conduct our trials and have completed the process of transferring the manufacturing of ubenimex to our third-party vendors in the US.

We rely and expect to continue to rely on third parties to manufacture our clinical product supplies, and if those third parties fail to obtain approval of government regulators, fail to provide us with sufficient quantities of drug product, or fail to do so at acceptable quality levels or prices our product candidates could be stopped, delayed, or made less profitable.

We do not currently have nor do we plan to acquire the infrastructure or capability internally to manufacture our clinical supplies for use in the conduct of our clinical trials, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. We currently rely on outside vendors to source raw materials and manufacture our clinical supplies of our product candidates and plan to continue relying on third parties to manufacture our product candidates on a commercial scale, if approved.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our marketing applications to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as cGMPs, for manufacture of our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their 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 a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing of our product candidates, and the actual cost to manufacture our product candidates could materially and adversely affect the commercial viability of our product candidates. As a result, we may never be able to develop a commercially viable product.

In addition, our reliance on third-party manufacturers exposes us to the following additional risks:

- We may be unable to identify manufacturers on acceptable terms or at all.
- Our third-party manufacturers might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any.
- Contract manufacturers may not be able to execute our manufacturing procedures appropriately.
- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.
- Manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.
- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates.
- Our third-party manufacturers could breach or terminate their agreement with us.

Each of these risks could delay our clinical trials, the approval, if any of our product candidates by the FDA or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenue. In addition, we rely on third parties to perform release testing on our product candidates prior to delivery to patients. If these tests are not appropriately conducted and test data are not reliable, patients could be put at risk of serious harm and could result in product liability suits.

The manufacture of medical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of biologic 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 our product candidates or in the manufacturing facilities, 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 our product candidates 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 product candidates 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.

If the market opportunities for our product candidates are smaller than we believe they are, we may not meet our revenue expectations and, even assuming approval of a product candidate, our business may suffer. Because the patient populations in the market for our product candidates may be small, we must be able to successfully identify patients and acquire a significant market share to achieve profitability and growth.

We focus our product development principally on treatments for orphan diseases. Given the small number of patients who have the diseases that we are targeting, our eligible patient population and pricing estimates may differ significantly from the actual market addressable by our product candidate. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, patient foundations, or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. For example, for LNF and lambda, HDV is associated with hepatitis B virus infection, which is a pre-requisite for the replication of HDV. Although we believe that the data are supportive of the increased severity of hepatitis in the presence of hepatitis D and hepatitis B virus co-infection compared to hepatitis B alone, there can be no assurance that our clinical trials will successfully address this condition. Likewise, the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business.

We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are similar, more advanced, or more effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our product candidates.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We are currently aware of various existing therapies that may compete with our product candidates. For example, we have competitors both in the United States and internationally, including multinational pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies. Some of the pharmaceutical and biotechnology companies we expect to compete with include Gilead, Merck, Roche, Replicor, Arrowhead, Novartis, Xoma, Reata and Arena as well as other smaller companies or biotechnology startups and large multinational pharmaceutical companies. 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. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able to and may be more effective in selling and marketing their products as well. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. 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, products that are more effective or less costly than any product candidate that we may develop, or achieve earlier patent protection, regulatory approval, product commercialization, and market penetration than we do. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors.

We currently have limited marketing and sales experience. If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.

Although certain of our employees may have marketed, launched and sold other pharmaceutical products in the past while employed at other companies, we have no recent experience selling and marketing our product candidates and we currently have no marketing or sales organization. To successfully commercialize any products that may result from our development programs, we will need to invest in and develop these capabilities, either on our own or with others, which would be expensive, difficult and time consuming. Any failure or delay in the timely development of our internal commercialization capabilities could adversely impact the potential for success of our products.

Further, given our lack of prior experience in marketing and selling biopharmaceutical products, we may rely on future collaborators to commercialize our products. If collaborators do not commit sufficient resources to commercialize our future products and we are unable to develop the necessary marketing and sales capabilities on our own, we will be unable to generate sufficient product revenue to sustain or grow our business. We may be competing with companies that currently have extensive and well-funded marketing and sales operations, in particular in the markets our product candidates are intended to address. Without appropriate capabilities, whether directly or through third-party collaborators, we may be unable to compete successfully against these more established companies.

The commercial success of any of our current or future product candidate will depend upon the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community.

Even with the approvals from the FDA and comparable foreign regulatory authorities, the commercial success of our products will depend in part on the health care providers, patients, and third-party payors accepting our product candidates as medically useful, cost-effective, and safe. Any product that we bring to the market may not gain market acceptance by physicians, patients, third-party payors and other health care providers. The degree of market acceptance of any of our products will depend on a number of factors, including without limitation:

- the efficacy of the product as demonstrated in clinical studies and potential advantages over competing treatments;
- the prevalence and severity of the disease and any side effects;
- the clinical indications for which approval is granted, including any limitations or warnings contained in a product’s approved labeling;
- the convenience and ease of administration;
- the cost of treatment;
- the willingness of the patients and physicians to accept these therapies;
- the marketing, sales and distribution support for the product;

- the publicity concerning our products or competing products and treatments; and
- the pricing and availability of third-party insurance coverage and reimbursement.

Even if a product displays a favorable efficacy and safety profile upon approval, market acceptance of the product remains uncertain. Efforts to educate the medical community and third-party payors on the benefits of the products may require significant investment and resources and may never be successful. If our products fail to achieve an adequate level of acceptance by physicians, patients, third-party payors, and other health care providers, we will not be able to generate sufficient revenue to become or remain profitable.

Failure to obtain or maintain adequate reimbursement or insurance coverage for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

The pricing, coverage and reimbursement of our products must be sufficient to support our commercial efforts and other development programs and the availability and adequacy of coverage and reimbursement by governmental and private payors are essential for most patients to be able to afford expensive treatments, particularly in orphan drug designated indications where the eligible patient population is small. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid for or reimbursed by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or government authorities, private health insurers, and other third-party payors. If coverage and reimbursement are not available, or are available only in limited amounts, we may have to subsidize or provide products for free or we may not be able to successfully commercialize our products.

In addition, there is significant uncertainty related to the insurance coverage and reimbursement for newly approved products. In the United States, the principal decisions about coverage and reimbursement for new drugs are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, as CMS decides whether and to what extent a new drug will be covered and reimbursed under Medicare. Private payors tend to follow the coverage reimbursement policies established by CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for products such as ours and what reimbursement codes our products may receive.

Outside the United States, international operations are generally subject to extensive governmental price controls and other price-restrictive regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada, and other countries has and will continue to put pressure on the pricing and usage of products. In many countries, the prices of products are subject to varying price control mechanisms as part of national health systems. Price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products. Accordingly, in markets outside the United States, the potential revenue may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to limit or reduce healthcare costs may result in restrictions on coverage and the level of reimbursement for new products and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with products due to the increasing trend toward managed healthcare, including the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs has and is expected to continue to increase in the future. As a result, profitability of our products may be more difficult to achieve even if they receive regulatory approval.

We intend to rely on a combination of exclusivity from orphan drug designation as well as patent rights for our product candidates and any future product candidates. If we are unable to obtain or maintain exclusivity from the combination of these approaches, we may not be able to compete effectively in our markets.

Our business strategy is to focus on product candidates for which orphan drug designation may be obtained in the major markets of the world. In addition, we rely or will rely upon a combination of patents, trade secret protection, and confidentiality agreements to protect the intellectual property related to our technologies and product candidates. For example, the portfolio of patents licensed from Merck expires before the anticipated launch date of the LNF

product candidate. Our success depends in large part on our and our licensors' ability to obtain regulatory exclusivity and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technology and products.

Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, the EMA's Committee for Orphan Medicinal Products, or COMP, grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union. Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biological product or where there is no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan drug designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. In the European Union, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Because the extent and scope of patent protection for our products may in some cases be limited, orphan drug designation is especially important for our products for which orphan drug designation may be available. For eligible drugs, we plan to rely on the exclusivity period under the Orphan Drug Act to maintain a competitive position. If we do not obtain orphan drug exclusivity for our drug products and biologic products that do not have broad patent protection, our competitors may then sell the same drug to treat the same condition sooner than if we had obtained orphan drug exclusivity and our revenue will be reduced.

Even though we have orphan drug designation for LNF in the United States and Europe, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan drug is approved, the FDA or EMA can subsequently approve the same drug with the same active moiety for the same condition if the FDA or EMA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a product candidate nor gives the product candidate any advantage in the regulatory review or approval process.

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates that are important to our business. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unsolved. The patent applications that we own or in-licenses may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending

patent application. Even if patents do successfully issue, and even if such patents cover our product candidates, third parties may challenge their validity, enforceability, or scope, which may result in such patents being narrowed, found unenforceable or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates, or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

We, independently or together with our licensors, have filed several patent applications covering various aspects of our product candidates. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful opposition to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

Although we have licensed a number of patents covering methods of use and certain compositions of matter, we do not have complete patent protection for our product candidates. For example, the patent coverage for LNF expires before the anticipated launch date. Likewise, most of the patents covering products that we have licensed in from Stanford have limited protection outside of the United States. Therefore, a competitor could develop the same or similar product that may compete with our product candidate.

Certain of our product licenses are limited to specified indications or therapeutic areas which may result in the same compound being developed and commercialized by a third party whom we have no control over or rights against. This may result in safety data, pricing or off label uses from that third party's product that may negatively affect the development and commercialization of our product candidates. For example, Kura has an exclusive license to tipifarnib for use in cancer indications while we have a license for anti-viral indications. As a result of Kura's right to use the same compound in a different indication, it is possible that development and sales may impact our product development and commercialization efforts. If we cannot obtain and maintain effective protection of exclusivity from our regulatory efforts and intellectual property rights, including patent protection, for our product candidates, we may not be able to compete effectively and our business and results of operations would be harmed.

We may not have sufficient patent term protections for our products to effectively protect our business.

Patents have a limited term. In the United States, the statutory expiration of a patent is generally 20 years after it is filed. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from generic medications. In addition, upon issuance in the United States any patent term can be adjusted based on certain delays caused by the applicant(s) or the United States Patent and Trademark Office, or USPTO. For example, a patent term can be reduced based on certain delays caused by the patent applicant during patent prosecution.

Patent term extensions under the Hatch-Waxman Act in the United States and under supplementary protection certificates in Europe may be available to extend the patent or data exclusivity terms of products. With respect to ubenimex, LNF, lambda and exendin 9-39, a substantial portion of the potential commercial opportunity will likely rely on patent term extensions, and we cannot provide any assurances that any such patent term extensions will be obtained and, if so, for how long. As a result, we may not be able to maintain exclusivity for our products for an extended period after regulatory approval, which would negatively impact our business and results of operations. If we do not have sufficient patent terms or regulatory exclusivity to protect our products, our business and results of operations will be adversely affected.

Patent laws and rule changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific

literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. We therefore cannot be certain that it or our licensors were the first to make the invention claimed in our owned and licensed patents or pending applications, or that we or our licensor were the first to file for patent protection of such inventions. Assuming the other requirements for patentability are met, in the United States prior to March 15, 2013, the first to make the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent. After March 15, 2013, under the Leahy-Smith America Invents Act, or the Leahy-Smith Act, enacted on September 16, 2011, the United States has moved to a first to file system. The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and may also affect patent litigation. The effects of these changes are currently unclear as the USPTO must still implement various regulations, the courts have yet to address any of these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. In general, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

If we are unable to maintain effective proprietary rights for our product candidates or any future product candidates, we may not be able to compete effectively in our markets.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors, and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

Although we expect all of our employees and consultants to assign their inventions to us, and 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 provide any assurances that all such agreements have been duly executed or 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. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret.

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

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, and reexamination proceedings before the USPTO and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture, or methods for treatment related to the use or manufacture of our product candidates. We have conducted freedom to

operate analyses with respect to only certain of our product candidates, and therefore we do not know whether there are any third-party patents that would impair our ability to commercialize these product candidates. We also cannot guarantee that any of our analyses are complete and thorough, nor can we be sure that we have identified each and every patent and pending application in the United States and abroad that is relevant or necessary to the commercialization of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates 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 aspects of our formulations, the manufacturing process of any of our product candidates, methods of use, 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 such product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Such a license may not be available on commercially reasonable terms, or at all.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. 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, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

We may not be successful in meeting our diligence obligations under our existing license agreements necessary to maintain our product candidate licenses in effect. In addition, if required in order to commercialize our product candidates, we may be unsuccessful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

We currently have rights to the intellectual property, through licenses from third parties and under patents that we do not own, to develop and commercialize our product candidates. Because our programs may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to maintain in effect these proprietary rights. For example, we have certain specified diligence obligations under our Stanford license agreements for our ubenimex and LNF product candidates. We may not be able to achieve the required diligence milestones in a timely manner, which may result in a right of termination by Stanford, and we may be unable to successfully negotiate an extension or waiver of those termination rights. Any termination of license agreements with third parties with respect to our product candidates would be expected to negatively impact our business prospects.

We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Even if we are able to license or acquire third-party intellectual property rights that are necessary for our product candidates, there can be no assurance that they will be available on favorable terms.

We collaborate with U.S. and foreign academic institutions to identify product candidates, accelerate our research and conduct development. Typically, these institutions have provided us with an option to negotiate an exclusive license to any of the institution's rights in the patents or other intellectual property resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue a program of interest to us.

If we are unable to successfully obtain and maintain rights to required third-party intellectual property, we may have to abandon development of that product candidate or pay additional amounts to the third party, and our business and financial condition could suffer.

Our product candidates may be subject to generic competition.

Under the Hatch-Waxman Act, a pharmaceutical manufacturer may file an abbreviated new drug application, or ANDA, seeking approval of a generic copy of an approved innovator product. Under the Hatch-Waxman Act, a manufacturer may also submit an NDA under section 505(b)(2) that references the FDA's finding of safety and effectiveness of a previously approved drug. A 505(b)(2) NDA product may be for a new or improved version of the original innovator product. Innovative small molecule drugs may be eligible for certain periods of regulatory exclusivity (e.g., five years for new chemical entities, three years for changes to an approved drug requiring a new clinical study, seven years for orphan drugs), which preclude FDA approval (or in some circumstances, FDA filing and review of) an ANDA or 505(b)(2) NDA relying on the FDA's finding of safety and effectiveness for the innovative drug. In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, product formulation or an approved use of the drug, which would be listed with the product in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the "Orange Book." If there are patents listed in the Orange Book, a generic applicant that seeks to market its product before expiration of the patents must include in the ANDA or 505(b)(2) what is known as a "Paragraph IV certification," challenging the validity or enforceability of, or claiming non-infringement of, the listed patent or patents. Notice of the certification must be given to the innovator, too, and if within 45 days of receiving notice the innovator sues to protect its patents, approval of the ANDA is stayed for 30 months, or as lengthened or shortened by the court.

If there are patents listed for our product candidates in the Orange Book, ANDAs and 505(b)(2) NDAs with respect to those product candidates would be required to include a certification as to each listed patent indicating whether the ANDA applicant does or does not intend to challenge the patent. We cannot predict whether any patents issuing from our pending patent applications will be eligible for listing in the Orange Book, how any generic competitor would address such patents, whether we would sue on any such patents, or the outcome of any such suit.

We may not be successful in securing or maintaining proprietary patent protection for products and technologies we develop or license. Moreover, if any patents that are granted and listed in the Orange Book are successfully challenged by way of a Paragraph IV certification and subsequent litigation, the affected product could more immediately face generic competition and its sales would likely decline materially. Should sales decline, we may have to write off a portion or all of the intangible assets associated with the affected product and our results of operations and cash flows could be materially and adversely affected.

The patent protection and patent prosecution for some of our product candidates is dependent on third parties.

While we normally seek and gain the right to fully prosecute the patents relating to our product candidates, there may be times when patents relating to our product candidates are controlled by our licensors. This is the case with our agreements with Stanford and Nippon Kayaku, each of whom is primarily responsible for the prosecution of patents and patent applications licensed to us under the applicable collaboration agreements. If they or any of our future licensors fail to appropriately and broadly prosecute and maintain patent protection for patents covering any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using, importing, and selling competing products. In addition, even where we now have the right to control patent prosecution of patents and patent applications we have licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensors in effect from actions prior to us assuming control over patent prosecution.

If we fail to comply with obligations in the agreements under which we license intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are a party to a number of intellectual property license and supply agreements that are important to our business and expects to enter into additional license agreements in the future. Our existing agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty, purchasing, and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, our agreements may be subject to termination by the licensor, in which event we would not be able to develop, manufacture or market products covered by the license or subject to supply commitments.

Although we are not currently involved in any intellectual property litigation, we may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming, and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. Although we are not currently involved in any intellectual property litigation, if we or one of our licensing partners were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

Interference proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. 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. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring our product candidates to market.

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. There could also 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 material adverse effect on the price of our common stock.

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

We employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we have written agreements and make every effort to ensure that our employees, consultants and independent contractors do not use the proprietary information or intellectual property rights of others in their work forums, and we are not currently subject to any claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties, we may in the future be subject to such claims. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. Likewise, certain of our license agreements, for example for ubenimex, do not include patents or patent applications outside of the United States as our licensor elected not to file in foreign jurisdictions. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Risks Related to our Business Operations

We have previously identified a material weakness in our internal control over financial reporting and our current management team may fail to maintain an effective system of internal control, which may result in material misstatements of our financial statements or cause us to fail to meet our periodic reporting obligations as a public company.

In connection with the audit of our consolidated financial statements for the years ended December 31, 2015 and 2014 as a private company, we and our independent auditors identified a material weakness in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the subject company's annual or interim financial statements will not be prevented or detected on a timely basis. Our lack of sufficient accounting personnel resulted in the identification of a material weakness in our internal control over financial reporting. Specifically, the material weakness that was identified related to a lack of sufficient accounting resources and personnel that had limited our ability to adequately segregate duties, perform sufficient review and approval of manual journal entries posted to the general ledger, establish defined accounting policies and procedures or perform timely reviews of account reconciliations or accounting estimates.

During 2016 we implemented measures to improve our internal control over financing reporting to address the underlying causes of the previously identified material weakness, including (i) the hiring of our Controller and other accounting personnel, (ii) establishing segregation of duties for review and approval of manual journal entries, (iii) establishing accounting policies and procedures, (iv) performing timely reviews of account reconciliations and accounting estimates, and (v) implementing appropriate disclosure controls and procedures. We believe the remediation steps outlined above were sufficient to remediate the previously identified material weakness in internal control over financial reporting as discussed above.

Our failure to implement and maintain effective internal control over financial reporting could result in errors in our financial statements that could result in a restatement of our financial statements or cause us to fail to meet our reporting obligations. In addition, although we are not currently required to formally test our internal controls for attestation, we are required as an "emerging growth company" to report on our internal controls. After we are no longer an emerging growth company, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies

in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. Inadequate internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

Our future success depends in part on our ability to retain our President and Chief Executive Officer and to attract, retain, and motivate other qualified personnel.

We are highly dependent on David Cory, our President and Chief Executive Officer, the loss of whose services may adversely impact the achievement of our objectives. Mr. Cory could leave our employment at any time, as he is an "at will" employee. Recruiting and retaining other qualified employees, consultants, and advisors for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of highly qualified personnel in our industry, which is likely to continue. As a result, competition for personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for individuals with similar skill sets. In addition, failure to succeed in development and commercialization of our product candidates may make it more challenging to recruit and retain qualified personnel. The inability to recruit and retain qualified personnel, or the loss of the services of Mr. Cory may impede the progress of our research, development, and commercialization objectives and would negatively impact our ability to succeed in our in-licensing strategy.

We will need to expand our organization and we may experience difficulties in managing this growth, which could disrupt our operations.

As of December 31, 2016, we had 20 full-time employees. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, manufacturing, sales, marketing, financial, legal, and other resources. Our management may need to divert a disproportionate amount of their attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees, and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Failure in our information technology and storage systems could significantly disrupt the operation of our business.

Our ability to execute our business plan and maintain operations depends on the continued and uninterrupted performance of our information technology, or IT, systems. IT systems are vulnerable to risks and damages from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our and our vendors' servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite precautionary measures to prevent unanticipated problems that could affect our IT systems, sustained or repeated system failures that interrupt our ability to generate and maintain data could adversely affect our ability to operate our business.

We may not be successful in any efforts to identify, license, discover, develop or commercialize additional product candidates.

Although a substantial amount of our effort will focus on the continued clinical testing, potential approval, and commercialization of our existing product candidates, the success of our business is also expected to depend in part upon our ability to identify, license, discover, develop, or commercialize additional product candidates. Research programs to identify new product candidates require substantial technical, financial, and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. Our research programs or licensing efforts may fail to yield additional product candidates for clinical development and commercialization for a number of reasons, including but not limited to the following:

- our research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates;
- we may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in preclinical or clinical testing;
- our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during our program so that such a product may become unreasonable to continue to develop;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community, or third-party payors.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, license, discover, develop, or commercialize additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the ACA, was passed, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the ACA. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress also could consider subsequent legislation to replace elements of the ACA that are repealed. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand or lower pricing for our product candidates, or additional pricing pressures.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, and health information privacy and security laws. If we are unable to comply, or has not fully complied, with such laws, it could face substantial penalties.

If we obtain FDA approval for any of our product candidates and begins commercializing those products in the United States, our operations may be subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and physician sunshine laws and regulations. These laws may impact, among other things, our proposed sales, marketing, and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty 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;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and our implementing regulations, which imposes certain requirements relating to the privacy, security, and transmission of individually identifiable health information;
- The Physician Payments Sunshine Act requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payors, including commercial insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraudulent conduct or other illegal activity by our employees, independent contractors, principal investigators, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: comply with the regulations of the FDA and non-U.S. regulators, provide accurate information to the FDA and non-U.S. regulators, comply with healthcare fraud and abuse laws in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, promotion, sales, marketing and certain business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of patient recruitment or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of business conduct and ethics applicable to all of our employees, 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 comply with these 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.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs. If the use or misuse of our product candidates harm patients, or is perceived to harm patients even when such harm is unrelated to our product candidates, our regulatory approvals could be revoked or otherwise negatively impacted and we could be subject to costly and damaging product liability claims.

The use or misuse of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. There is a risk that our product candidates may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- initiation of investigations by regulators;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management’s attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates;
- product recalls, withdrawals or labeling, marketing or promotional restrictions; and
- decreased demand for our product candidates, if approved for commercial sale.

We believe our current product liability insurance coverage is appropriate in light of our clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for product candidates, we intend to increase our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Patients with the diseases targeted by our product candidates are often already in severe and advanced stages of disease and have both known and unknown significant pre-existing and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may or may not be related to our product candidates. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our products, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may interrupt our sales efforts, delay our regulatory approval process in other countries, or impact and limit the type of regulatory approvals our product candidates receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use, and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling, and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our licensors and our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently, and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

We are currently conducting and will continue to conduct clinical trials in foreign countries, which could expose us to risks that could have a material adverse effect on the success of our business and the delivery of clinical trial data.

We currently conduct clinical trials in the United States; Ankara, Turkey; Hannover, Germany; Karachi, Pakistan; Auckland, New Zealand and Tel Aviv/Beersheba, Israel, and accordingly, we are subject to risks associated with doing business globally, including commercial, political, and financial risks. Emerging regions, such as Eastern Europe, Latin America, Asia, and Africa, as well as more developed markets, such as the United Kingdom, France, Germany, and Australia, provide clinical study opportunities for us. In addition, we are subject to potential disruption caused by military conflicts; potentially unstable governments or legal systems; civil or political upheaval or unrest; local labor policies and conditions; possible expropriation, nationalization, or confiscation of assets; problems with repatriation of foreign earnings; economic or trade sanctions; closure of markets to imports; anti-American sentiment; terrorism or other types of violence in or outside the United States; health pandemics; and a significant reduction in global travel. For example, Turkey is a key region for clinical activity relating to Hepatitis Delta, and further outbreaks of violence and political instability in the region could disrupt our clinical operations. Our success will depend, in part, on our ability to overcome the challenges we encounter with respect to these risks and other factors affecting U.S. companies with global operations. If our global clinical trials were to experience significant disruption due to these risks or for other reasons, it could have a material adverse effect on our financial results.

We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate headquarters are located in the San Francisco Bay Area which has in the past experienced severe earthquakes and other natural disasters. We do not carry earthquake insurance. Earthquakes or other natural disasters could severely disrupt our operations or those of our collaborators, and have a material adverse effect on our business, results of operations, financial condition, and prospects. If a natural disaster, terrorist attack, power outage, or other event occurred that prevented us from using or damaged critical elements of our business and operations (such as the manufacturing facilities of our third-party contract manufacturers) our business may be disrupted for a substantial period of time. We have limited or no disaster recovery and business continuity plans in place currently and our business would be impaired in the event of a serious disaster or similar event. We may incur substantial expenses to develop and implement any disaster recovery and business continuity plans, which could have a material adverse effect on our business.

Risks Related to Celladon's Historical Business Operations

We are the subject of securities class action lawsuits that were filed against Celladon in 2015, and additional securities litigation may be brought against us in the future.

In July 2015, following Celladon's announcements of the negative CUPID 2 data and the suspension of further research and development activities and the subsequent declines of the price of its common stock, three putative class actions were filed in the U.S. District Court for the Southern District of California against Celladon and certain of its current and former officers. The complaints generally alleged that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, by making materially false and misleading statements regarding the clinical trial program for MYDICAR, thereby artificially inflating the price of Celladon's common stock. The complaints sought unspecified monetary damages and other relief, including attorneys' fees. On December 9, 2015, the district court consolidated the three putative securities class actions and appointed a lead plaintiff to represent the putative class. The lead plaintiff filed a consolidated amended complaint on February 29, 2016.

On October 7, 2016, the district court granted defendants' motion to dismiss the consolidated amended complaint and granted leave to amend within 60 days from the date of the district court's order. The lead plaintiff subsequently filed a notice of intent not to amend the consolidated amended complaint and instead indicated that it intended to appeal the district court's decision. On December 9, 2016, the district court closed the case.

On December 28, 2016, the lead plaintiff filed a notice to the United States Court of Appeals for the Ninth Circuit appealing the district court's order dismissing the consolidated amended complaint. The deadline to file the appellant's opening brief is April 7, 2017.

It is possible that additional suits will be filed, or allegations made by stockholders, with respect to these same or other matters and also naming us and/or our former officers and directors as defendants. We believe that we have meritorious defenses and intend to defend these lawsuits vigorously. Due to the early stage of these proceedings, we are not able to predict or reasonably estimate the ultimate outcome or possible losses relating to these claims. While we and Celladon's former directors and officers have a separate liability insurance policy dedicated to any claims that may arise from premerger events, there is no assurance that the coverage will be sufficient. In addition, any such litigation could result in substantial costs and a diversion of our management's attention and resources, which could harm our business.

Risks Related to Ownership of our Common Stock

The market price of our common stock may be highly volatile, and you may not be able to resell some or all of your shares at a desired market price.

The market price of our common stock has been and is likely to continue to be volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- results or delays in preclinical studies or clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- unanticipated serious safety concerns related to the use of any of our product candidates;
- reports of adverse events in other gene therapy products or clinical trials of such products;
- inability to obtain additional funding;
- any delay in filing an IND or NDA for any of our product candidates and any adverse development or perceived adverse development with respect to the FDA's review of that IND or NDA;
- our ability to obtain regulatory approvals for LNF or other product candidates, and delays or failures to obtain such approvals;
- failure of any of our product candidates, if approved, to achieve commercial success;
- failure to obtain orphan drug designation;
- failure to maintain our existing third-party license and supply agreements;
- failure by our licensors to prosecute, maintain, or enforce our intellectual property rights;
- changes in laws or regulations applicable to our product candidates;
- any inability to obtain adequate supply of our product candidates or the inability to do so at acceptable prices;
- adverse regulatory authority decisions;
- introduction of new products, services, or technologies by our competitors;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators, and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinions regarding our business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions;
- sales of our common stock by us or our stockholders in the future;

- trading volume of our common stock;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity relating to the hepatitis market generally, including with respect to other products and potential products in such markets;
- the introduction of technological innovations or new therapies that compete with potential products of ours;
- changes in the structure of health care payment systems; and
- period-to-period fluctuations in our financial results.

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

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

We will incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies.

We have incurred and will continue to incur significant legal, accounting and other expenses associated with public company reporting requirements. We also incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act, as well as rules implemented by the SEC and The NASDAQ Stock Market LLC. These rules and regulations impose significant legal and financial compliance costs and make some activities more time-consuming and costly. For example, our management team consists of certain executive officers who have not previously managed and operated a public company. These executive officers and other personnel will need to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations. In addition, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers, which may adversely affect investor confidence and could cause our business or stock price to suffer.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our management.

Provisions in our certificate of incorporation and bylaws may delay or prevent an acquisition or a change in management. These provisions include a classified board of directors, a prohibition on actions by written consent of our stockholders and the ability of the board of directors to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the DGCL, which prohibits stockholders owning in excess of 15% of our voting stock from merging or combining with us. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

We do not anticipate that we will pay any cash dividends in the foreseeable future.

We expect to retain our future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders, if any, for the foreseeable future.

Future sales of shares by existing stockholders could cause our stock price to decline.

If existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after legal restrictions on resale lapse, the trading price of our common stock could decline. Certain of our existing stockholders, including Vivo Ventures Fund VI, L.P. and Interwest Partners X, L.P., and their respective affiliated entities, own substantial ownership interest in our common stock and any decision to sell a significant number of shares may negatively impact the price of our common stock.

The ownership of our common stock is highly concentrated, and it may prevent stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause our stock price to decline.

Our executive officers, directors and 5% stockholders and their affiliates beneficially own or control a significant portion of the outstanding shares of our common stock. Accordingly, these executive officers, directors, 5% stockholders and their affiliates, acting as a group, have substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transactions. These stockholders may also delay or prevent a change of control of us, even if such a change of control would benefit our other stockholders. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

Because the recent Merger resulted in an ownership change under Section 382 of the Internal Revenue Code our net operating loss carryforwards and certain other tax attributes are now subject to limitations.

If a corporation undergoes an "ownership change" within the meaning of Section 382 of the Internal Revenue Code of 1986, as amended, or Section 382, the corporation's net operating loss carryforwards and certain other tax attributes arising from before the ownership change are subject to limitations on use after the ownership change. In general, an ownership change occurs if there is a cumulative change in the corporation's equity ownership by certain stockholders that exceeds fifty percentage points over a rolling three-year period. Similar rules may apply under state tax laws. The recent Merger resulted in an ownership change and, accordingly, both parties' net operating loss carryforwards and certain other tax attributes will be subject to further limitations on their use. We assessed whether Eiger had an ownership change, as defined by Section 382 of the Code, occurred from our formation through December 31, 2016. Based upon this assessment no reduction was made to the federal and state NOL carryforwards or federal and state tax credit carryforwards under these rules. Additional ownership changes in the future could result in additional limitations on the combined organization's net operating loss carryforwards. Consequently, even if we achieve profitability, we may not be able to utilize a material portion of our net operating loss carryforwards and other tax attributes, which could have a material adverse effect on cash flow and results of operations.

ITEM 1B. Unresolved Staff Comments

Not applicable.

ITEM 2. Properties

Our corporate headquarters are located at 350 Cambridge Avenue, Suite 350, Palo Alto, California 94306 in a facility we lease encompassing approximately 1,570 square feet of office space. In December 2015, we entered into a sublease for 4,029 square feet of additional office space located at 366 Cambridge Avenue in Palo Alto, California 94306. The sublease commenced on January 26, 2016 and expires on March 30, 2017. In October 2016, the lease was modified to include two additional suites, 125 and 130 bringing our total leased space at 350 Cambridge Avenue to 3,877 square feet. The modified lease for this office space commenced on January 4, 2017 and expires in March 2018, has one two-year renewal option prior to expiration and includes rent escalation clauses through the lease term.

ITEM 3. Legal Proceedings

In July 2015, following Celladon's announcements of the negative CUPID 2 data and the suspension of further research and development activities and the subsequent declines of the price of its common stock, three putative class actions were filed in the U.S. District Court for the Southern District of California against Celladon and certain of its current and former officers. The complaints generally alleged that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, by making materially false and misleading statements regarding the clinical trial program for MYDICAR, thereby artificially inflating the price of Celladon's common stock. The complaints sought unspecified monetary damages and other relief, including attorneys' fees. On December 9, 2015, the district court consolidated the three putative securities class actions and appointed a lead plaintiff to represent the putative class. The lead plaintiff filed a consolidated amended complaint on February 29, 2016.

On October 7, 2016, the district court granted defendants' motion to dismiss the consolidated amended complaint and granted leave to amend within 60 days from the date of the district court's order. The lead plaintiff subsequently filed a notice of intent not to amend the consolidated amended complaint and instead indicated that it intended to appeal the district court's decision. On December 9, 2016, the district court closed the case.

On December 28, 2016, the lead plaintiff filed a notice to the United States Court of Appeals for the Ninth Circuit appealing the district court's order dismissing the consolidated amended complaint. The deadline to file the appellant's opening brief is April 7, 2017.

It is possible that additional suits will be filed, or allegations made by stockholders, with respect to these same or other matters and also naming us and/or our former officers and directors as defendants. We believe that we have meritorious defenses and intend to defend these lawsuits vigorously. Due to the early stage of these proceedings, we are not able to predict or reasonably estimate the ultimate outcome or possible losses relating to these claims. While we and Celladon's former directors and officers have a separate liability insurance policy dedicated to any claims that may arise from premerger events, there is no assurance that the coverage will be sufficient. In addition, any such litigation could result in substantial costs and a diversion of our management's attention and resources, which could harm our business.

ITEM 4. Mine Safety Disclosures

Not applicable.

PART II

ITEM 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

On March 22, 2016, Celladon and Private Eiger completed the Merger. Immediately prior to the Merger, Celladon completed a 1-for-15 reverse stock split. Following the Merger, we changed the name of the combined company to Eiger BioPharmaceuticals, Inc. and changed the symbol to "EIGR." Our common stock originally began trading on The NASDAQ Global Market on January 30, 2014. Prior to January 30, 2014, there was no public market for our common stock. The following table sets forth the high and low sales prices per share of our common stock as reported on The NASDAQ Global Market for the period indicated, adjusted for the reverse stock split.

	Price Range	
	High	Low
Year Ended December 31, 2016		
First Quarter	$ 25.80	$ 12.90
Second Quarter	$ 23.10	$ 17.06
Third Quarter	$ 20.63	$ 13.15
Fourth Quarter	$ 14.75	$ 10.71
Year Ended December 31, 2015		
First Quarter	$ 423.73	$ 226.34
Second Quarter	$ 299.69	$ 18.60
Third Quarter	$ 20.70	$ 15.00
Fourth Quarter	$ 28.35	$ 15.00

Holders of Record

As of March 16, 2017, there were approximately 29 stockholders of record of our common stock. Certain shares are held in "street" name and accordingly, the number of beneficial owners of such shares is not known or included in the foregoing number.

Dividend Policy

We have never declared or paid any dividends on our common stock. We currently intend to retain all available funds and future earnings, if any, to fund the development and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay dividends, if permitted, will be made at the discretion of our board of directors.

ITEM 6. Selected Financial Data

As a "smaller reporting company" as defined by Rule 12b-2 of the Exchange Act, the Company is not required to provide this information.

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

You should read the following discussion and analysis together with our financial statements and related notes included elsewhere in this Annual Report. The following discussion contains forward-looking statements that *involve risks and uncertainties. Our actual results could differ materially from those expressed or implied in any forward-looking statements as a result of various factors, including those set forth under the caption "Item 1A. Risk Factors."*

Unless otherwise indicates, references to the terms the "combined company," "Eiger," the "Company," "we," "our" and "us" refer to Eiger BioPharmaceuticals, Inc. (formerly known as Celladon Corporation) and its subsidiaries after the merger described herein. The term "Private Eiger" refers to privately-held Eiger BioPharmaceuticals, Inc. prior to its merger with Celladon Merger Sub, Inc. a wholly-owned subsidiary of Celladon Corporation. The term "Celladon" refers to Celladon Corporation and its subsidiaries prior to the Merger.

Introduction

We are a clinical stage biopharmaceutical company focused on bringing to market novel product candidates for the treatment of orphan diseases. Since our founding in 2008, we have worked with investigators at Stanford University and evaluated a number of potential development candidates from pharmaceutical companies to comprise a pipeline of novel product candidates. Our resulting pipeline includes four Phase 2 candidates addressing four distinct orphan diseases. The programs have several aspects in common: the disease targets represent conditions of high medical need which are inadequately treated by current standard of care; the therapeutic approaches are supported by an understanding of disease biology and mechanism as elucidated by our academic research relationships; prior clinical experience with the product candidates guides an understanding of safety; and the development paths leverage the experience and capabilities of our experienced, commercially focused management team. The pipeline includes lonafarnib for Hepatitis Delta Virus, or HDV, lambda for HDV, exendin 9-39 for PBH and ubenimex for PAH and lymphedema. We plan to deliver data from all ongoing Phase 2 clinical trials over the course of the next eighteen months.

We have no products approved for commercial sale and have not generated any revenue from product sales. We have never been profitable and have incurred operating losses in each year since inception. Our net losses were $47.1 million, $13.3 million and $1.5 million for the years ended December 31, 2016, 2015 and 2014, respectively. As of December 31, 2016, we had an accumulated deficit of $76.4 million. Substantially all of our operating losses resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We expect to incur significant expenses and increasing operating losses for at least the next several years as we initiate and continue the clinical development of, and seek regulatory approval for, our product candidates and add personnel necessary to operate as a public company with an advanced clinical candidate pipeline of products. In addition, we are now operating as a publicly traded company following the reverse merger with Celladon, and we will be hiring additional financial and other personnel, upgrading our financial information systems and incurring costs associated with operating as a public company. We expect that our operating losses will fluctuate significantly from quarter to quarter and year to year due to timing of clinical development programs and efforts to achieve regulatory approval.

Merger with Celladon

On March 22, 2016, we completed the reverse merger between Private Eiger and Celladon in accordance with the terms of the Agreement and Plan of Merger, dated as of November 18, 2015, by and among Private Eiger, Celladon and Celladon Merger Sub, Inc., or the Merger. Also on March 22, 2016, in connection with, and prior to the completion of the Merger, we effected a fifteen for one reverse stock split of our common stock, or the Reverse Stock Split, and changed our name to "Eiger BioPharmaceuticals, Inc."

On November 18, 2015, in connection with the Merger, we entered into a subscription agreement, or the "Subscription Agreement" with investors for the sale of shares of our common stock, or the "Private Placement", which closed on March 22, 2016.

Immediately prior to and in connection with the Merger, each share of Private Eiger's preferred stock outstanding was converted into shares of Private Eiger's common stock at an exchange ratio of one share of common stock for each share of preferred stock.

Under the terms of the Merger Agreement, at the effective time of the Merger, Celladon issued shares of common stock to Private Eiger stockholders, at an exchange ratio of approximately 0.09 shares of common stock, after taking into account the Reverse Stock Split, in exchange for each share of Private Eiger's common stock outstanding immediately prior to the Merger. The exchange ratio was calculated by a formula that was determined through arms-length negotiations between Celladon and Private Eiger. Immediately after the Merger, the former Private Eiger equity holders beneficially owned approximately 78% of post-merger Eiger's common stock. The Merger was accounted for as a reverse asset acquisition.

Financial Operations Overview

Research and Development Expenses

Research and development expenses represent costs incurred to conduct research and development, such as the development of our product candidates. We recognize all research and development costs as they are incurred. Research and development expenses consist primarily of the following:

- expenses incurred under agreements with consultants and clinical trial sites that conduct research and development activities on our behalf;
- laboratory and vendor expenses related to the execution of clinical trials;
- contract manufacturing expenses, primarily for the production of clinical supplies;
- license fees associated with our license agreements; and
- internal costs that are associated with activities performed by our research and development organization and generally benefit multiple programs. These costs are not separately allocated by product candidate. Unallocated internal research and development costs consist primarily of:
  - personnel costs, which include salaries, benefits and stock-based compensation expense;
  - allocated facilities and other expenses, which include expenses for rent and maintenance of facilities and depreciation expense; and
  - regulatory expenses and technology license fees related to development activities.

The largest component of our operating expenses has historically been the investment in research and development activities. However, we do not allocate internal research and development costs, such as salaries, benefits, stock-based compensation expense and indirect costs to product candidates on a program-specific basis. The following table shows our research and development expenses for the years ended December 31, 2016, 2015 and 2014 (in thousands):

	Year Ended December 31,		
	2016	2015	2014
Product candidates:			
LNF HDV	$ 5,237	$ 2,052	$ 515
Lambda HDV	7,244	—	—
Exendin 9-39 PBH	2,984	115	—
Ubenimex PAH	10,393	648	—
Ubenimex Lymphedema	2,271	198	—
Internal research and development costs	4,885	5,104	129
Total research and development expense	$ 33,014	$ 8,117	$ 644

We expect research and development expenses will increase in the future as we advance our product candidates into and through later stage clinical trials and pursue regulatory approvals, which will require a significant investment in regulatory support and contract manufacturing and inventory build-up related costs. In addition, we continue to evaluate opportunities to acquire or in-license other product candidates and technologies, which may result in higher research and development expenses due to license fee and/or milestone payments.

The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We may never succeed in timely developing and achieving regulatory approval for our product candidates. The probability of success of our product candidates may be affected by numerous factors, including clinical data, competition, intellectual property rights, manufacturing capability and commercial viability. As a result, we are unable to determine the duration and completion costs of our development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

General and Administrative Expenses

General and administrative expenses consist of personnel costs, allocated expenses and expenses for outside professional services, including legal, audit, accounting services and investor relations. Personnel costs consist of salaries, benefits and stock-based compensation. Allocated expenses consist of facilities and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation expense and other supplies. During the year ended December 31, 2016, we incurred incremental expenses as a result of the Merger and additional expenses as a result of becoming a public company following completion of the Merger, including expenses related to compliance with the rules and regulations of the SEC and NASDAQ, additional insurance, investor relations and other administrative expenses and professional services.

Interest Expense

Interest expense consists of interest and amortization of the debt discount related to the outstanding convertible promissory notes issued in November 2015 and then converted into common stock in March 2016, or the Notes.

Other expense, net

Other expense, net consists of the change in fair value of the obligation to issue common stock to Eiccose and the change in fair value of warrant liability.

The change in fair value of the obligation to issue common stock to Eiccose was related to our obligation to issue shares to Eiccose upon the closing of the next round of financing that resulted in at least $25.0 million in gross proceeds to us. Upon the closing of the Private Placement on March 22, 2016, we issued to Eiccose 96,300 fully vested shares of our common stock in settlement of this obligation. In connection with this transaction we remeasured the fair value of the obligation to issue common stock at the settlement date and the change in fair value of $0.2 million was recognized within other expense, net during the year ended December 31, 2016. Upon the settlement of the obligation with the issuance of shares on March 22, 2016, the liability was reclassified to common stock and additional paid-in capital within stockholders' equity.

In connection with our issuance of the Notes, we issued warrants to the noteholders to purchase shares of our common stock at an exercise price of $0.11 per share, on a post-Merger and post-Reverse Stock Split basis, or the Warrants. The number of shares into which the Warrants could be exercised was equal to the warrant coverage amount divided by the per share price of the equity securities sold in a qualified financing and thus was accounted for as a liability. Upon the closing of the Private Placement on March 22, 2016, the number of shares of common stock issuable upon exercise of the Warrants was fixed and the fair value remeasured at that date, and the warrants were automatically exercised. During the year ended December 31, 2016, we recognized a loss related to the change in fair value of the warrant liability of $0.2 million. The warrant liability was reclassified to common stock and additional paid-in capital within stockholders' equity, upon the exercise of the Warrants and issuance of shares on March 22, 2016.

Critical Accounting Policies 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 generally accepted accounting principles in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, we evaluate these estimates and judgments. We base our estimates on historical experience and on various assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results may differ materially from these estimates. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Accrued Research and Development Expenses

We record accrued expenses for estimated costs of research and development activities conducted by external service providers, which include the conduct of clinical research and contract formulation and manufacturing activities. We record the estimated costs of development activities based upon the estimated amount of services provided but not yet invoiced, and include these costs in accrued liabilities in the consolidated balance sheet and within development expense in the consolidated statement of operations. We record accrued expenses for these costs based on the estimated amount of work completed and in accordance with agreements established with these external service providers.

We estimate the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. We make judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, we adjust our accrued estimates.

Stock-Based Compensation

We recognize compensation costs related to stock options granted to employees based on the estimated fair value of the awards on the date of grant, net of estimated forfeitures. We estimate the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option-pricing model. The grant date fair value of the stock-based awards is generally recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards.

The Black-Scholes option-pricing model requires the use of highly subjective assumptions, which determine the fair value of stock-based awards. These assumptions include:

Expected Term. Our expected term represents the period that our stock-based awards are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term).

Expected Volatility. Since we have only been publicly traded for a short period and do not have adequate trading history for our common stock, the expected volatility was estimated based on the average volatility for comparable publicly traded biopharmaceutical companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle, or area of specialty.

Risk-Free Interest Rate. The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of option.

Expected Dividend. We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

In addition to the Black-Scholes assumptions, we estimate our forfeiture rate based on an analysis of our actual forfeitures and will continue to evaluate the adequacy of the forfeiture rate based on actual forfeiture experience, analysis of employee turnover behavior, and other factors. The impact from any forfeiture rate adjustment would be recognized in full in the period of adjustment and if the actual number of future forfeitures differs from our estimates, we might be required to record adjustments to stock-based compensation in future periods.

Prior to the completion of the Merger in March 2016, the fair value of the shares of common stock underlying our share-based awards were estimated on each grant date by our Board of Directors. In order to determine the fair value of our common stock underlying option grants, our Board of Directors considered, among other things, timely valuations of our common stock prepared by an unrelated third-party valuation firm in accordance with the guidance provide by the American Institute of Certified Public Accountants Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Given the absence of a public trading market for our common stock, our Board of Directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common stock, including our stage of development; progress of our research and development efforts; the rights, preferences and privileges of our preferred stock relative to those of our common stock; equity market conditions affecting comparable public companies and the lack of marketability of our common stock. After the completion of the Merger, our Board of Directors determined the fair value of each share of underlying common stock based on the closing price of our common stock as reported by the NASDAQ Global Market on the date of grant.

Results of Operations

Comparison of the Years Ended December 31, 2016 and 2015

The following table summarizes results of operations for the years ended December 31, 2016 and 2015 (in thousands):

	Years Ended December 31,		Increase / (Decrease)	% Change
	2016	2015		
Operating expenses:				
Research and development	$ 33,014	$ 8,117	$ 24,897	307%
General and administrative	13,106	4,855	8,251	170%
Total operating expenses	46,120	12,972	33,148	
Loss from operations	(46,120)	(12,972)	(33,148)	
Interest expense	(690)	(350)	(340)	97%
Other expense, net	(277)	—	(277)	100%
Net loss	$ (47,087)	$ (13,322)	$ (33,765)	

Research and development expenses

Research and development expenses increased by $24.9 million to $33.0 million for the year ended December 31, 2016, from $8.1 million for the same period in 2015. The increase was primarily due to a $15.0 million increase in clinical expenditures due to increased program activity, a $5.2 million expense related to upfront payments under our License Agreement with Bristol-Meyers Squibb Company (the BMS License Agreement), a $2.2 million increase in compensation and personnel related expenses and a $0.7 million increase in stock-based compensation expense due to an increase in headcount, a $1.6 million increase in consulting fees related to increased program activity and a $0.2 million increase in facility related and insurance expenses.

General and administrative expenses

General and administrative expenses increased by $8.3 million to $13.1 million for the year ended December 31, 2016, from $4.9 million for the same period in 2015. The increase was primarily due to a $3.4 million increase in consulting, advisory, legal and accounting services incurred in connection with the Merger with Celladon and being a public company, a $2.3 million increase in stock-based compensation expense and a $1.4 million increase in compensation and personnel related expenses due to an increase in headcount, a $0.6 million increase in litigation expenses related to the Celladon shareholder law suit and a $0.5 million increase in facility related and insurance expenses.

Interest expense, net

Interest expense increased by $0.3 million to $0.7 million for the year ended December 31, 2016, from $0.4 million for the same period in 2015. Interest expense consisted of interest and amortization of the debt discount related to the Notes outstanding prior to their conversion into common stock in March 2016. The increase was primarily due to a longer outstanding period in 2016 compared to 2015.

Other expenses, net

Other expense, net of $0.3 million for the year ended December 31, 2016, primarily consists of the change in fair value of the obligation to issue common stock to Eiccose and the change in fair value of warrant liability. We did not have any such items outstanding during the year ended December 31, 2015.

Comparison of the Years Ended December 31, 2015 and 2014

The following table summarizes results of operations for the years ended December 31, 2015 and 2014 (in thousands):

	Years Ended December 31,		Increase / (Decrease)	% Change
	2015	2014		
Operating expenses:				
Research and development	$ 8,117	$ 644	$ 7,473	1160%
General and administrative	4,855	872	3,983	457%
Total operating expenses	12,972	1,516	11,456	
Loss from operations	(12,972)	(1,516)	(11,456)	
Interest expense	(350)	—	(350)	100%
Net loss	$ (13,322)	$ (1,516)	$ (11,806)	

Research and development

Research and development expenses increased by $7.5 million to $8.1 million for the year ended December 31, 2015 from $0.6 million for the same period in 2014. The increase was primarily due to a $1.7 million expense related to the fair value of the Company's obligation to issue common stock, the license fees and other expenses incurred in connection with the Eiccose purchase agreement, a $2.5 million increase in clinical expenditures due to increased program activity, a $1.1 million increase in costs to third-party consultants, a $1.1 million increase in personnel related costs due to increase in headcount, a $1.0 million milestone payment in May 2015 under the Merck license agreement related to the achievement of a development milestone related to clinical trials.

General and administrative

General and administrative expenses increased by $4.0 million to $4.9 million for the year ended December 31, 2015 from $0.9 million for the same period in 2014. The increase was primarily due to a $2.5 million increase in consulting, advisory, legal and accounting services incurred in connection with the Merger with Celladon, patent related matters and various business development activities, a $1.4 million increase in personnel related costs due to an increase in headcount, and $0.1 million in facility costs due to the new office facility leased in March 2015.

Interest Expense

Interest expense of $0.4 million for the year ended December 31, 2015 consists of interest and amortization of the debt discount related to the Notes outstanding. We did not have any debt obligations during the year ended December 31, 2014.

Sources of Liquidity

On March 22, 2016, we completed the Merger with Celladon, which provided $28.0 million in cash, and issued common stock in a Private Placement, which provided $32.1 million in cash, net of issuance costs. Prior to that time, our operations had been financed primarily by net proceeds from the sale of convertible preferred stock and the issuance of warrants and convertible promissory notes.

In June 2016, we filed a shelf registration statement on Form S-3 (File No. 333-212114) with the Securities and Exchange Commission which permits the offering, issuance and sale by us of up to a maximum aggregate offering price of $125.0 million of our common stock, preferred stock, debt securities and warrants. Up to a maximum of $25.0 million of the maximum aggregate offering price of $125.0 million may be issued and sold pursuant to an At-The-Market, or ATM, financing facility under a sales agreement with Cantor Fitzgerald &Co. On August 23, 2016, we completed an underwritten public offering of 1,250,000 shares of common stock at an offering price of $16.00 for gross cash proceeds of $20.0 million under our shelf registration statement. As a result of the sale, our aggregate offering price was reduced to $105.0 million.

In December 2016, we entered into a secured loan agreement with Oxford Finance LLC, pursuant to which we borrowed $15.0 million and will be permitted to borrow up to an additional $10.0 million upon achievement of positive top line data from the lonafarnib Phase 2 trials in HDV and positive top line Phase 2 data from at least one of the following programs, including: (i) Lambda in HDV, (ii) exendin 9-39 in PBH based on the Company's own IND, (iii) ubenimex in PAH, or (iv) ubenimex in Lymphedema.

As of December 31, 2016, we had $27.8 million of cash and cash equivalents, $32.2 million of short-term marketable securities and an accumulated deficit of $76.4 million. We believe that the currently available resources will be sufficient to fund our operations for at least the next 12 months following the issuance date of these consolidated financial statements.

Our primary uses of cash are to fund operating expenses, including research and development expenditures and general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in outstanding accounts payable and accrued expenses.

Future Funding Requirements

We have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate any revenue from product sales unless and until we obtain regulatory approval for and commercialize any of our product candidates. At the same time, we expect our expenses to increase in connection with our ongoing development and manufacturing activities, particularly as we continue the research, development, manufacture and clinical trials of, and seek regulatory approval for, our product candidates.

Our primary uses of capital are, and we expect will continue to be, funding research efforts and the development of our product candidates, compensation and related expenses, hiring additional staff, including clinical, scientific, operational, financial, and management personnel, and costs associated with operating as a public company. We expect to incur substantial expenditures in the foreseeable future for the development and potential commercialization of our product candidates.

We plan to continue to fund losses from operations and capital funding needs through future equity and/or debt financings, as well as potential additional collaborations or strategic partnerships with other companies. 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. We can provide no assurance 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 delay, 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.

Cash Flows

The following table summarizes our cash flows for the periods indicated (in thousands):

	Years Ended December 31,		
	2016	2015	2014
Net cash provided by (used in):			
Operating activities	$ (37,970)	$ (9,134)	$ (1,280)
Investing activities	(4,194)	(45)	(3)
Financing activities	65,142	13,180	1,915
Net increase in cash and cash equivalents	$ 22,978	$ 4,001	$ 632

Cash flows from operating activities

Cash used in operating activities for the year ended December 31, 2016, was $38.0 million, primarily consisted of a net loss of $47.1 million, offset by $3.2 million expense related to a non-cash issuance of common stock to Bristol-Meyers Squibb in connection with the BMS License Agreement, $3.2 million of stock-based compensation expense, $0.7 million of non-cash interest expense related to the Notes outstanding prior to their conversion into common stock in March 2016 and $0.4 million change in fair value of warrant liability and obligation to issue shares to Eiccose. Additionally, cash used in operating activities reflected changes in net operating assets primarily due to an increase of $1.5 million in accounts payable and accrued expenses and other liabilities primarily associated with increase in business activity, and decrease of $0.3 million in prepaid expenses and other current assets.

Cash used in operating activities for the year ended December 31, 2015 was $9.1 million, primarily consisted of a net loss of $13.3 million, offset by $1.5 million change in fair value of obligation to issue shares to Eiccose, $0.4 million of non-cash interest expense related to the Notes, $0.2 million expense related to a non-cash issuance of common stock to Dr. Tracey McLaughlin and Dr. Colleen Craig in connection with the acquisition of assets related to the compound exendin 9-39 and $0.2 million of stock-based compensation expense. Additionally, cash used in operating activities reflected changes in net operating assets primarily due to an increase of $2.7 million in accounts payable and accrued expenses and other liabilities primarily associated with increase in business activity, offset by a $0.7 million increase in prepaid expenses and other current assets primarily associated with the prepayment of a license agreement.

Cash used in operating activities for the year ended December 31, 2014 was $1.3 million and primarily consisted of a net loss of $1.5 million, offset by a $0.2 million increase in accrued expenses and other liabilities primarily associated with increase in research and development activities.

Cash flows from investing activities

Net cash used in investing activities of $4.2 million for the year ended December 31, 2016, and primarily consisted of a $34.2 million purchase of marketable securities, offset by $28.0 million of proceeds received upon the consummation of the Merger and $2.0 million proceeds from maturities of marketable securities.

Cash used in investing activities for the year ended December 31, 2015 and 2014 was related to the purchase of property and equipment.

Cash flows from financing activities

Cash provided by financing activities for the year ended December 31, 2016, primarily consisted of $32.1 million of proceeds from the issuance of common stock in the Private Placement on March 22, 2016, net of issuance costs, net proceeds of $18.2 million from the issuance of common stock in the underwritten public offering, after deducting underwriting discounts and commissions and expenses payable by us, and proceeds of $14.8 million from borrowings in connection with Oxford loan, net of issuance costs.

Cash provided by financing activities for the year ended December 31, 2015 consisted of $7.2 million of proceeds from the issuance of convertible preferred stock, net of issuance costs and $6.0 million of proceeds from issuance of the Notes, net of issuance costs.

Cash provided by financing activities for the year ended December 31, 2014 consisted of $1.9 million of proceeds from the issuance of convertible preferred stock, net of issuance costs.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at December 31, 2016 (in thousands):

	Payments due by period				
	Total	Less than 1 year	1 – 3 Years	3 – 5 Years	More than 5 years
Operating lease obligations (1)	$ 401	$ 330	$ 71	$ —	$ —
Term loan debt (2)	$ 15,000	$ —	$ 12,083	$ 2,917	$ —
Interest on term loan debt (3)	$ 4,378	$ 979	$ 2,205	$ 1,194	$ —
Total	$ 19,779	$ 1,309	$ 14,359	$ 4,111	$ —

(1) Represents future rent payments under two Palo Alto facility lease contracts.
(2) Represents the Oxford first tranche Loan of $15.0 million.
(3) Includes an exit fee on the Oxford Loan of $1.125 million due at maturity.

We are obligated to make future payments to third parties under asset purchase and license agreements, including royalties and payments that become due and payable on the achievement of certain development and commercialization milestones. We have not included these potential payment obligations in the table above as the amount and timing of such payments are not known.

Oxford Finance Term Loan

On December 30 2016, we entered into the Oxford Loan for $25.0 million. The Oxford Loan bears interest at a floating rate per annum equal to the greater of either the 30-day U.S. Dollar LIBOR reported in the Wall Street Journal plus 6.41% or 6.95%, with interest only payments through July 1, 2018 followed by 36 equal monthly payments of principal and interest until maturity at July 1, 2021. At the time of final payment, we are required to pay an exit fee of 7.5% of the original principal balance of the Oxford Loan, which was $1.125 million at December 31, 2016. The loan is secured by the perfected first priority liens on our assets, including our commitment to not allow any liens to be placed upon our intellectual property. The Oxford Loan includes customary events of default, including failure to pay amounts due, breaches of covenants and warranties, material adverse effect events, certain cross defaults and judgments, and insolvency. As of December 31, 2016, we were in compliance with all loan terms.

Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements as defined under the rules of the SEC and do not have any holdings in variable interest entities.

Recent Accounting Pronouncements

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements – Going Concern (Subtopic 205-40)* – Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (ASU 2014-15), which requires the Company's management to evaluate whether there is substantial doubt about the Company's ability to continue as a going concern. The pronouncement is effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early adoption is permitted. The Company adopted ASU 2014-15 during its fiscal year ended December 31, 2016, which did not have a material effect on the Company's consolidated financial statements and related disclosures.

In January 2016, the FASB issued ASU No. 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities*. ASU No. 2016-01 supersedes and amends the guidance to classify equity securities with readily determinable fair values into different categories (that is, trading or available-for-sale) and require equity securities to be measured at fair value with changes in the fair value recognized through net income. The amendments allow equity investments that do not have readily determinable fair values to be remeasured at fair value either upon the occurrence of an observable price change or upon identification of an impairment. The amendments also require enhanced disclosures about those investments. ASU No. 2016-01 is effective for annual reporting beginning after December 15, 2017, including interim periods within the year of adoption, and calls for prospective application. The Company is currently in the process of evaluating the impact that the standard will have on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which requires lessees to recognize most leases on their balance sheet. The standard requires use of the modified retrospective transition method, with elective relief, which requires application of the guidance for all periods presented. The new standard will be effective for fiscal years beginning after December 15, 2018. Early adoption is permitted. The Company is currently in the process of evaluating the impact that the standard will have on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, *Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, which is intended to simplify several aspects of the accounting for employee share-based payment transactions, including the accounting and reporting of income taxes, the determination of forfeiture rates, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years and interim periods within those years beginning after December 15, 2016 and early adoption is permitted. The Company does not anticipate the adoption of ASU 2016-09 will have a material impact of its consolidated financial statements and related disclosures.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326)*. The standard changes how entities will measure credit losses for most financial assets and certain other instruments that are not measured at fair value through net income. Financial assets measured at amortized cost will be presented at the net amount expected to be collected by using an allowance for credit losses. The standard is effective for fiscal years and interim periods beginning after December 15, 2019. Early adoption is permitted for all periods beginning after December 15, 2018. The Company is currently in the process of evaluating the impact that the standard will have on its consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, *"Statement of Cash Flows (Topic 230)*: *Classification of Certain Cash Receipts and Cash Payments.* ASU 2016-15 identifies how certain cash receipts and cash payments are presented and classified in the Statement of Cash Flows. The standard is effective for fiscal years and interim periods beginning after December 15, 2017. The standard should be applied retrospectively and early adoption is permitted, including adoption in an interim period. The Company is currently in the process of evaluating the impact that the standard will have on its consolidated financial statements.

ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and are not required to provide the information under this item.

ITEM 8. Financial Statements and Supplementary Data

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of
Eiger BioPharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Eiger BioPharmaceuticals, Inc. and subsidiaries (the Company), as of December 31, 2016 and 2015, and the related consolidated statements of operations, comprehensive loss, stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2016. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Eiger BioPharmaceuticals, Inc. and subsidiaries as of December 31, 2016 and 2015, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles.

/s/ KPMG LLP

San Francisco, CA
March 22, 2017

Eiger BioPharmaceuticals, Inc.

Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	December 31,	
	2016	2015
Assets		
Current assets:		
Cash and cash equivalents	$ 27,756	$ 4,778
Short-term marketable securities	32,180	—
Prepaid expenses and other current assets	581	717
Total current assets	60,517	5,495
Property and equipment, net	76	41
Other assets	143	46
Total assets	$ 60,736	$ 5,582
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 2,639	$ 1,940
Accrued liabilities	2,649	1,006
Convertible promissory note	—	5,444
Total current liabilities	5,288	8,390
Long term debt, net	14,727	—
Warrant liability	—	885
Obligation to issue common stock	—	1,457
Other long term liabilities	—	2
Total liabilities	$ 20,015	$ 10,734
Commitments and contingencies		
Stockholders' equity (deficit):		
Convertible preferred stock, $0.0001 par value: 0 and 2,694,579 shares authorized as of December 31, 2016 and 2015, respectively; 0 and 2,609,102 shares issued and outstanding as of December 31, 2016 and 2015, respectively; liquidation preference of $0 and $22,269 as of December 31, 2016 and 2015, respectively	—	22,567
Preferred stock, $0.0001 par value: 10,000,000 and 0 shares authorized as of December 31, 2016 and 2015, respectively; 0 shares issued and outstanding as of December 31, 2016 and 2015, respectively	—	—
Common stock, $0.0001 par value, 200,000,000 and 5,951,487 shares authorized as of December 31, 2016 and 2015, respectively; 8,356,659 and 273,993 shares issued and outstanding as of December 31, 2016 and 2015, respectively	8	—
Additional paid-in capital	117,086	1,552
Accumulated other comprehensive loss	(15)	—
Accumulated deficit	(76,358)	(29,271)
Total stockholders' equity (deficit)	40,721	(5,152)
Total liabilities and stockholders' equity (deficit)	$ 60,736	$ 5,582

See accompanying notes to the consolidated financial statements.

Eiger BioPharmaceuticals, Inc.

Consolidated Statements of Operations

(In thousands, except share and per share amounts)

	Year Ended December 31,		
	2016	**2015**	**2014**
Operating expenses:			
Research and development	$ 33,014	$ 8,117	$ 644
General and administrative	13,106	4,855	872
Total operating expenses	46,120	12,972	1,516
Loss from operations	(46,120)	(12,972)	(1,516)
Interest expense	(690)	(350)	—
Other expense, net	(277)	—	—
Net loss	$ (47,087)	$ (13,322)	$ (1,516)
Net loss per share, basic and diluted	$ (7.84)	$ (62.19)	$ (7.82)
Weighted-average common shares outstanding, basic and diluted	6,007,027	214,228	193,850

See accompanying notes to the consolidated financial statements.

Eiger BioPharmaceuticals, Inc.

Consolidated Statements of Comprehensive Loss

(In thousands)

	Year Ended December 31,		
	2016	2015	2014
Net loss	$ (47,087)	$ (13,322)	$ (1,516)
Other comprehensive loss:			
Unrealized loss on marketable securities, net	(15)	—	—
Comprehensive loss	$ (47,102)	$ (13,322)	$ (1,516)

See accompanying notes to the consolidated financial statements.

Eiger BioPharmaceuticals, Inc.

Consolidated Statements of Stockholders' Equity (Deficit)

(In thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Loss	Deficit	Equity (Deficit)
Balance at December 31, 2013	1,228,418	$ 13,451	193,850	$ —	$ 1,087	$ —	$ (14,433)	$ 105
Issuance of Series A-1 convertible preferred stock, net of $13 of issuance costs	290,856	1,915	—	—	—	—	—	1,915
Stock-based compensation expense	—	—	—	—	27	—	—	27
Net loss	—	—	—	—	—	—	(1,516)	(1,516)
Balance at December 31, 2014	1,519,274	15,366	193,850	—	1,114	—	(15,949)	531
Issuance of Series A-1 convertible preferred stock, net of $22 of issuance costs	1,089,828	7,201	—	—	—	—	—	7,201
Issuance of common stock in connection with a license and asset purchase agreement	—	—	15,378	—	211	—	—	211
Issuance of common stock upon stock option exercises	—	—	64,765	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	227	—	—	227
Net loss	—	—	—	—	—	—	(13,322)	(13,322)
Balance at December 31, 2015	2,609,102	22,567	273,993	—	1,552	—	(29,271)	(5,152)
Issuance of common stock upon private placement, net of $1,300 of issuance cost	—	—	1,954,390	2	32,106	—	—	32,108
Issuance of common stock upon conversion of convertible promissory note	—	—	350,040	—	6,129	—	—	6,129
Issuance of common stock upon exercise of warrants	—	—	61,254	—	1,057	—	—	1,057
Issuance of common stock to Eiccose upon private placement	—	—	96,300	—	1,661	—	—	1,661
Conversion of preferred stock into common stock	(2,609,102)	(22,567)	2,609,102	3	22,564	—	—	—
Issuance of common stock upon reverse merger	—	—	1,596,959	2	27,388	—	—	27,390
Issuance of common stock upon execution of license agreement	—	—	157,587	—	3,172	—	—	3,172
Issuance of common stock upon public offering, net of $1,800 of issuance costs	—	—	1,250,000	1	18,228	—	—	18,229
Issuance of common stock upon exercise of stock option	—	—	7,034	—	39	—	—	39
Stock-based compensation expense	—	—	—	—	3,190	—	—	3,190
Unrealized loss on marketable securities, net	—	—	—	—	—	(15)	—	(15)
Net loss	—	—	—	—	—	—	(47,087)	(47,087)
Balance at December 31, 2016	—	$ —	8,356,659	$ 8	$ 117,086	$ (15)	$ (76,358)	$ 40,721

See accompanying notes to the consolidated financial statements.

Eiger BioPharmaceuticals, Inc.

Consolidated Statements of Cash Flows

(In thousands)

	Year Ended December 31,		
	2016	**2015**	**2014**
Operating Activities			
Net loss	$ (47,087)	$ (13,322)	$ (1,516)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	23	11	8
Amortization of premiums on marketable securities	(41)	—	—
Stock-based compensation	3,190	227	27
Noncash interest expense	685	350	—
Issuance of common stock in connection with a license and asset purchase agreement	3,172	211	—
Change in fair value of obligation to issue shares to Eiccose	204	1,457	—
Change in fair value of warrants liability	165	—	—
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	326	(685)	(14)
Other non-current assets	(89)	(46)	—
Accounts payable	699	1,881	40
Accrued and other liabilities	783	782	175
Net cash used in operating activities	(37,970)	(9,134)	(1,280)
Investing Activities			
Purchase of marketable securities	(34,154)	—	—
Proceeds from maturities of marketable securities	2,000	—	—
Cash received from merger transaction	28,018	—	—
Purchase of property and equipment	(58)	(45)	(3)
Net cash used in investing activities	(4,194)	(45)	(3)
Financing Activities			
Proceeds from borrowings in connection with term loan, net of issuance cost	14,759	—	—
Proceeds from issuance of common stock upon private placement, net of issuance cost	32,108	—	—
Proceeds from issuance of common stock upon public offering, net of issuance cost	18,229	—	—
Proceeds from issuance of common stock upon options exercises	39	—	—
Proceeds from issuance of common stock upon warrants exercises	7	—	—
Proceeds from issuance of convertible promissory note, net of issuance costs	—	5,979	—
Proceeds from issuance of preferred stock, net of issuance costs	—	7,201	1,915
Net cash provided by financing activities	65,142	13,180	1,915
Net increase in cash and cash equivalents	22,978	4,001	632
Cash and cash equivalents at beginning of period	4,778	777	145
Cash and cash equivalents at end of period	$ 27,756	$ 4,778	$ 777
Supplemental disclosure of cash flow information			
Noncash investing and financing activities:			
Conversion of warrant liability to common stock upon private placement	$ 1,050	$ —	$ —
Issuance of common stock in connection with a license agreement	3,172	211	—
Issuance of common stock to Eiccose upon private placement	1,661	—	—
Noncash net liabilities assumed in reverse merger	671	—	—
Conversion of convertible promissory note to common stock upon private placement	6,129	—	—
Conversion of preferred stock to common stock upon reverse merger	22,567	—	—
Issuance of warrants in connection with convertible promissory note	—	885	—

See accompanying notes to the consolidated financial statements.

1. Description of Business

Eiger BioPharmaceuticals, Inc. (the "Company") was incorporated in the State of Delaware on November 6, 2008. The Company is a clinical-stage biopharmaceutical company committed to bringing to market novel products for the treatment of orphan diseases. The Company has built a diverse portfolio of well-characterized product candidates with the potential to address diseases for which the unmet medical need is high, the biology for treatment is clear, and for which an effective therapy is urgently needed. The Company's principal operations are based in Palo Alto, California and it operates in one segment.

Reverse Merger

On March 22, 2016, Eiger BioPharmaceuticals, Inc. ("Eiger") completed its merger with Celladon Corporation ("Celladon") in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated November 18, 2015 (the "Merger Agreement"), by and among Celladon, Celladon Merger Sub, Inc. ("Merger Sub") and Eiger (the "Merger"). Pursuant to the Merger Agreement, Merger Sub merged with and into Eiger, with Eiger becoming a wholly-owned subsidiary of Celladon and the surviving corporation of the Merger. Pursuant to the terms and subject to the conditions set forth in the Merger Agreement, Eiger stockholders became the majority stockholders of the surviving company. In connection with, and immediately prior to, the closing of the Merger, on March 22, 2016, Celladon filed an amendment to its amended and restated certificate of incorporation with the Secretary of State of the State of Delaware to affect a fifteen-for-one reverse stock split of its common stock (the "Reverse Stock Split"). In connection with and immediately following the consummation of the Merger, on March 22, 2016, Celladon filed an amendment to its amended and restated certificate of incorporation with the Secretary of State of the State of Delaware to change its name to Eiger BioPharmaceuticals, Inc. The Company's shares of common stock listed on the NASDAQ Global Market, previously trading through the close of business on Tuesday, March 22, 2016 under the ticker symbol "CLDN," commenced trading on the NASDAQ Global Market, on a post-reverse stock split adjusted basis, under the ticker symbol "EIGR" on March 23, 2016. On March 22, 2016, a Certificate of Merger was filed with the Secretary of State of the State of Delaware to affect the Merger of Merger Sub with and into Eiger. See Note 5 for further details.

The Company, or Eiger, as used in the accompanying notes to the consolidated financial statements, refers to Private Eiger prior to the completion of the Merger and Public Eiger subsequent to the completion of the Merger.

Reverse Stock Split and Exchange Ratio

On March 22, 2016, and prior to the closing of the Merger, Celladon completed a fifteen-for-one reverse stock split. As a result of the reverse stock split, every fifteen shares of Celladon common stock outstanding immediately prior to the Merger were combined and reclassified into one share of Celladon common stock. No fractional shares were issued in connection with the reverse stock split.

The holders of shares of Eiger common stock outstanding immediately prior to the Merger received approximately 0.09 shares of Celladon common stock in exchange for each share of Eiger common stock in the Merger. Following the reverse stock split and the Merger on March 22, 2016, the combined company had 6,945,401 shares of common stock outstanding.

The accompanying consolidated financial statements and notes to the consolidated financial statements give retroactive effect to the reverse stock split for all periods presented.

Liquidity

As of December 31, 2016, the Company had $27.8 million of cash and cash equivalents, $32.2 million of short-term marketable securities, an accumulated deficit of $76.4 million and negative cash flows from operating activities. The Company expects to continue to incur losses for the next several years.

Management believes that the currently available resources will be sufficient to fund its operations for at least the next 12 months following the issuance date of these consolidated financial statements. However, if the Company's anticipated operating results are not achieved in future periods, management believes that planned expenditures may need to be reduced in order to extend the time period over which the then-available resources would be able to fund the Company's operations.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The consolidated financial statements include the accounts of Eiger BioPharmaceuticals, Inc. and its wholly owned subsidiaries, EB Pharma LLC and Eiger BioPharmaceuticals Europe Limited, and have been prepared in conformity with accounting principles generally accepted in the United States of America, ("U.S. GAAP"). All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. 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. On an ongoing basis, the Company evaluates its estimates, including those related to clinical trial accrued liabilities, stock-based compensation and income taxes. The Company bases its estimates on historical experience and on various other market-specific and relevant assumptions that the Company believes to be reasonable under the circumstances. Actual results could differ from those estimates.

Concentrations of Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consists of cash, cash equivalents and investments. The Company's cash is held by a financial institution in the United States. Amounts on deposit may at times exceed federally insured limits. Management believes that the financial institution is financially sound, and accordingly, minimal credit risk exists with respect to the financial institution.

For each product candidate, the Company relies on one supply chain for each of the four product candidates. If any of the single source suppliers in any of the supply chains fail to satisfy the Company's requirements on a timely basis, it could suffer delays in its clinical development programs and activities, which could adversely affect its operating results.

Cash and Cash Equivalents

Cash and cash equivalents include all cash balances and highly liquid investments with original maturities of three months or less from the date of purchase. Cash equivalents consists primarily of amounts invested in money market funds held at financial institutions and corporate debt securities. The recorded carrying amount of cash equivalents approximates their fair value.

Investments

Short-term investments consist of debt securities classified as available-for-sale and have maturities greater than 90 days, but less than 365 days from the date of acquisition. All investments are carried at fair value based upon quoted market prices. Unrealized gains and losses on available-for-sale securities are excluded from earnings and are reported as a component of accumulated other comprehensive loss. The cost of available-for-sale securities sold is based on the specific-identification method. Realized gains and losses on the sale of marketable securities are determined using the specific-identification method and recorded in other expense, net on the accompanying consolidated statements of operations.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Depreciation expense is computed using the straight-line method over the estimated useful lives of the assets. Depreciation begins at the time the asset is placed into service. Maintenance and repairs are charged to operations as incurred. Property and equipment purchased for specific research and development projects with no alternative uses are expensed as incurred.

The useful lives of the property and equipment are as follows:

Lab equipment	5 years
Computer equipment and software	3 years

Impairment of Long-Lived Assets

The Company evaluates its long-lived assets, including property and equipment, for impairment whenever events or changes in circumstances indicate that the carrying value of these assets may not be recoverable. The Company assesses the recoverability of long-lived assets by determining whether or not the carrying value of such assets will be recovered through undiscounted expected future cash flows. If the asset is considered to be impaired, the amount of any impairment is measured as the difference between the carrying value and the fair value of the impaired asset. Through December 31, 2016, the Company has not impaired any long-lived assets.

Accrued Research and Development Costs

The Company accrues for estimated costs of research and development activities conducted by third-party service providers, which include the conduct of preclinical and clinical studies, and contract manufacturing activities. The Company records the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced, and includes these costs in accrued liabilities in the consolidated balance sheets and within research and development expense in the consolidated statements of operations. The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with agreements established with its third-party service providers. The Company makes judgments and estimates in determining the accrued liabilities balance in each reporting period. As actual costs become known, the Company adjusts its accrued liabilities.

Deferred Financing Costs

Financing costs incurred with securing a term debt are recorded in the Company’s consolidated balance sheets as an offset to the term debt and amortized to interest expense in the Company’s consolidated statements of operations over the contractual life of the loan using the effective interest method.

Warrant Liability

The Company issued warrants to purchase equity securities of the Company (the “Warrants”) in connection with the issuance of a convertible promissory notes (the “Notes”) (see Note 9). The Company accounted for the Warrants as a liability at fair value as the number of shares were not fixed and determinable at the issuance date. The Company continued to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the Warrants, or until the number of shares to be exercised became fixed, in which case the Warrants were classified in stockholders’ equity (deficit) as there were sufficient authorized and unissued shares of common stock to settle the Warrants and redeem any other contracts that may require settlement in shares of common stock. The change in fair value of the warrant liability was recognized as a component of other expense, net in the consolidated statements of operations. The warrant liability was settled in March 2016 (see Note 9), and thus is no longer subject to remeasurement.

Research and Development Costs

Research and development costs are expensed as incurred and consist of payroll expenses, stock-based compensation expense, lab supplies and allocated facility costs, as well as fees paid to third parties that conduct certain research and development activities on the Company's behalf. Amounts incurred in connection with license and asset purchase agreements are also included in research and development expense.

Stock-Based Compensation

Stock-based awards to employees and directors, including stock options, are recorded at fair value as of the grant date using the Black-Scholes option pricing model and recognized as expense on a straight line-basis over the employee's or director's requisite service period (generally the vesting period). Non-cash stock compensation expense is based on awards ultimately expected to vest and is reduced by an estimate for future forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from estimates. The determination of fair value for stock-based awards on the date of grant using an option pricing model requires management to make certain assumptions regarding subjective variables.

Stock-based awards and stock options issued to non-employee consultants are recorded at fair value and remeasured at the end of each period as they vest using the Black-Scholes option pricing model. Expense is recognized over the vesting period which is generally the same as the service period.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company must then assess the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Due to the Company's lack of earnings history, the net deferred tax assets have been fully offset by a valuation allowance.

The Company recognizes benefits of uncertain tax positions if it is more likely than not that such positions will be sustained upon examination based solely on their technical merits, as the largest amount of benefit that is more likely than not to be realized upon the ultimate settlement. The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense or benefit. To date, there have been no interest or penalties charged in relation to unrecognized tax benefits.

Internal Revenue Code Section 382 limits the use of net operating loss and tax credit carryforwards in certain situations where changes occur in the stock ownership of a company. In the event that the Company had a change of ownership, utilization of the net operating loss and tax credit carryforwards may be restricted. The Company has performed an Internal Revenue Code Section 382 limitation study as of December 31, 2016 (see Note 12).

Comprehensive Loss

Comprehensive loss represents all changes in stockholders' equity (deficit) except those resulting from and distributions to stockholders. The Company's unrealized gains and losses on available-for-sale securities represent the only component of other comprehensive loss that are excluded from the reported net loss and that are presented in the consolidated statements of comprehensive loss.

Net Loss per Share

Basic net loss per share of common stock is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding during the period, without consideration for potentially dilutive securities. Since the Company was in a loss position for all periods presented, diluted net loss per share is the same as basic net loss per share for all periods as the inclusion of all potential common shares outstanding would have been anti-dilutive.

The following table sets forth the outstanding potentially dilutive securities which have been excluded in the calculation of diluted net loss per share because including such securities would be anti-dilutive (in common stock equivalent shares):

	December 31,		
	2016	2015	2014
Options to purchase common stock	1,212,044	254,058	105,898
Warrants to purchase common stock	10,180	—	—
Convertible preferred stock	—	2,609,102	1,519,274
Total	1,222,224	2,863,160	1,625,172

Common stock issued in connection with the asset purchase agreements (see Note 7) and the note and warrants purchase agreement (see Note 9) were excluded from the total outstanding potentially dilutive securities as of December 31, 2015, as the amounts of common stock to be issued were not determinable as of December 31, 2015.

Recent Accounting Pronouncements

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements – Going Concern (Subtopic 205-40)* – Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (ASU 2014-15), which requires the Company's management to evaluate whether there is substantial doubt about the Company's ability to continue as a going concern. The pronouncement is effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early adoption is permitted. The Company adopted ASU 2014-15 during its fiscal year ended December 31, 2016, which did not have a material effect on the Company's consolidated financial statements and related disclosures.

In January 2016, the FASB issued ASU No. 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities*. ASU No. 2016-01 supersedes and amends the guidance to classify equity securities with readily determinable fair values into different categories (that is, trading or available-for-sale) and require equity securities to be measured at fair value with changes in the fair value recognized through net income. The amendments allow equity investments that do not have readily determinable fair values to be remeasured at fair value either upon the occurrence of an observable price change or upon identification of an impairment. The amendments also require enhanced disclosures about those investments. ASU No. 2016-01 is effective for annual reporting beginning after December 15, 2017, including interim periods within the year of adoption, and calls for prospective application. The Company is currently in the process of evaluating the impact that the standard will have on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which requires lessees to recognize most leases on their balance sheet. The standard requires use of the modified retrospective transition method, with elective relief, which requires application of the guidance for all periods presented. The new standard will be effective for fiscal years beginning after December 15, 2018. Early adoption is permitted. The Company is currently in the process of evaluating the impact that the standard will have on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, *Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, which is intended to simplify several aspects of the accounting for employee share-based payment transactions, including the accounting and reporting of income taxes, the determination of forfeiture rates, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years and interim periods within those years beginning after December 15, 2016 and early adoption is permitted. The Company does not anticipate the adoption of ASU 2016-09 will have a material impact of its consolidated financial statements and related disclosures.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326)*. The standard changes how entities will measure credit losses for most financial assets and certain other instruments that are not measured at fair value through net income. Financial assets measured at amortized cost will be presented at the net amount expected to be collected by using an allowance for credit losses. The standard is effective for fiscal years and interim periods beginning after December 15, 2019. Early adoption is permitted for all periods beginning after December 15, 2018. The Company is currently in the process of evaluating the impact that the standard will have on its consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, *"Statement of Cash Flows (Topic 230)*: *Classification of Certain Cash Receipts and Cash Payments.* ASU 2016-15 identifies how certain cash receipts and cash payments are presented and classified in the Statement of Cash Flows. The standard is effective for fiscal years and interim periods beginning after December 15, 2017. The standard should be applied retrospectively and early adoption is permitted, including adoption in an interim period. The Company is currently in the process of evaluating the impact that the standard will have on its consolidated financial statements.

3. Fair Value Measurements

Fair value accounting is applied for all financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). At December 31, 2016 and 2015 the carrying amount of prepaid expenses, accounts payable and accrued liabilities approximated their estimate fair value due to their relatively short maturities. Management believes the terms of the Notes and long term debt reflect current market conditions for an instrument with similar terms and maturity, therefore the carrying value of the Company's debt approximated its fair value.

Assets and liabilities recorded at fair value on a recurring basis in the consolidated balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

Level 1: Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2: Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and

Level 3: Unobservable inputs that are significant to the measurement of the fair value of the assets or liabilities that are supported by little or no market data.

The Company's money market funds are classified as Level 1 because they are valued using quoted market prices. The Company's marketable securities consist of available-for-sale securities and are classified as Level 2 because their value is based on valuations using significant inputs derived from or corroborated by observable market data. The Company's financial instruments as of December 31, 2015 included a warrant liability and an obligation to issue common stock in connection with the asset purchase agreement with Eiccose, LLC ("Eiccose") (see Note 7), which were classified as Level 3.

As of December 31, 2015, in order to determine the fair value of the Company's warrant liability and the obligation to issue common stock in connection with the Eiccose asset purchase agreement, the Company engaged an independent third-party valuation expert to determine the fair value of these instruments based on the common stock value which is based on probability weighted scenarios, each based on an income approach. The income approach estimates enterprise value based on the expectation of future cash flows that the Company will generate over the forecast horizon and a terminal value at the end of the forecast horizon. These future cash flows and terminal value are discounted to their present values using a discount rate based upon the required rate of return based on the risks associated with the investment. Upon settlement in March 2016, the Company remeasured the fair value of the Company's warrant liability and the obligation to issue common stock in connection with the Eiccose asset purchase agreement based on the fair value of the common stock that was issued upon settlement of these instruments.

There were no transfers between Level 1, Level 2 or Level 3 of the fair value hierarchy during the periods presented.

The following tables present the fair value hierarchy for assets and liabilities measured at fair value (in thousands):

	December 31, 2016			
	Level 1	Level 2	Level 3	Total
Financial Assets:				
Money market funds	$ 9,657	$ —	$ —	$ 9,657
Corporate debt securities	—	11,469	—	11,469
Commercial paper	—	22,891	—	22,891
Total	$ 9,657	$ 34,360	$ —	$ 44,017

	December 31, 2015			
	Level 1	Level 2	Level 3	Total
Financial liabilities:				
Warrant liability	$ —	$ —	$ 885	$ 885
Obligation to issue common stock	—	—	1,457	1,457
Total	$ —	$ —	$ 2,342	$ 2,342

There were no financial liabilities as of December 31, 2016. There were no financial assets as of December 31, 2015.

The following table provides a reconciliation of liabilities measured at fair value using Level 3 significant unobservable inputs (in thousands):

	Year Ended December 31,	
	2016	2015
Balance, beginning of period	$ 2,342	$ —
Issuance of common stock warrants	—	885
Initial recognition of obligation to issue common stock to Eiccose	—	1,457
Change in fair value of common stock warrants and obligation to issue common stock to Eiccose (1)	369	—
Settlement of warrant liability upon exercise of common stock warrants	(1,050)	—
Settlement of Eiccose obligation upon issuance of common stock	(1,661)	—
Balance, end of period	$ —	$ 2,342

(1) Changes in fair value of the obligation to issue common stock and the common stock warrant liability are recorded in other expense, net on the accompanying consolidated statements of operations.

The following table summarizes the estimated value of the Company's cash equivalents and marketable securities and the gross unrealized holding gains and losses (in thousands):

	December 31, 2016			
	Amortized cost	Unrealized gain	Unrealized loss	Estimated Fair Value
Cash equivalents:				
Money market funds	9,657	—	—	9,657
Corporate debt securities	2,180	—	—	2,180
Total cash equivalents	$ 11,837	$ —	$ —	$ 11,837
Marketable securities:				
Corporate debt securities	$ 9,294	$ —	$ (5)	$ 9,289
Commercial paper	22,901	3	(13)	22,891
Total marketable securities	$ 32,195	$ 3	$ (18)	$ 32,180

As of December 31, 2016, the contractual maturity of the available-for-sale marketable securities is less than one year. There were no cash equivalents and marketable securities at December 31, 2015.

4. Balance Sheet Components

Property and Equipment, Net

Property and equipment, net consist of the following (in thousands):

	December 31,	
	2016	2015
Lab equipment	$ 35	$ 35
Computer equipment and software	107	49
Total property and equipment	142	84
Less: accumulated depreciation	(66)	(43)
Property and equipment, net	$ 76	$ 41

Depreciation expense for the years ended December 31, 2016, 2015 and 2014 was $23,000, $11,000 and $8,000, respectively.

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2016	2015
Compensation and related benefits	$ 1,299	$ 586
Consulting costs	106	245
Contract research costs	834	152
Franchise tax	97	—
Contract manufacturing costs	122	—
Other	191	23
Total accrued liabilities	$ 2,649	$ 1,006

5. Reverse Merger

On March 22, 2016, Eiger completed the Merger with Celladon as discussed in Note 1. For accounting purposes, Eiger is considered to have acquired Celladon in the Merger. Eiger was determined to be the accounting acquirer based upon the terms of the Merger and other factors including; (i) Eiger security holders owned approximately 78% of the combined company immediately following the closing of the Merger, (ii) Eiger directors held all of the board seats in the combined company, and (iii) Eiger management held all key positions in the management of the combined company. The Merger was accounted for as an asset acquisition rather than business combination because the assets acquired and liabilities assumed by Eiger did not meet the definition of a business as defined by U.S. GAAP. The net assets acquired in connection with this transaction were recorded at their estimated acquisition date fair values as of March 22, 2016, the date the Merger with Celladon was completed.

Immediately prior to the effective date of the Merger and in connection with the Private Placement, the Notes converted into shares of common stock of Eiger. Further, all of the Warrants were exercised for common stock (see Note 9) and all shares of preferred stock of Eiger converted into shares of common stock of Eiger.

At the effective date of the Merger, Celladon issued shares of its common stock to Eiger stockholders, at an exchange rate of approximately 0.09 shares of common stock, after taking into account the Reverse Stock Split, in exchange for each share of Eiger common stock outstanding immediately prior to the Merger. The exchange rate was calculated by a formula that was determined through arms-length negotiations between Celladon and Eiger. The combined Company assumed all of the outstanding options, whether or not vested, under the Eiger 2009 Equity Incentive Plan (the “Eiger Plan”) with such options henceforth representing the right to purchase a number of shares of Celladon common stock equal to approximately 0.09 multiplied by the number of shares of Eiger common stock previously represented by such options.

Immediately after the Reverse Stock Split and the Merger on March 22, 2016, there were 6,945,401 shares of the combined Company's common stock outstanding. In addition, immediately after the Merger, pre-Merger Eiger stockholders, warrant holders and option holders owned approximately 78% of the aggregate number of shares of the combined Company's common stock, and the stockholders of Celladon immediately prior to the Merger owned approximately 22% of the aggregate number of shares of the combined Company's common stock (on a fully diluted basis).

On March 22, 2016, Celladon had 1,596,959 shares of common stock outstanding and a market capitalization of $27.5 million. The estimated fair value of the net assets of Celladon on March 22, 2016 was $27.3 million. The fair value of Celladon's common stock on the Merger closing date was above the fair value of Celladon's net assets. As Celladon's net assets were predominantly comprised of cash offset by current liabilities, the fair value of Celladon's net assets as of March 22, 2016 was considered to be the best indicator of the fair value and, therefore, the estimated purchase consideration.

The following table summarizes the net assets acquired based on their estimated fair values as of March 22, 2016 (in thousands):

Cash and cash equivalents	$	28,018
Prepaid and other assets		198
Current liabilities		(857)
Non-current liabilities		(12)
Net acquired tangible assets		27,347
Estimated total purchase consideration	$	27,347

6. License Agreements

Bristol-Meyers Squibb License Agreement

On April 20, 2016, the Company and Bristol-Myers Squibb Company ("BMS") entered into a License Agreement (the "BMS License Agreement") and a Common Stock Purchase Agreement (the "BMS Purchase Agreement").

Under the BMS License Agreement, BMS granted the Company an exclusive, worldwide, license to research, develop, manufacture, and sell products containing the proprietary BMS molecule known as PEG-interferon Lambda-1a (the "Licensed Product") for all therapeutic and diagnostic uses in humans and animals. The Company is responsible for the development and commercialization of the Licensed Product at its sole cost and expense. The License Agreement requires the Company to make an upfront payment of $2.0 million in cash and issue $3.0 million in Company common stock and includes development and regulatory milestone payments totaling $61.0 million and commercial sales milestones of up to $128.0 million. The Company is obligated to pay BMS annual net sales royalties in the range of mid-single to mid-teens, depending on net sales levels. In addition, if the Company grants a sublicense, the Company is obligated to pay BMS a portion of the sublicensing income received.

The Company paid BMS an upfront payment of $2.0 million in cash in April 2016, which was charged to research and development expense in the consolidated statement of operations as there is no future alternative use for the intellectual property licensed.

The Company also paid BMS $3.0 million of stock as an element of the upfront payment. The BMS Purchase Agreement provides for the issuance of 157,587 shares of common stock of the Company to BMS in consideration of the license granted to the Company under the BMS License Agreement. The BMS Purchase Agreement grants BMS certain registration rights with respect to the shares of common stock delivered, and BMS has agreed to certain trading and other restrictions with respect to the shares issued. In April 2016, the Company issued 157,587 common shares to BMS for an aggregate fair value of $3.2 million, which was charged to research and development expense in the consolidated statement of operations as there is no future alternative use for the intellectual property licensed.

Merck License Agreement

In September 2010, the Company entered into an exclusive license agreement with Schering Corporation, subsequently acquired by Merck & Co., Inc. ("Merck"), which provides the Company with the exclusive right to develop, manufacture, and sell products containing the compounds lonafarnib for the treatment of all human viruses except certain specified viruses such as hepatitis B and hepatitis C alone. As consideration for such exclusive right, the Company issued Private Eiger convertible preferred stock with a fair value of $0.5 million when the agreement was executed in September 2010. This preferred stock was converted to 27,350 shares of common stock upon the Merger. In addition, the Company is obligated to pay Merck up to an aggregate of $27.0 million in development milestones and will be required to pay tiered royalties based on aggregate annual net sales of all licensed products ranging from mid-single to low double-digit royalties on net sales. The Company's obligation to pay royalties to Merck expires on a country-by-country and product-by-product basis on the later of the expiration of the last to expire patent assigned to the Company under the agreement, which was estimated to be in December 2016; or on the tenth anniversary of the first commercial sale of the product. In May 2015, the first regulatory milestone was achieved and the Company paid the related milestone payment of $1.0 million to Merck. The amount has been recorded as a charge to research and development expense during the year ended December 31, 2015. No additional charges were recorded during the year ended December 31, 2016.

Janssen License Agreement

In December 2014, the Company entered into a license agreement with Janssen Pharmaceutica NV, ("Janssen"), which provides to the Company with the exclusive worldwide license to develop, manufacture, and sell products containing the compound tipifarnib for all therapeutic and diagnostic uses in humans, including any such uses for human virology diseases, but excluding oncology diseases. The Company is responsible for the development of at least one product in a major market country and for commercialization of products in all countries where necessary authorization is obtained, at its sole cost and expense. The Company may manufacture, develop, and commercialize the products itself or grant one or more sublicenses for such purposes. However, for a period of time following completion of the proof of concept trial, Janssen has a first right of negotiation for an exclusive license back from the Company to develop and commercialize tipifarnib in any country in the world. The agreement will continue for so long as the Company owe royalty payments to Janssen under the agreement or for so long as there is a valid patent claim under the agreement, whichever is longer.

In connection with this license agreement, the Company is obligated to make development milestone payments in aggregate of up to $38.0 million, sales milestone payments in aggregate up to $65.8 million and will be required to pay tiered royalties based on aggregate annual net sales of all licensed products ranging from mid-single to low double-digit royalties of net sales. As of December 31, 2016, the product has not reached commercialization and no milestones have been paid.

7. Asset Purchase Agreements and Related License Agreements

EGI Asset Purchase Agreement

In December 2010, the Company entered into an asset purchase agreement with Eiger Group International, Inc. ("EGI"). Dr. Jeffrey Glenn, a founder and director of the Company, is the sole owner of EGI. Pursuant to the agreement, the Company purchased all of the assets including the intellectual property rights related to the use of farnesyl transferase inhibitors as anti-viral agents and methods to treat viral infections with those inhibitors and inhibitors of prenylation, prenyl cysteine methyltranferase and a protease as anti-viral agents and methods to treat viral infection with those inhibitors. The Company paid EGI an upfront payment of $0.4 million when the agreement was executed in December 2010. Additionally, the Company will pay EGI a low single-digit royalty based on aggregate annual net sales of products developed using the intellectual property. Within the first ten years after commercialization, the Company may make a one-time payment of $0.5 million for each contract for the three types of product related to such intellectual property that would reduce the payment term for the three products to the tenth anniversary of the first commercial sale. The obligation to pay royalties expires on a country-by-country and product-by-product basis on the later of either when the product is no longer sold in any country or the earliest of the tenth anniversary of the first commercial sale of the product. As of December 31, 2016, the product has not achieved regulatory approval.

In November 2012, the Company entered into an agreement with EGI whereby the Company sold all of the assets related to the compound clemizole, including any related intellectual property. EGI will pay to the Company a high single-digit royalty on future aggregate annual net sales, subject to certain reductions and exceptions. EGI's obligation to pay royalties expires on a country-by-country and product-by-product basis on the later of either expiration of the last to expire patent sold to EGI under the agreement or the earliest of the tenth anniversary of the first commercial sale of the product. As of December 31, 2016, the product has not achieved regulatory approval.

Exendin 9-39 Purchase Agreement and Related Stanford License Agreement

In September 2015, the Company entered into an asset purchase agreement with two individuals, Dr. Tracey McLaughlin and Dr. Colleen Craig, (the "Sellers"), whereby the Company purchased all of the assets related to the compound exendin 9-39 including any related intellectual property from the Sellers (the "Exendin APA"). The Company also entered into a consulting agreement with the Sellers as part of the agreement. The Company issued 15,378 shares of common stock that were valued at $0.2 million and options to purchase 46,134 shares of common stock with an exercise price of $2.06 per share when the agreement was executed in September 2015.

Of the 46,134 options to purchase common stock, 15,378 shares vest monthly over four years as services are provided by the Sellers and 30,756 vest upon the earlier of the first commercial sale of the product or the approval of new drug application by the U.S. Food and Drug Administration (the milestone-vested options).

On March 22, 2016, immediately following the closing of the Merger, the Company issued additional "top-up" options to Dr. Tracey McLaughlin and Dr. Colleen Craig to purchase an aggregate of 48,544 shares of common stock, pursuant to the terms of the Exendin APA, with an exercise price of $17.25 per share. The top-up options consist of both time-vested and milestone-vested options.

The fair value of the time-vested options is recognized as non-employee share-based compensation expense as the awards vest over time, with the unvested portion revalued each period. The fair value of the milestone-vested options will be recognized as research and development expense when it is probable that the earliest milestone will be achieved at their then fair value. During the years ended December 31, 2016, 2015 and 2014, the Company recognized $0.3 million, $15,000 and zero of non-employee compensation expense related to the time-vested options, respectively. No expense was recognized for the milestone vested options during the year ended December 31, 2016, 2015 and 2014.

The Company is also obligated to pay development milestone payments in an aggregate amount of up to $1.0 million to each Seller. Additionally, the Company is obligated to pay each Seller royalties of low single-digits based on aggregate annual net sales of all products developed based on exendin 9-39, subject to certain reductions and exceptions. The Company's obligation to pay royalties expires on the expiration of the last to expire patent assigned to the Company under the agreement. Additionally, the Company has assumed the license agreement the Sellers had previously entered into with the Board of Trustees of the Leland Stanford Junior University ("Stanford"). Prior to the consummation of the Merger, Stanford was a holder of preferred stock of the Company, which converted into shares of common stock upon the consummation of the Merger and then was sold during the year ended December 31, 2016. The Company is obligated to pay a royalty to Stanford in the low single-digits on annual net sales after the first commercial sale of any products developed based on exendin 9-39. As of December 31, 2016, the Company had not reached any of the milestone events.

Eiccose Purchase Agreement and Related Stanford and Nippon License Agreements

In October 2015, the Company entered into an asset purchase agreement with Eiccose whereby Eiccose sold all of the assets related to the treatment of pulmonary arterial hypertension ("PAH"), treatment of lymphedema and products containing ubenimex for the treatment of disorders involving LTB4, and any related intellectual property to the Company (the "Eiccose APA"). David Cory, the President, Chief Executive Officer and a director of the Company, is the sole managing member and significant equity interest holder of Eiccose. The Company made a payment to Eiccose of $0.1 million representing reimbursement of certain previously incurred expenses, including payments and accrued amounts owed to Stanford in connection with the license agreement for the treatment of Lymphedema (the "Lymphedema License Agreement") and the license agreement for the treatment of PAH (the

"PAH License Agreement"). The Eiccose APA also provided that, upon a next round of financing pursuant to which the Company sold shares of capital stock resulting in gross proceeds to the Company of at least $25.0 million, the Company would issue to Eiccose fully vested shares of the Company's common stock equal to 1.75% of the total number of the Company's outstanding capital stock, before Merger. In October 2015, the Company recorded $1.5 million in research and development expenses and a corresponding liability representing the fair value of the Company's obligation to issue common stock to Eiccose.

On March 22, 2016, the Company issued to Eiccose 96,300 fully vested shares of the Company's common stock pursuant to the terms of the Eiccose APA. In connection with this transaction the Company remeasured the fair value of the obligation to issue common stock at the settlement date and the change in fair value of $0.2 million was recognized within other expense, net in the consolidated statement of operations during the year ended December 31, 2016. Upon the settlement of the obligation with the issuance of shares on March 22, 2016, the liability was reclassified to common stock and additional paid-in capital within stockholders' equity.

The Company is also obligated to pay to Eiccose an aggregate of up to a maximum of $10.0 million of commercial milestones in connection with future sales of the product and royalties in the low single-digits based on aggregate annual net sales following the first commercial sale of any product. As of December 31, 2016, the product has not reached commercialization and no milestones have been paid.

In addition, as a result of this agreement, the Company has assumed the license agreements Eiccose had previously entered into. These include the PAH License Agreement, the Lymphedema License Agreement for the treatment of lymphedema and the license agreement with Nippon Kayaku Co., Ltd, ("Nippon"). As part of the agreement, Nippon is obligated to make a payment for royalties in the low single-digits of sales to the Company. In connection with the PAH License Agreement and the Lymphedema License Agreement, the Company is obligated to make development and commercial milestone payments of up to $0.5 million in the aggregate under each contract, increasing annual license maintenance fees ranging from $10,000 to $75,000 over the term of each license agreement and royalty payments in low single-digits on annual net sales after the first commercial sale of a product under each license. For the year ended December 31, 2015, the Company has recorded $0.2 million to research and development expense including $0.1 million for license fees and $0.1 million for the reimbursement of incurred expenses in connection with the Eiccose APA. For the year ended December 31, 2016, no amounts have been recorded to in connection with the Eiccose APA.

8. Debt

In December 2016, the Company entered into an aggregate $25.0 million loan with Oxford Finance LLC (or "Oxford Loan"). The loan matures on July 1, 2021. The Company borrowed $15.0 million in December 2016 (or "Tranche A"). The remaining $10.0 million (or "Tranche B") will be available to the Company upon achievement of positive top line data from the lonafarnib Phase 2 trial in HDV and positive top line Phase 2 data from at least one of the following programs, including: (i) Lambda in HDV, (ii) Exendin 9-39 in PBH based on the Company's own IND, (iii) ubenimex in PAH, or (iv) ubenimex in Lymphedema.

The Oxford Loan bears interest at a floating rate per annum equal to the greater of either the 30-day U.S. Dollar LIBOR reported in the Wall Street Journal plus 6.41% or 6.95%. The Company is required to repay the Tranche A in 18 monthly interest only payments followed by 36 equal monthly payments of principal and interest commencing on the first day of the month following the funding of Tranche A. If the Company receives the Tranche B funds, then the interest only period is extended by six months followed by 30 equal monthly payments of principal plus accrued interest. At the time of final payment, the Company is required to pay an exit fee of 7.5% of the original principal balance of each tranche, which will be $1.1 million for Tranche A. The Company recorded as a liability and debt discount the exit fee at the origination of the term loan. In addition, the Company incurred loan origination fees and debt issuance costs of $0.3 million which were recorded as a direct deduction from the carrying amount of the related debt liability. The Company is also required to pay a 5.0% success fee within 30 days following the FDA's approval of the Company's first product. This fee is enforceable within 10 years from the funding of Tranche A. In connection with the execution of the Loan Agreement, the Company agreed to certain customary representations and warranties.

The loan is secured by the perfected first priority liens on the Company's assets, including a commitment by the Company to not allow any liens to be placed upon the Company's intellectual property. The Oxford Loan includes customary events of default, including failure to pay amounts due, breaches of covenants and warranties, material adverse effect events, certain cross defaults and judgments, and insolvency. If the Company is unable to comply with these covenants or if the Company default on any portion of the outstanding borrowings, the lenders can also impose a 5.0% penalty and restrict access to additional borrowings under the loan and security agreement. The Company was in compliance with the terms under the Oxford Loan as of December 31, 2016.

The Company is permitted to make voluntary prepayments of the Oxford Loan with a prepayment fee, calculated as of the loan origination date, equal to (i) 3.0% of the loan prepaid during the first 12 months, (ii) 2.0% of the loan prepaid in months 13-24 and (iii) 1.0% of the loan prepaid thereafter. The Company is required to make mandatory prepayments of the outstanding loan upon the acceleration by lender following the occurrence of an event of default, along with a payment of the final payment, the prepayment fee and any other obligations that are due and payable at the time of prepayment.

The Company accounts for the amortization of the debt discount utilizing the effective interest method. The Company recorded interest expense of $5,000 for the year ended December 31, 2016. Long-term debt and unamortized discount balances are as follows (in thousands):

	December 31, 2016
Face value of term loan	$ 15,000
Exit fee	1,125
Unamortized debt discount associated with exit fee, debt issuance costs and loan origination fees	(1,398)
Term loan, net	$ 14,727

As of December 31, 2016, future minimum payments of principal, exit fee and interest expense under the Oxford Loan were as follows (in thousands):

Year ending December 31,	
2017	$ 979
2018	3,128
2019	5,758
2020	5,402
2021	4,111
Total future payments	19,378
Less: unamortized interest	(3,253)
Less: unamortized exit fee	(1,125)
Face value of term loan	$ 15,000

9. Convertible Promissory Note and Warrant Purchase Agreement

On November 12, 2015, the Company entered into a convertible note and warrant purchase agreement (the "Note and Warrant Purchase Agreement") with three lenders under which the Company issued the Notes for an aggregate principal amount of $6.0 million and the Warrants exercisable for shares of the Company's equity securities at a purchase price of $0.11 per share, on a post-Merger and post-Reverse Stock Split basis. The terms of the Notes included a provision whereby the Notes would be automatically converted into equity securities from a qualified financing with proceeds of at least $25.0 million. The terms of the Warrants included a provision whereby the Warrants would be automatically exercised if the Company consummated a public offering including a reverse merger ("PO"). If the PO did not occur on or prior to February 28, 2016, the warrant coverage amount was equal to 17.5% of the outstanding principal balance of the Notes. The number of warrant shares into which the Warrants could be exercised was equal to the warrant coverage amount divided by the per share price of the equity securities sold in a qualified financing for an exercise price of $0.11 per share, on a post-Merger and post-Reverse Stock Split basis. The Warrants also include a provision whereby in the event of a PO which would result in the automatic

exercise of the Warrants and the automatic conversion of the Notes, the exercise price of the warrants would be paid by cancelling any unpaid interest on the Notes.

On November 18, 2015, the Company entered into the Subscription Agreement with the holders of the Notes and new investors for the sale of 2,304,430 shares of its common stock at purchase price of $17.14 per share for total gross proceeds of $39.5 million. The proceeds were comprised of approximately $6.0 million from the conversion of the Notes and approximately $33.5 million of cash.

The Company allocated the aggregate proceeds from the issuance of the Notes first to the Warrants based on the warrants' fair value and then the residual proceeds were allocated to the debt obligation. As of December 31, 2015 the fair value of warrants of $0.9 million was recorded as a debt discount to be amortized as interest expense over the term of the Note using the effective interest rate method. The fair value of the Warrants was also recorded as a corresponding warrant liability.

In addition, the Company incurred debt issuance costs of $21,000 in connection with the Note and Warrant Purchase Agreement. The debt issuance costs were being amortized to interest expense over the term of the Note using the effective interest rate method.

Upon the closing of the Private Placement on March 22, 2016, immediately prior to the closing of the Merger, the outstanding balance of the Notes totaling approximately $6.0 million was converted into 350,040 shares of the Company's common stock. The Warrants were exercised for 61,254 shares of the Company's common stock. During the year ended December 31, 2016, the Company recognized a loss related to the change in fair value of the Warrants of $0.2 million. The warrant liability was reclassified to common stock and additional paid-in capital within stockholders' equity, upon the exercise of the Warrants and issuance of shares on March 22, 2016.

For the year ended December 31, 2016, the Company recognized $0.7 million related to the accrued interest and amortization of the debt discount within interest expense on the Company's consolidated statements of operations. The discount was fully amortized upon the conversion of the Notes.

10. Stockholders' Equity (Deficit)

Convertible Preferred Stock

As of December 31, 2016, the number of shares of common stock and preferred stock authorized to issue was 200,000,000 and 10,000,000, respectively.

The Company has the following series of convertible preferred stock outstanding as of December 31, 2015 (in thousands, except share and per share data):

December 31, 2015	Shares Authorized	Shares Issued and Outstanding	Issuance Price and Conversion Price (Per Share)	Net Carrying Value	Liquidation Preference
Series A	454,020	426,680	$ 18.28	$ 7,668	$ 7,800
Series A-1	2,240,559	2,182,422	$ 6.63	14,899	14,469
	2,694,579	2,609,102		$ 22,567	$ 22,269

On March 22, 2016, all convertible preferred stock outstanding was converted into common stock as part of the Merger transaction (see Note 5). The convertible preferred stock was not redeemable.

Common Stock

The holders of the Company's common stock have one vote for each share of common stock. Common stockholders are entitled to dividends when, as, and if declared by the Board of Directors, subject to the prior rights of the

convertible preferred stockholders. As of December 31, 2016, no dividends had been declared by the Board of Directors.

The Company had reserved shares of common stock for issuance as follows:

	December 31,	
	2016	2015
Convertible preferred stock, on as-converted basis	—	2,609,102
Options issued and outstanding	1,212,044	254,058
Options available for future grants	646,778	19,689
Total	1,858,822	2,882,849

Common stock issued in connection with the Asset Purchase Agreement (see Note 7), the Note and Warrant Purchase Agreement (see Note 9) were excluded from the total of reserved shares of common stock for issuance as of December 31, 2015, as these shares were not determinable as of December 31, 2015.

Warrant Liability

The Company issued the Warrants in connection with the issuance of the Notes (see Note 9). As of December 31, 2015, the Company accounted for the Warrants as a liability at fair value as the number of shares were not fixed and determinable at the issuance date. The Company adjusted the liability for changes in fair value until the exercise of the Warrants in March, 2016, when the number of shares to be exercised became fixed, and the Warrants were automatically exercised into common stock. The warrant liability was immediately reclassified to common stock and additional paid in capital within stockholders' deficit. The change in fair value of the warrant liability was recognized as a component of other expense, net in the consolidated statements of operations.

The Company assumed from Celladon fully exercisable warrants outstanding for the purchase of 10,180 shares of common stock. The warrants have an exercise price of $84.15 and expire in October 2018.

11. Stock Option Plan

In 2009, the Company adopted the 2009 Equity Incentive Plan or the Plan. Under the Plan, shares of the Company's common stock have been reserved for the issuance of stock options to employees, directors, and consultants under terms and provisions established by the Board of Directors. Under the terms of the Plan, options may be granted at an exercise price not less than fair market value. For employees holding more than 10% of the voting rights of all classes of stock, the exercise prices for incentive and non-statutory stock options may not be less than 110% of fair market value, as determined by the Board of Directors. The terms of options granted under the Plan may not exceed ten years. The vesting schedule of newly issued option grants is generally four years.

As discussed in Note 5, the Company assumed all of the outstanding options, whether or not vested, under the Eiger Plan, with such options henceforth representing the right to purchase a number of shares of the Company's common stock equal to approximately 0.09 multiplied by the number of shares of Eiger common stock previously represented by such options. For accounting purposes, however, the Company is deemed to have assumed the Celladon 2013 Equity Incentive Plan.

Because the Company is considered to be the acquirer for accounting purposes, the pre-Merger vested stock options granted by Celladon are deemed to have been exchanged for equity awards of the Company and, as such, the portion of the acquisition date fair value of these equity awards attributable to pre-Merger service to Celladon were accounted for as a component of the consideration transferred, which was inconsequential to the consolidated financial statements.

The exchange of options to purchase shares of Eiger common stock for options to purchase shares of the Combined Company, was accounted for as a modification of the awards because the legal exchange of the awards is considered a modification of Eiger stock options. The modification of the stock options did not result in any incremental compensation expense as the modification did not increase the fair value of the stock options.

In June 2016, the Company's board of directors adopted and in August 2016 the Company's stockholders approved the amended and restated 2013 Equity Incentive Plan (the "Restated 2013 Plan"), which increased the number of shares reserved for grant by 1,296,683 shares. Under the terms of the Restated 2013 Plan, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units and other awards to individuals who are then employees, officers, non-employee directors or consultants of the Company. All awards granted prior to the approval of the Restated 2013 Plan remain subject to the terms of the previous plans and the applicable award agreements. The following table summarizes stock option activity under the Company's stock based compensation plan during the year ended December 31, 2016 (in thousands, except share data):

	Shares Available for Grant	Number of Options	Weighted-Average Exercise Price Per Option	Weighted-Average Remaining Contractual Life (in Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2015	19,689	254,058	$ 1.94		$ 3,369
Additional options authorized	1,554,833				
Options assumed in the merger		37,276	$ 177.57		
Granted	(950,572)	950,572	$ 15.87		
Exercised		(7,034)	$ 5.93		
Canceled	22,828	(22,828)	$ 224.21		
Outstanding as of December 31, 2016	646,778	1,212,044	$ 14.06	9.0	$ 2,414
Vested and expected to vest as of December 31, 2016		1,131,223	$ 14.16	9.0	$ 2,230
Vested and exercisable as of December 31, 2016		248,505	$ 15.95	8.4	$ 882

The aggregate intrinsic values of options outstanding, exercisable, vested and expected to vest were calculated as the difference between the exercise price of the options and the fair value of the Company's common stock as of December 31, 2016.

The aggregate intrinsic value of stock options exercised in 2016, 2015 and 2014 was $0.1 million, $0.9 million and zero, respectively.

Stock Options Granted to Employees

During the years ended December 31, 2016 and 2015, the Company granted employees the stock options for 902,028 and 166,793 shares, respectively, with weighted-average grant date fair value of $10.40 and $1.09 per share, respectively. There were no employee stock options granted during the year ended December 31, 2014. The total grant date fair value of employee options that vested during the years ended December 31, 2016, 2015 and 2014 was $2.0 million, $6,000 and $70,000, respectively.

The Company records stock-based compensation of stock options granted to employees by estimating the fair value of stock-based awards using the Black-Scholes option pricing model and amortizing the fair value of the stock-based awards granted over the applicable vesting period of the awards on a straight-line basis. The fair value of employee stock options was estimated using the following weighted-average assumptions:

	Year Ended December 31,		
	2016	2015	2014
Expected term (in years)	5.27 - 6.08	5.00 - 6.08	—
Volatility	73.91% - 78.00%	77.58% - 97.62%	—
Risk free interest rate	1.21% - 2.27%	1.44% - 1.75%	—
Dividend yield	—	—	—

Each of these inputs is subjective and generally requires significant judgment to determine.

Fair Value of Common Stock: Prior to the Merger, the fair value of the shares of common stock underlying stock options was determined by the Company's Board of Directors. In order to determine the fair value of the common stock at the time of grant of the option, the Board of Directors considered, among other things, valuations performed by an independent third-party. Because there was no public market for the Company's common stock, the Board of Directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of the Company's common stock, including important developments in the Company's operations, sales of convertible preferred stock, actual operating results and financial performance, the conditions in the life sciences industry and the economy in general, the stock price performance and volatility of comparable public companies, and the lack of liquidity of the Company's common stock, among other factors. Following the Merger, the Company's Board of Directors determined the fair value of each share of underlying common stock based on the closing price of the Company's common stock as reported on the date of grant.

Expected Term: The Company's expected term represents the period that the Company's stock-based awards are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term for employee options).

Expected Volatility: Since the Company does not have a long trading history for its common stock, the expected volatility was estimated based on the average volatility for comparable publicly traded biotechnology companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, or stage in the life cycle.

Risk-Free Interest Rate: The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of option.

Expected Dividend: The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.

Stock Options Granted to Non-Employees

The Company grants stock options to non-employees in exchange for services rendered. During the years ended December 31, 2016, 2015 and 2014, the Company granted to non-employees stock options for 48,544, 46,134 and 24,506 shares, respectively. Stock-based compensation expense related to stock options granted to non-employees is recognized as the stock options are earned and will fluctuate as the estimated fair value of the common stock fluctuates until the awards vest. The Company believes that the estimated fair value of the stock options is more readily measurable than the fair value of the services rendered.

The fair value of the stock options granted to non-employees is estimated at each reporting date using the Black-Scholes option-pricing model using similar assumptions as for employees except that the expected term is based on the options' remaining contractual term instead of the simplified method:

	Year Ended December 31,		
	2016	2015	2014
Remaining contractual term (in years)	6.75 – 10.00	7.75 – 10.00	8.75 – 9.67
Volatility	84.42% – 98.13%	85.83% – 90.50%	87.53% – 94.17%
Risk-free interest rate	1.37% – 2.50%	1.73% – 2.24%	2.17% – 2.69%
Dividend yield	—	—	—

Stock-Based Compensation Expense

Total stock-based compensation expense recognized for options granted to employees and non-employees was as follows (in thousands):

	Year Ended December 31,		
	2016	2015	2014
Research and development	$ 737	$ 64	$ 13
General and administrative	2,453	163	14
Total stock-based compensation expense	$ 3,190	$ 227	$ 27

As of December 31, 2016, the total unrecognized compensation expense related to unvested employee options was $9.4 million, which the Company expects to recognize over an estimated weighted average period of 3.4 years.

12. Income Taxes

No provision for income taxes was recorded for the years ended December 31, 2016, 2015 and 2014. The Company has incurred net operating losses for all the periods presented. The Company has not reflected any benefit of such net operating loss carryforwards in the accompanying consolidated financial statements. The Company has established a full valuation allowance against its deferred tax assets due to the uncertainty surrounding the realization of such assets.

The effective tax rate of the provision for income taxes differs from the federal statutory rate as follows:

	Year Ended December 31,		
	2016	2015	2014
Federal statutory income tax rate	34.00%	34.00%	34.00%
State income taxes, net of federal benefit	(0.21)	6.11	6.14
Federal and state tax credits	4.68	2.54	4.30
Change in valuation allowance	(36.67)	(42.14)	(44.19)
Stock-based compensation	(1.26)	(0.49)	(0.23)
Other, net	(0.54)	(0.02)	(0.02)
Provision (benefit) for income taxes	—%	—%	—%

The components of the deferred tax assets and liabilities are as follows (in thousands):

	2016	2015
Deferred tax assets:		
Net operating loss carryforwards	$ 19,882	$ 9,030
Tax credits	5,344	1,133
Depreciation and amortization	3,025	1,501
Accruals and reserves	936	254
Gross deferred tax assets	29,187	11,918
Valuation allowance	(29,187)	(11,918)
Net deferred tax assets	$ —	$ —

Due to the Company’s lack of earnings history, the deferred tax assets have been fully offset by a valuation allowance as of December 31, 2016 and 2015. The valuation allowance increased by $17.3 million and $5.6 million during the years ended December 31, 2016 and 2015, respectively.
Certain amounts in the prior year's presentation of gross deferred tax assets have been reclassified to conform to the current year's presentation. These reclassifications had no impact on previously reported consolidated statements of operations.

As of December 31, 2016, the Company had approximately $54.4 million and $25.2 million, respectively, of federal and state operating loss carryforwards available to reduce future taxable income that will begin to expire in 2030 and 2028, respectively, for federal and state tax purposes.

As of December 31, 2016, the Company also had research and development tax credit carryforwards of approximately $0.2 million and $0.6 million for federal and state purposes available to offset future taxable income tax, respectively. If not utilized, the federal carryforwards will expire in various amounts beginning in 2028, and the state credits can be carried forward indefinitely.

As of December 31, 2016, the Company had orphan drug tax credit carryforwards of approximately $6.6 million for federal purposes available to offset future taxable income tax. If not utilized, the federal carryforwards will begin to expire in 2033.

Utilization of the NOL and tax credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred or that could occur in future, as required by Section 382 of the Code, as well as similar state and foreign provisions. These ownership changes may limit the amount of NOL and tax credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. The Company assessed whether an ownership change, as defined by Section 382 of the Code, occurred from its formation through December 31, 2016. Based upon this assessment no reduction was made to the federal and state NOL carryforwards or federal and state tax credit carryforwards under these rules.

Uncertain Tax Positions

A reconciliation of the Company's unrecognized tax benefits for the years ended December 31, 2016, 2015 and 2014 is as follows (in thousands):

	Year Ended December 31,		
	2016	2015	2014
Balance at beginning of year	$ 404	$ 99	$ 97
Additions based on tax positions related to prior year	19	46	—
Additions based on tax positions related to current year	1,408	259	2
Balance at end of year	$ 1,831	$ 404	$ 99

If the $1.8 million of unrecognized tax benefits is recognized, there would not be an effect on the effective tax rate. The Company does not expect the unrecognized tax benefits to change significantly over the next 12 months. At December 31, 2016, the unrecognized tax benefits for uncertain tax positions were offset against deferred tax assets and would not affect the income tax rate if recognized due to the Company being in a full valuation allowance position.

The Company's policy is to account for interest and penalties in tax expense on the statement of operations. The Company files income tax returns in the U.S. federal and state jurisdictions. All periods since inception are subject to examination by U.S. federal and state jurisdictions. There were no such interest or penalties during the years ended December 31, 2016, 2015 and 2014.

13. Legal Matters

In July 2015, following Celladon's announcements of the negative CUPID 2 data and the suspension of further research and development activities and the subsequent declines of the price of its common stock, three putative class actions were filed in the U.S. District Court for the Southern District of California against Celladon and certain of its current and former officers. The complaints generally alleged that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), by making materially false and misleading statements regarding the clinical trial program for MYDICAR, thereby artificially inflating the price of Celladon's common stock. The complaints sought unspecified monetary damages and other relief, including

attorneys' fees. On December 9, 2015, the district court consolidated the three putative securities class actions and appointed a lead plaintiff to represent the putative class. The lead plaintiff filed a consolidated amended complaint on February 29, 2016.

On October 7, 2016, the district court granted defendants' motion to dismiss the consolidated amended complaint and granted leave to amend within 60 days from the date of the district court's order. The lead plaintiff subsequently filed a notice of intent not to amend the consolidated amended complaint and instead indicated that it intended to appeal the district court's decision. On December 9, 2016, the district court closed the case.

On December 28, 2016, the lead plaintiff filed a notice to the United States Court of Appeals for the Ninth Circuit appealing the district court's order dismissing the consolidated amended complaint. The deadline to file the appellant's opening brief is April 7, 2017.

It is possible that additional suits will be filed, or allegations made by stockholders, with respect to these same or other matters and also naming the Company and/or Celladon's former officers and directors as defendants. The Company believes that it has meritorious defenses and intends to defend these lawsuits vigorously. Due to the early stage of these proceedings, the Company is not able to predict or reasonably estimate the ultimate outcome or possible losses relating to these claims.

14. Commitments and Contingencies

Lease Agreement

In March 2015, the Company entered into a non-cancelable facility lease agreement for an office facility in Palo Alto, California. The lease commenced on April 1, 2015 and expires 36 months after the commencement date. The lease has one two-year renewal option prior to expiration and includes rent escalation clauses through the lease term. Scheduled rent increases are recognized as deferred rent and are amortized on a straight-line basis over the term of the lease. The Company has provided a security deposit of $21,000 as collateral for the lease, which is included in other assets in the Company's consolidated balance sheet as of December 31, 2015.

In October 2016, the Palo Alto lease was modified to include two additional suites, bringing the total leased space to 3,877 square feet. The lease commenced on January 4, 2017 and expires in March 2018. The lease has one two-year renewal option prior to expiration and includes rent escalation clauses through the lease term. The security deposit was increased up to $49,000, which is included in other assets in the Company's consolidated balance sheet as of December 31, 2016.

In December 2015, the Company entered into a sublease agreement for an office facility in Palo Alto, California. The sublease commenced on January 26, 2016 and expires on March 30, 2017. The Company provided a security deposit of $16,000 as collateral for the sublease, which is included in other assets in the Company's consolidated balance sheet as of December 31, 2016 and 2015.

Future aggregate minimum lease payments under the non-cancelable operating leases are as follows (in thousands):

Year ending December 31,	Amounts
2017	330
2018	71
Total	$ 401

Rent expense was $ 0.3 million, $0.1 million and $42,000 for the years ended December 31, 2016, 2015 and 2014, respectively.

Other Commitments

The Company is obligated to make future payments to third parties under asset purchase and license agreements, including royalties and payments that become due and payable on the achievement of certain development and commercialization milestones. The Company has not included these potential payment obligations in the table above as the amount and timing of such payments are not known.

15. Related Party Transactions

In connection with the license agreement the Company holds with Stanford, Stanford owned Series A and Series A-1 convertible preferred shares of the Company. For the year ended December 31, 2015, the Company recorded research and development expense of $89,000 for charges including the reimbursement of patent fees and license fees in connection with the Exendin 9-39 Purchase Agreement and the Lymphedema License Agreement. As of December 31, 2015, the Company owed $55,000 to Stanford, which is recorded in accounts payable. This preferred stock was converted into common stock upon the Merger and then sold during the year ended December 31, 2016.

As disclosed in Note 7, the Company entered into license agreements with EGI, which is owned by the founder of the Company.

As disclosed in Note 7, the Company entered into an asset purchase agreement with Eiccose, which is owned by the Company’s chief executive officer.

ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None

ITEM 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

We are responsible for maintaining disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Disclosure controls and procedures are controls and other procedures designed to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Based on our management's evaluation (with the participation of our principal executive officer and our principal financial officer) of our disclosure controls and procedures as required by Rule 13a-15 under the Exchange Act, our principal executive officer and our principal financial officer have concluded that our disclosure controls and procedures were effective to achieve their stated purpose as of December 31, 2016, the end of the period covered by this report.

Management's Report on Internal Control over Financial Reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Exchange Act Rule 13a-15(f). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

During the audit of our consolidated financial statements for the years ended December 31, 2015 and 2014, a material weakness was identified in our internal control over financial reporting. The material weakness that was identified related to a lack of sufficient accounting resources and personnel that limits our ability to adequately segregate duties, perform sufficient review and approval of manual journal entries posted to the general ledger, establish defined accounting policies and procedures or perform timely reviews of account reconciliations or accounting estimates. Because of the material weakness, our principal executive officer and principal financial officer concluded that the Company did not maintain effective internal control over financial reporting as of December 31, 2015 and 2014.

During 2016 we implemented measures to improve our disclosure controls and procedures and internal control over financing reporting to address the underlying causes of the previously identified material weakness, including (i) the hiring of our Controller and other accounting personnel, (ii) establishing segregation of duties for review and approval of manual journal entries, (iii) establishing accounting policies and procedures, (iv) performing timely reviews of account reconciliations and accounting estimates, and (v) implementing appropriate disclosure controls and procedures. We believe the remediation steps outlined above were sufficient to remediate the previously identified material weakness in internal control over financial reporting as discussed above.

As of December 31, 2016, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework (2013 Framework). Based on this assessment, our management concluded that, as of December 31, 2016, our internal control over financial reporting was effective based on those criteria.

Pursuant to Regulation S-K 308(b), this Annual Report on Form 10-K does not include an attestation report of our company's registered public accounting firm regarding internal control over financial reporting.

Changes in Internal Control over Financial Reporting.

Except as otherwise described above under “Management’s Report on Internal Control over Financial Reporting”, there were no material changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended December 31, 2016, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. Other Information

None.

PART III

ITEM 10. Directors, Executive Officers and Corporate Governance

Except as set forth below, the information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2017 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2016.

We have adopted a Code of Business Conduct and Ethics that applies to all of our directors, officers and employees, including our principal executive officer and principal financial officer. A current copy of the code is posted on the Investors Corporate Governance section of our website, which is located at www.eigerbio.com.

We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of this Code of Business Conduct and Ethics by posting such information on our website, at the address and location specified above and, to the extent required by the listing standards of The NASDAQ Global Market, by filing a Current Report on Form 8-K with the SEC, disclosing such information.

ITEM 11. Executive Compensation

The information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2017 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2016.

ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2017 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2016.

ITEM 13. Certain Relationships and Related Party Transactions, and Director Independence

The information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2017 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2016.

ITEM 14. Principal Accounting Fees and Services

The information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2017 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2016.

PART IV

ITEM 15. Exhibits and Financial Statement Schedules

(a) Financial Statements and Financial Statement Schedules

1. Financial Statements
   See Index to Financial Statements at Item 8 herein.

2. Financial Statement Schedules

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

3. Exhibits

   The exhibits listed in the Exhibit Index immediately following the signature page of this Annual Report on Form 10-K are filed or incorporated by reference as part of this report.

(b) See Exhibits listed under Item 15(a)3.

(c) See Item 15(a)2 above.

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.

Eiger BioPharmaceuticals, Inc.

Date: 22 March, 2017

By: /s/ David A. Cory
David A. Cory
Director, President and Chief Executive Officer
(Principal Executive Officer)

Eiger BioPharmaceuticals, Inc.

Date: 22 March, 2017

By: /s/ James Welch
James Welch
Chief Financial Officer
(Principal Financial Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints David Cory and James Welch, and each of them, as his or her attorneys-in-fact, with the power of substitution, for him or her in any and all capacities, to sign any amendments to this report, and to file the same, with exhibits thereto and other documents in connection therewith with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorneys-in-fact, and each of them, or his or her substitute or substitutes may do or cause to be done by virtue hereof.

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 in the capacities and on the dates indicated:

Signature	Title	Date
/s/ David A. Cory David Cory	President and Chief Executive Officer *(Principal Executive Officer)*	22 March, 2017
/s/ James Welch James Welch	Chief Financial Officer *(Principal Financial and Accounting Officer)*	22 March, 2017
/s/ Thomas J. Dietz Thomas J. Dietz	Chairman of the Board of Directors	22 March, 2017
/s/ Edgar G. Engleman Edgar G. Engleman	Member of the Board of Directors	22 March, 2017
/s/ Nina Kjellson Nina Kjellson	Member of the Board of Directors	22 March, 2017
/s/ Jeffrey S. Glenn Jeffrey S. Glenn	Member of the Board of Directors	22 March, 2017
/s/ Charles J. Bramlage Charles J. Bramlage	Member of the Board of Directors	22 March, 2017

INDEX TO EXHIBITS

Exhibit Number	Description of Document
2.1	Agreement and Plan of Merger and Reorganization, dated as of November 18, 2015, by and among Celladon Corporation, Celladon Merger Sub, Inc., and Eiger BioPharmaceuticals, Inc. (incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed with the SEC on November 19, 2015).
3.1	Amended and Restated Certificate of Incorporation of Celladon Corporation (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K of Celladon Corporation, filed with the SEC on February 10, 2014).
3.2	Amended and Restated Bylaws of Celladon Corporation (incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K, filed with the SEC on February 10, 2014).
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Celladon Corporation (incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K, filed with the SEC on March 23, 2016).
3.4	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Celladon Corporation (incorporated by reference to Exhibit 3.2 to Current Report on Form 8-K, filed with the SEC on March 23, 2016).
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-1, as amended (File No. 333-191688), originally filed with the SEC on October 29, 2013).
4.2	Amended and Restated Investor Rights Agreement by and among Celladon Corporation and certain of its stockholders, dated February 4, 2014 (incorporated by reference to Exhibit 4.2 to the Registration Statement on Form S-1, as amended (File No. 333-191688), originally filed with the SEC on October 11, 2013).
4.3	Form of Warrant to Purchase Common Stock issued to participants in Celladon Corporation's Convertible Debt and Warrant financing, dated October 15, 2013 (incorporated by reference to Exhibit 4.3 to the Registration Statement on Form S-1, as amended (File No. 333-191688), originally filed with the SEC on October 11, 2013).
10.1+	Form of Indemnity Agreement by and between Celladon Corporation and its directors and officers (incorporated by reference to Exhibit 10.1 to the Registration Statement on Form S-1, as amended (File No. 333-191688), originally filed with the SEC on October 11, 2013).
10.2+	Celladon Corporation 2001 Stock Option Plan and Form of Notice of Grant of Stock Option, Stock Option Agreement and Stock Option Exercise Notice thereunder (incorporated by reference to Exhibit 10.2 to the Registration Statement on Form S-1, as amended (File No. 333-191688), originally filed with the SEC on October 11, 2013).
10.3+	Celladon Corporation 2012 Equity Incentive Plan and Form of Stock Option Grant Notice, Option Agreement and Notice of Exercise thereunder (incorporated by reference to Exhibit 10.3 to the Registration Statement on Form S-1, as amended (File No. 333-191688), originally filed with the SEC on October 11, 2013).
10.4+	Celladon Corporation Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.6 to the Registration Statement on Form S-1, as amended (file No. 333-191688), originally filed with the SEC on October 11, 2013).
10.5	Eiger BioPharmaceuticals, Inc. 2009 Equity Incentive Plan and Form of Notice of Grant of Stock Option, Stock Option Agreement and Stock Option Exercise Notice thereunder (incorporated by reference to Exhibit 10.44 to the Registration Statement on Form S-4, as amended (File No. 333-208521), originally filed with the SEC on December 14, 2015).

Exhibit Number	Description of Document
10.6+	Eiger BioPharmaceuticals, Inc. 2013 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registration Statement on Form 10-Q (File No. 001-36183), filed with the SEC on November 8, 2016).
10.7+	Eiger BioPharmaceuticals, Inc. Amended and Restated 2013 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.1 to the Registration Statement on Form 10-Q (File No. 001-36183), filed with the SEC on November 8, 2016).
10.8	Lease, dated as of March 19, 2015 by and between JTC, a California general partnership and Eiger BioPharmaceuticals, Inc. (incorporated by reference to Exhibit 10.38 to the Registration Statement on Form S-4, as amended (File No. 333-208521), originally filed with the SEC on December 14, 2015).
10.9+	Offer Letter, dated as of December 5, 2008, by and between Eiger BioPharmaceuticals, Inc. and David Cory (incorporated by reference to Exhibit 10.39 to the Registration Statement on Form S-4, as amended (File No. 333-208521), originally filed with the SEC on December 14, 2015).
10.10+	Offer Letter, dated as of August 10, 2015, by and between Eiger BioPharmaceuticals, Inc. and James Welch (incorporated by reference to Exhibit 10.40 to the Registration Statement on Form S-4, as amended (File No. 333-208521), originally filed with the SEC on December 14, 2015).
10.11+	Offer Letter, dated as of July 31, 2015, by and between Eiger BioPharmaceuticals, Inc. and James Shaffer (incorporated by reference to Exhibit 10.41 to the Registration Statement on Form S-4, as amended (File No. 333-208521), originally filed with the SEC on December 14, 2015).
10.12+	Offer Letter, dated as of April 3, 2015, by and between Eiger BioPharmaceuticals, Inc. and Joanne Quan (incorporated by reference to Exhibit 10.42 to the Registration Statement on Form S-4, as amended (File No. 333-208521), originally filed with the SEC on December 14, 2015).
10.13+	Offer Letter, dated as of October 1, 2015, by and between Eiger BioPharmaceuticals, Inc. and Eduardo Martins (incorporated by reference to Exhibit 10.43 to the Registration Statement on Form S-4, as amended (File No. 333-208521), originally filed with the SEC on December 14, 2015).
10.14†	Asset Purchase Agreement, effective as of December 8, 2010, by and between Eiger BioPharmaceuticals, Inc. and Eiger Group International, Inc. (incorporated by reference to Exhibit 10.45 to the Registration Statement on Form S-4, as amended (File No. 333-208521), originally filed with the SEC on December 14, 2015).
10.15†	Asset Purchase Agreement, dated September 25, 2015, by and between Eiger BioPharmaceuticals, Inc. and Tracey McLaughlin and Colleen Craig (incorporated by reference to Exhibit 10.46 to the Registration Statement on Form S-4, as amended (File No. 333-208521), originally filed with the SEC on December 14, 2015).
10.16†	Asset Purchase Agreement, dated October 29, 2015, by and between Eiccose, LLC and Eiger BioPharmaceuticals, Inc. (incorporated by reference to Exhibit 10.47 to the Registration Statement on Form S-4, as amended (File No. 333-208521), originally filed with the SEC on December 14, 2015).
10.17†	Exclusive Agreement, dated May 1, 2015, by and between Eiccose, LLC and the Board of Trustees of the Leland Stanford Junior University (incorporated by reference to Exhibit 10.48 to the Registration Statement on Form S-4, as amended (File No. 333-208521), originally filed with the SEC on December 14, 2015).
10.18†	Exclusive Agreement, dated October 27, 2015, by and between Eiccose, LLC and the Board of Trustees of the Leland Stanford Junior University (incorporated by reference to Exhibit 10.49 to the Registration Statement on Form S-4, as amended (File No. 333-208521), originally filed with the SEC on December 14, 2015).
10.19†	License Agreement, dated September 3, 2010, by and between Eiger BioPharmaceuticals, Inc. and Merck Corporation (incorporated by reference to Exhibit 10.50 to the Registration Statement on Form S-4, as amended (File No. 333-208521), originally filed with the SEC on December 14, 2015).

Exhibit Number	Description of Document
10.20†	License Agreement, effective as of December 19, 2014, by and between EB Pharma, LLC and Janssen Parmaceutica NV (incorporated by reference to Exhibit 10.51 to the Registration Statement on Form S-4, as amended (File No. 333-208521), originally filed with the SEC on December 14, 2015).
10.21†	License Agreement, dated as of May 1, 2015, by and between Eiccose, LLC and Nippon Kayaku Co., Ltd. (incorporated by reference to Exhibit 10.52 to the Registration Statement on Form S-4, as amended (File No. 333-208521), originally filed with the SEC on December 14, 2015).
10.22	Sublease Agreement, dated as of January 8, 2016, by and between Baker Hughes Oilfield Operations, Inc. and Eiger BioPharmaceuticals, Inc. (incorporated by reference to Exhibit 10.53 to the Registration Statement on Form S-4, as amended (File No. 333-208521), originally filed with the SEC on December 14, 2015).
10.23†	License Agreement, dated as of April 20, 2016, by and between Eiger BioPharmaceuticals, Inc. and Bristol-Myers Squibb Company (incorporated by reference to Exhibit 10.1 to the Registration Statement on Form S-3/A (File No. 333-212114), filed with the SEC on August 2, 2016).
10.24	Common Stock Purchase Agreement, dated as of April 20, 2016, by and between Eiger BioPharmaceuticals, Inc. and Bristol-Myers Squibb Company (incorporated by reference to Exhibit 10.2 to the Registration Statement on Form S-3, as amended (File No. 333-212114) filed with the SEC on June 17, 2016).
10.25	Controlled Equity Offering Sales Agreement, dated June 17, 2016, by and between Eiger BioPharmaceuticals, Inc. and Cantor Fitzgerald & Co. (incorporated by reference to Exhibit 1.2 to the Registration Statement on Form S-3, filed with the SEC on June 17, 2016).
10.26	Loan and Security Agreement, dated December 30, 2016, by and between Eiger BioPharmaceuticals, Inc. and Oxford Finance LLC.
16.1	Letter of Ernst & Young LLP dated April 28, 2016 (incorporated by reference to Exhibit 16.1 to the Current Report on 8-K, filed with the SEC on April 28, 2016).
21.1	List of subsidiaries.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney. Reference is made to the signature page hereto.
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted 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

+ Indicates management contract or compensatory plan.

† Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

LOAN AND SECURITY AGREEMENT

THIS LOAN AND SECURITY AGREEMENT (as the same may from time to time be amended, modified, supplemented or restated, this "**Agreement**") dated as of December 30, 2016 (the "**Effective Date**") among OXFORD FINANCE LLC, a Delaware limited liability company with an office located at 133 North Fairfax Street, Alexandria, Virginia 22314 ("**Oxford**"), as collateral agent (in such capacity, "**Collateral Agent**"), the Lenders listed on Schedule 1.1 hereof or otherwise a party hereto from time to time including Oxford in its capacity as a Lender (each a "**Lender**" and collectively, the "**Lenders**"), and EIGER BIOPHARMACEUTICALS, INC., a Delaware corporation ("**Parent**"), EB Pharma, LLC, a Delaware limited liability company ("**EB Pharma**") and EBPI Merger, Inc. ("**EBPI**"), each with offices located at 350 Cambridge Ave. Suite 350, Palo Alto, CA 94306 (Parent, EB Pharma and EBPI, individually and collectively, jointly and severally, "**Borrower**"), provides the terms on which the Lenders shall lend to Borrower and Borrower shall repay the Lenders. The parties agree as follows:

1. ACCOUNTING AND OTHER TERMS

1.1 Accounting terms not defined in this Agreement shall be construed in accordance with GAAP. Calculations and determinations must be made in accordance with GAAP. Capitalized terms not otherwise defined in this Agreement shall have the meanings set forth in Section 13. All other terms contained in this Agreement, unless otherwise indicated, shall have the meaning provided by the Code to the extent such terms are defined therein. All references to "**Dollars**" or "**$**" are United States Dollars, unless otherwise noted.

2. LOANS AND TERMS OF PAYMENT

2.1 Promise to Pay. Borrower hereby unconditionally promises to pay each Lender, the outstanding principal amount of all Term Loans advanced to Borrower by such Lender and accrued and unpaid interest thereon and any other amounts due hereunder as and when due in accordance with this Agreement.

2.2 Term Loans.

(a) Availability. (i) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, to make term loans to Borrower on the Effective Date in an aggregate amount of Fifteen Million Dollars ($15,000,000.00) according to each Lender's Term A Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a "**Term A Loan**", and collectively as the "**Term A Loans**"). After repayment, no Term A Loan may be re-borrowed.

(ii) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, during the Second Draw Period, to make term loans to Borrower in an aggregate amount up to Ten Million Dollars ($10,000,000.00) according to each Lender's Term B Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a "**Term B Loan**", and collectively as the "**Term B Loans**"; each Term A Loan or Term B Loan is hereinafter referred to singly as a "**Term Loan**" and the Term A Loans and the Term B Loans are hereinafter referred to collectively as the "**Term Loans**"). After repayment, no Term B Loan may be re-borrowed.

(b) Repayment. Borrower shall make monthly payments of interest only commencing on the first (1st) Payment Date following the Funding Date of each Term Loan, and continuing on the Payment Date of each successive month thereafter through and including the Payment Date immediately preceding the Amortization Date. Borrower agrees to pay, on the Funding Date of each Term Loan, any initial partial monthly interest payment otherwise due for the period between the Funding Date of such Term Loan and the first Payment Date thereof. Commencing on the Amortization Date, and continuing on the Payment Date of each month thereafter, Borrower shall make consecutive equal monthly payments of principal, together with applicable interest, in arrears, to each Lender, as calculated by Collateral Agent (which calculations shall be deemed correct absent manifest error) based upon: (1) the amount of such Lender's Term Loan then outstanding, (2) the effective rate of interest, as determined in Section 2.3(a), and (3) a repayment schedule equal to thirty-six (36) months, if the Amortization Date is August 1, 2018, or thirty (30) months if the Amortization Date is February 1, 2019. All unpaid principal and accrued and unpaid interest with respect to each Term Loan is due and payable in full on the Maturity Date. Each Term Loan may only be prepaid in accordance with Sections 2.2(c) and 2.2(d).

(c) Mandatory Prepayments. If the Term Loans are accelerated following the occurrence of an Event of Default, Borrower shall immediately pay to Lenders, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of: (i) all outstanding principal of the Term Loans plus accrued and unpaid interest thereon through the prepayment date, (ii) the Final Payment, (iii) the Prepayment Fee, plus (iv) all other Obligations that are due and payable, including Lenders' Expenses and interest at the Default Rate with respect to any past due amounts. Notwithstanding (but without duplication with) the foregoing, on the Maturity Date, if the Final Payment had not previously been paid in full in connection with the prepayment of the Term Loans in full, Borrower shall pay to Collateral Agent, for payment to each Lender in accordance with its respective Pro Rata Share, the Final Payment in respect of the Term Loans.

(d) Permitted Prepayment of Term Loans. Borrower shall have the option to prepay all, but not less than all, of the Term Loans advanced by the Lenders under this Agreement, provided Borrower (i) provides written notice to Collateral Agent of its election to prepay the Term Loans at least thirty (30) days prior to such prepayment, and (ii) pays to the Lenders on the date of such prepayment, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of (A) all outstanding principal of the Term Loans plus accrued and unpaid interest thereon through the prepayment date, (B) the Final Payment, (C) the Prepayment Fee, plus (D) all other Obligations that are due and payable, including Lenders' Expenses, if any, and interest at the Default Rate with respect to any past due amounts.

2.3 Payment of Interest on the Credit Extensions.

(a) Interest Rate. Subject to Section 2.3(b), the principal amount outstanding under the Term Loans shall accrue interest at a floating per annum rate equal to the Basic Rate, determined by Collateral Agent on the Funding Date of the applicable Term Loan, which interest shall be payable monthly in arrears in accordance with Sections 2.2(b) and 2.3(e). Interest shall accrue on each Term Loan commencing on, and including, the Funding Date of such Term Loan, and shall accrue on the principal amount outstanding under such Term Loan through and including the day on which such Term Loan is paid in full.

(b) Default Rate. Immediately upon the occurrence and during the continuance of an Event of Default, Obligations shall accrue interest at a floating per annum rate equal to the rate that is otherwise applicable thereto plus five percentage points (5.00%) (the "**Default Rate**"). Payment or acceptance of the increased interest rate provided in this Section 2.3(b) is not a permitted alternative to timely payment and shall not constitute a waiver of any Event of Default or otherwise prejudice or limit any rights or remedies of Collateral Agent.

(c) 360-Day Year. Interest shall be computed on the basis of a three hundred sixty (360) day year, and the actual number of days elapsed.

(d) Debit of Accounts. Collateral Agent and each Lender may debit (or ACH) any deposit accounts, maintained by Borrower or any of its Subsidiaries, including the Designated Deposit Account, for principal and interest payments or any other amounts Borrower owes the Lenders under the Loan Documents when due. Any such debits (or ACH activity) shall not constitute a set-off. Without limiting the foregoing, Collateral Agent and each Lender shall use commercially reasonable efforts to notify Borrower of any amounts (other than principal and interest payments) debited from Borrower's deposit accounts with respect to this Agreement.

(e) Payments. Except as otherwise expressly provided herein, all payments by Borrower under the Loan Documents shall be made to the respective Lender to which such payments are owed, at such Lender's office in immediately available funds on the date specified herein. Unless otherwise provided, interest is payable monthly on the Payment Date of each month. Payments of principal and/or interest received after 12:00 noon Eastern time are considered received at the opening of business on the next Business Day. When a payment is due on a day that is not a Business Day, the payment is due the next Business Day and additional fees or interest, as applicable, shall continue to accrue until paid. All payments to be made by Borrower hereunder or under any other Loan Document, including payments of principal and interest, and all fees, expenses, indemnities and reimbursements, shall be made without set-off, recoupment or counterclaim, in lawful money of the United States and in immediately available funds.

2.4 **Secured Promissory Notes.** The Term Loans shall be evidenced by a Secured Promissory Note or Notes in the form attached as Exhibit D hereto (each a "**Secured Promissory Note**"), and shall be repayable as set forth in this Agreement. Borrower irrevocably authorizes each Lender to make or cause to be made, on or about the Funding Date of any Term Loan or at the time of receipt of any payment of principal on such Lender's Secured Promissory Note, an appropriate notation on such Lender's Secured Promissory Note Record reflecting the making of such Term Loan or (as the case may be) the receipt of such payment. The outstanding amount of each Term Loan set forth on such Lender's Secured Promissory Note Record shall be prima facie evidence of the principal amount thereof owing and unpaid to such Lender, but the failure to record, or any error in so recording, any such amount on such Lender's Secured Promissory Note Record shall not limit or otherwise affect the obligations of Borrower under any Secured Promissory Note or any other Loan Document to make payments of principal of or interest on any Secured Promissory Note when due. Upon receipt of an affidavit of an officer of a Lender as to the loss, theft, destruction, or mutilation of its Secured Promissory Note**,** Borrower shall issue, in lieu thereof, a replacement Secured Promissory Note in the same principal amount thereof and of like tenor.

2.5 **Fees.** Borrower shall pay to Collateral Agent:

(a) Facility Fee. A fully earned, non-refundable facility fee of One Hundred Twenty Five Thousand Dollars ($125,000.00) to be shared between the Lenders pursuant to their respective Commitment Percentages payable as follows: (i) Seventy Five Thousand Dollars ($75,000.00) of the facility fee shall be due and payable on the Effective Date and (ii) the remaining Fifty Thousand Dollars ($50,000.00) of the facility fee shall be due and payable on the Funding Date of the Term B Loan;

(b) Final Payment. The Final Payment, when due hereunder, to be shared between the Lenders in accordance with their respective Pro Rata Shares;

(c) Prepayment Fee. The Prepayment Fee, when due hereunder, to be shared between the Lenders in accordance with their respective Pro Rata Shares; and

(d) Lenders' Expenses. All Lenders' Expenses (including reasonable attorneys' fees and expenses for documentation and negotiation of this Agreement) incurred through and after the Effective Date, when due.

2.6 **Withholding.** Payments received by the Lenders from Borrower hereunder will be made free and clear of and without deduction for any and all present or future taxes, levies, imposts, duties, deductions, withholdings, assessments, fees or other charges imposed by any governmental authority (including any interest, additions to tax or penalties applicable thereto). Specifically, however, if at any time any Governmental Authority, applicable law, regulation or international agreement requires Borrower to make any withholding or deduction from any such payment or other sum payable hereunder to the Lenders, Borrower hereby covenants and agrees that the amount due from Borrower with respect to such payment or other sum payable hereunder will be increased to the extent necessary to ensure that, after the making of such required withholding or deduction, each Lender receives a net sum equal to the sum which it would have received had no withholding or deduction been required and Borrower shall pay the full amount withheld or deducted to the relevant Governmental Authority. Borrower will, upon request, furnish the Lenders with proof reasonably satisfactory to the Lenders indicating that Borrower has made such withholding payment; provided, however, that Borrower need not make any withholding payment if the amount or validity of such withholding payment is contested in good faith by appropriate and timely proceedings and as to which payment in full is bonded or reserved against by Borrower. The agreements and obligations of Borrower contained in this Section 2.6 shall survive the termination of this Agreement.

3. CONDITIONS OF LOANS

3.1 **Conditions Precedent to Initial Credit Extension.** Each Lender's obligation to make a Term A Loan is subject to the condition precedent that Collateral Agent and each Lender shall consent to or shall have received, in form and substance satisfactory to Collateral Agent and each Lender, such documents, and completion of such other matters, as Collateral Agent and each Lender may reasonably deem necessary or appropriate, including, without limitation:

(a) original Loan Documents, each duly executed by Borrower and each Subsidiary, as applicable;

(b) duly executed original Control Agreements with respect to any Collateral Accounts maintained by Borrower or any of its Subsidiaries;

(c) duly executed original Secured Promissory Notes in favor of each Lender according to its Term A Loan Commitment Percentage;

(d) the certificate(s) for the Shares, together with Assignment(s) Separate from Certificate, duly executed in blank;

(e) the Operating Documents and good standing certificates of Borrower and its Subsidiaries certified by the Secretary of State (or equivalent agency) of Borrower's and such Subsidiaries' jurisdiction of organization or formation and each jurisdiction in which Borrower and each Subsidiary is qualified to conduct business, each as of a date no earlier than thirty (30) days prior to the Effective Date**;**

(f) a completed Perfection Certificate for Borrower and each of its Subsidiaries;

(g) the Annual Projections, for the current calendar year (receipt of which Collateral Agent hereby acknowledges);

(h) duly executed original officer's certificate for Borrower and each Subsidiary that is a party to the Loan Documents, in a form acceptable to Collateral Agent and the Lenders;

(i) certified copies, dated as of date no earlier than thirty (30) days prior to the Effective Date, of financing statement searches, as Collateral Agent shall request, accompanied by written evidence (including any UCC termination statements) that the Liens indicated in any such financing statements either constitute Permitted Liens or have been or, in connection with the initial Credit Extension, will be terminated or released;

(j) a landlord's consent executed in favor of Collateral Agent in respect of all of Borrower's and each Subsidiaries' leased locations if either (i) the assets at such location are valued in excess of Two Hundred Thousand Dollars ($200,000.00) in the aggregate or (ii) Borrower's Books are maintained at any such location;

(k) a bailee waiver executed in favor of Collateral Agent in respect of each third party bailee where Borrower or any Subsidiary maintains Collateral having a book value in excess of Two Hundred Fifty Thousand Dollars ($250,000.00);

(l) a duly executed legal opinion of counsel to Borrower dated as of the Effective Date;

(m) evidence satisfactory to Collateral Agent and the Lenders that the insurance policies required by Section 6.5 hereof are in full force and effect, together with appropriate evidence showing loss payable and/or additional insured clauses or endorsements in favor of Collateral Agent, for the ratable benefit of the Lenders;

(n) a subordination agreement, duly executed by each holder of Subordinated Debt;

(o) the Success Fee Agreement; and

(p) payment of the fees and Lenders' Expenses then due as specified in Section 2.5 hereof.

3.2 Conditions Precedent to all Credit Extensions. The obligation of each Lender to make each Credit Extension, including the initial Credit Extension, is subject to the following conditions precedent:

(a) receipt by Collateral Agent of an executed Disbursement Letter in the form of Exhibit B attached hereto;

(b) the representations and warranties in Section 5 hereof shall be true, accurate and complete in all material respects on the date of the Disbursement Letter and on the Funding Date of each Credit Extension; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date, and no Event of Default shall have occurred and be continuing or result from the Credit Extension. Each Credit Extension is Borrower's representation and warranty on that date that the representations and warranties in Section 5 hereof are true, accurate and complete in all material respects; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date;

(c) in such Lender's sole and reasonable discretion, there has not been any Material Adverse Change or any material adverse deviation by Borrower from the Annual Projections of Borrower presented to and accepted by Collateral Agent and each Lender;

(d) to the extent not delivered at the Effective Date, duly executed original Secured Promissory Notes and Warrants, in number, form and content acceptable to each Lender, and in favor of each Lender according to its Commitment Percentage, with respect to each Credit Extension made by such Lender after the Effective Date; and

(e) payment of the fees and Lenders' Expenses then due as specified in Section 2.5 hereof.

3.3 Covenant to Deliver. Borrower agrees to deliver to Collateral Agent and the Lenders each item required to be delivered to Collateral Agent under this Agreement as a condition precedent to any Credit Extension. Borrower expressly agrees that a Credit Extension made prior to the receipt by Collateral Agent or any Lender of any such item shall not constitute a waiver by Collateral Agent or any Lender of Borrower's obligation to deliver such item, and any such Credit Extension in the absence of a required item shall be made in each Lender's sole discretion.

3.4 Procedures for Borrowing. Subject to the prior satisfaction of all other applicable conditions to the making of a Term Loan set forth in this Agreement, to obtain a Term Loan, Borrower shall notify the Lenders (which notice shall be irrevocable) by electronic mail, facsimile, or telephone by 12:00 noon Eastern time five (5) Business Days prior to the date the Term Loan is to be made. Together with any such electronic, facsimile or telephonic notification, Borrower shall deliver to the Lenders by electronic mail or facsimile a completed Disbursement Letter executed by a Responsible Officer or his or her designee. The Lenders may rely on any telephone notice given by a person whom a Lender reasonably believes is a Responsible Officer or designee. On the Funding Date, each Lender shall credit and/or transfer (as applicable) to the Designated Deposit Account, an amount equal to its Term Loan Commitment.

4. CREATION OF SECURITY INTEREST

4.1 Grant of Security Interest. Borrower hereby grants Collateral Agent, for the ratable benefit of the Lenders, to secure the payment and performance in full of all of the Obligations, a continuing security interest in, and pledges to Collateral Agent, for the ratable benefit of the Lenders, the Collateral, wherever located, whether now owned or hereafter acquired or arising, and all proceeds and products thereof. Borrower represents, warrants, and covenants that the security interest granted herein is and shall at all times continue to be a first priority perfected security interest in the Collateral, subject only to Permitted Liens that are permitted by the terms of this Agreement to have priority to Collateral Agent's Lien. If Borrower shall acquire a commercial tort claim (as defined in the Code), Borrower, shall promptly notify Collateral Agent in a writing signed by Borrower after Borrower becomes aware of such tort claim, as the case may be, of the general details thereof (and further details as may be required by Collateral Agent) and grant to Collateral Agent, for the ratable benefit of the Lenders, in such writing a security interest therein and in the proceeds thereof, all upon the terms of this Agreement, with such writing to be in form and substance reasonably satisfactory to Collateral Agent.

If this Agreement is terminated, Collateral Agent's Lien in the Collateral shall continue until the Obligations (other than inchoate indemnity obligations) are repaid in full in cash. Upon payment in full in cash of the Obligations (other than inchoate indemnity obligations) and at such time as the Lenders' obligation to make Credit Extensions has terminated, Collateral Agent shall, at the sole cost and expense of Borrower, release its Liens in the Collateral and all rights therein shall revert to Borrower.

4.2 **Authorization to File Financing Statements.** Borrower hereby authorizes Collateral Agent to file financing statements or take any other action required to perfect Collateral Agent's security interests in the Collateral, without notice to Borrower, with all appropriate jurisdictions to perfect or protect Collateral Agent's interest or rights under the Loan Documents, including a notice that any disposition of the Collateral, except to the extent permitted by the terms of this Agreement, by Borrower, or any other Person, shall be deemed to violate the rights of Collateral Agent under the Code.

4.3 **Pledge of Collateral.** Borrower hereby pledges, assigns and grants to Collateral Agent, for the ratable benefit of the Lenders, a security interest in all the Shares, together with all proceeds and substitutions thereof, all cash, stock and other moneys and property paid thereon, all rights to subscribe for securities declared or granted in connection therewith, and all other cash and noncash proceeds of the foregoing, as security for the performance of the Obligations. On the Effective Date, or, to the extent not certificated as of the Effective Date, within ten (10) days of the certification of any Shares, the certificate or certificates for the Shares will be delivered to Collateral Agent, accompanied by an instrument of assignment duly executed in blank by Borrower. To the extent required by the terms and conditions governing the Shares, Borrower shall cause the books of each entity whose Shares are part of the Collateral and any transfer agent to reflect the pledge of the Shares. Upon the occurrence and during the continuance of an Event of Default hereunder, Collateral Agent may effect the transfer of any securities included in the Collateral (including but not limited to the Shares) into the name of Collateral Agent and cause new (as applicable) certificates representing such securities to be issued in the name of Collateral Agent or its transferee. Borrower will execute and deliver such documents, and take or cause to be taken such actions, as Collateral Agent may reasonably request to perfect or continue the perfection of Collateral Agent's security interest in the Shares. Unless an Event of Default shall have occurred and be continuing, Borrower shall be entitled to exercise any voting rights with respect to the Shares and to give consents, waivers and ratifications in respect thereof, provided that no vote shall be cast or consent, waiver or ratification given or action taken which would be inconsistent with any of the terms of this Agreement or which would constitute or create any violation of any of such terms. All such rights to vote and give consents, waivers and ratifications shall terminate upon the occurrence and continuance of an Event of Default.

5. REPRESENTATIONS AND WARRANTIES

Borrower represents and warrants to Collateral Agent and the Lenders as follows:

5.1 **Due Organization, Authorization: Power and Authority.** Borrower and each of its Subsidiaries is duly existing and in good standing as a Registered Organization in its jurisdictions of organization or formation and Borrower and each of its Subsidiaries is qualified and licensed to do business and is in good standing in any jurisdiction in which the conduct of its businesses or its ownership of property requires that it be qualified except where the failure to do so could not reasonably be expected to have a Material Adverse Change. In connection with this Agreement, Borrower and each of its Subsidiaries has delivered to Collateral Agent a completed perfection certificate signed by an officer of Borrower or such Subsidiary (each as updated from time to time, as permitted hereunder, a "**Perfection Certificate**" and collectively, the "**Perfection Certificates**"). Borrower represents and warrants that (a) Borrower and each of its Subsidiaries' exact legal name is that which is indicated on its respective Perfection Certificate and on the signature page of each Loan Document to which it is a party; (b) Borrower and each of its Subsidiaries is an organization of the type and is organized in the jurisdiction set forth on its respective Perfection Certificate; (c) each Perfection Certificate accurately sets forth each of Borrower's and its Subsidiaries' organizational identification number or accurately states that Borrower or such Subsidiary has none; (d) each Perfection Certificate accurately sets forth Borrower's and each of its Subsidiaries' place of business, or, if more than one, its chief executive office as well as Borrower's and each of its Subsidiaries' mailing address (if different than its chief executive office); (e) Borrower and each of its Subsidiaries (and each of its respective predecessors) have not, in the past five (5) years, changed its jurisdiction of organization, organizational structure or type, or any organizational number assigned by its jurisdiction; and (f) all other information set forth on the Perfection Certificates pertaining to Borrower and each of its Subsidiaries, is accurate and complete (it being understood and agreed that Borrower and each of its Subsidiaries may from time to time update certain information in the Perfection Certificates (including the information set forth in clause (d) above) after the Effective Date to the extent permitted by one or more specific provisions in this Agreement); such updated Perfection Certificates subject to the review and approval of Collateral Agent. If Borrower or any of its Subsidiaries is not now a Registered Organization but later becomes one, Borrower shall notify Collateral Agent of such occurrence and provide Collateral Agent with such Person's organizational identification number within five (5) Business Days of receiving such organizational identification number.

The execution, delivery and performance by Borrower and each of its Subsidiaries of the Loan Documents to which it is a party have been duly authorized, and do not (i) conflict with any of Borrower's or such Subsidiaries' organizational documents, including its respective Operating Documents, (ii) contravene, conflict with, constitute a default under or violate any material Requirement of Law applicable thereto, (iii) contravene, conflict or violate any applicable order, writ, judgment, injunction, decree, determination or award of any Governmental Authority by which Borrower or such Subsidiary, or any of their property or assets may be bound or affected, (iv) require any action by, filing, registration, or qualification with, or Governmental Approval from, any Governmental Authority (except such Governmental Approvals which have already been obtained and are in full force and effect) or are being obtained pursuant to Section 6.1(b), or (v) constitute an event of default under any material agreement by which Borrower or any of such Subsidiaries, or their respective properties, is bound. Neither Borrower nor any of its Subsidiaries is in default under any agreement to which it is a party or by which it or any of its assets is bound in which such default could reasonably be expected to have a Material Adverse Change.

5.2 Collateral.

(a) Borrower and each its Subsidiaries have good title to, have rights in, and the power to transfer each item of the Collateral upon which it purports to grant a Lien under the Loan Documents, free and clear of any and all Liens except Permitted Liens, and neither Borrower nor any of its Subsidiaries have any Deposit Accounts, Securities Accounts, Commodity Accounts or other investment accounts other than the Collateral Accounts or the other investment accounts, if any, described in the Perfection Certificates delivered to Collateral Agent in connection herewith (as the same may be updated from time to time, provided that any such updates shall be in form and substance acceptable to Collateral Agent and each Lender, in its sole discretion) with respect of which Borrower or such Subsidiary has given Collateral Agent notice and taken such actions as are necessary to give Collateral Agent a perfected security interest therein. The Accounts are bona fide, existing obligations of the Account Debtors.

(b) On the Effective Date, and except as disclosed on the Perfection Certificate (as the same may be updated from time to time, provided that any such updates shall be in form and substance acceptable to Collateral Agent and each Lender, in its sole discretion) (i) the Collateral is not in the possession of any third party bailee (such as a warehouse), and (ii) no such third party bailee possesses components of the Collateral in excess of Two Hundred Fifty Thousand Dollars ($250,000.00). None of the components of the Collateral shall be maintained at locations other than as disclosed in the Perfection Certificates on the Effective Date or as permitted pursuant to Section 6.11.

(c) All Inventory is in all material respects of good and marketable quality, free from material defects.

(d) Borrower and each of its Subsidiaries is the sole owner of the Intellectual Property each respectively purports to own, free and clear of all Liens other than Permitted Liens. Except as noted on the Perfection Certificates, neither Borrower nor any of its Subsidiaries is a party to, nor is bound by, any material license or other material agreement with respect to which Borrower or such Subsidiary is the licensee that (i) prohibits or otherwise restricts Borrower or its Subsidiaries from granting a security interest in Borrower's or such Subsidiaries' interest in such material license or material agreement or any other property, or (ii) for which a default under or termination of could interfere with Collateral Agent's or any Lender's right to sell any Collateral. Borrower shall provide written notice to Collateral Agent and each Lender within twenty (20) days of Borrower or any of its Subsidiaries entering into or becoming bound by any license or agreement with respect to which Borrower or any Subsidiary is the licensee (other than over-the-counter software that is commercially available to the public).

5.3 Litigation. Except as disclosed (i) on the Perfection Certificates, or (ii) in accordance with Section 6.9 hereof, there are no actions, suits, investigations, or proceedings pending or, to the knowledge of the Responsible Officers, threatened in writing by or against Borrower or any of its Subsidiaries involving more than Two Hundred Fifty Thousand Dollars ($250,000.00).

5.4 No Material Deterioration in Financial Condition; Financial Statements. All consolidated financial statements for Borrower and its Subsidiaries, delivered to Collateral Agent fairly present, in conformity with GAAP, in all material respects the consolidated financial condition of Borrower and its Subsidiaries, and the consolidated results of operations of Borrower and its Subsidiaries as of the dates and for

the periods presented. Lender understands that interim financial statements may not be audited and may be subject to ordinary course year-end adjustments, such as for the sake of example only, changes in the fair market value of warrants. Lender therefore understands and agrees that such financial statements are therefore considered to be in draft form and subject to adjustment. There has not been any material deterioration in the consolidated financial condition of Borrower and its Subsidiaries since the date of the most recent financial statements submitted to any Lender.

5.5 Solvency. Borrower is solvent and each of its Subsidiaries, on a consolidated basis, is Solvent.

5.6 Regulatory Compliance. Neither Borrower nor any of its Subsidiaries is an "investment company" or a company "controlled" by an "investment company" under the Investment Company Act of 1940, as amended. Neither Borrower nor any of its Subsidiaries is engaged as one of its important activities in extending credit for margin stock (under Regulations X, T and U of the Federal Reserve Board of Governors). Borrower and each of its Subsidiaries has complied in all material respects with the Federal Fair Labor Standards Act. Neither Borrower nor any of its Subsidiaries is a "holding company" or an "affiliate" of a "holding company" or a "subsidiary company" of a "holding company" as each term is defined and used in the Public Utility Holding Company Act of 2005. Neither Borrower nor any of its Subsidiaries has violated any laws, ordinances or rules, the violation of which could reasonably be expected to have a Material Adverse Change. Neither Borrower's nor any of its Subsidiaries' properties or assets has been used by Borrower or such Subsidiary or, to Borrower's knowledge, by previous Persons, in disposing, producing, storing, treating, or transporting any hazardous substance other than in material compliance with applicable laws. Borrower and each of its Subsidiaries has obtained all consents, approvals and authorizations of, made all declarations or filings with, and given all notices to, all Governmental Authorities that are necessary to continue their respective businesses as currently conducted.

None of Borrower, any of its Subsidiaries, or any of Borrower's or its Subsidiaries' Affiliates or any of their respective agents acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement is (i) in violation of any Anti-Terrorism Law, (ii) engaging in or conspiring to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding or attempts to violate, any of the prohibitions set forth in any Anti-Terrorism Law, or (iii) is a Blocked Person. None of Borrower, any of its Subsidiaries, or to the knowledge of Borrower and any of their Affiliates or agents, acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement, (x) conducts any business or engages in making or receiving any contribution of funds, goods or services to or for the benefit of any Blocked Person, or (y) deals in, or otherwise engages in any transaction relating to, any property or interest in property blocked pursuant to Executive Order No. 13224, any similar executive order or other Anti-Terrorism Law.

5.7 Investments. Neither Borrower nor any of its Subsidiaries owns any stock, shares, partnership interests or other equity securities except for Permitted Investments.

5.8 Tax Returns and Payments; Pension Contributions. Borrower and each of its Subsidiaries has timely filed or filed extensions for all required tax returns and reports, and Borrower and each of its Subsidiaries, has timely paid or filed extensions for all foreign, federal, state, and local taxes, assessments, deposits and contributions owed by Borrower and such Subsidiaries, in all jurisdictions in which Borrower or any such Subsidiary is subject to taxes, including the United States, unless such taxes are being contested in accordance with the following sentence. Borrower and each of its Subsidiaries, may defer payment of any contested taxes, provided that Borrower or such Subsidiary, (a) in good faith contests its obligation to pay the taxes by appropriate proceedings promptly and diligently instituted and conducted, (b) notifies Collateral Agent in writing of the commencement of, and any material development in, the proceedings, and (c) posts bonds or takes any other steps required to prevent the Governmental Authority levying such contested taxes from obtaining a Lien upon any of the Collateral that is other than a "**Permitted Lien**." Neither Borrower nor any of its Subsidiaries is aware of any claims or adjustments proposed in writing for any of Borrower's or such Subsidiaries', prior tax years which could result in additional taxes becoming due and payable by Borrower or its Subsidiaries. Borrower and each of its Subsidiaries have paid all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with their terms, and neither Borrower nor any of its Subsidiaries have, withdrawn from participation in, and have not permitted partial or complete termination of, or permitted the occurrence of any other event with respect to, any such plan which could reasonably be expected to result in any liability of Borrower or its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

5.9 Use of Proceeds. Borrower shall use the proceeds of the Credit Extensions solely as working capital and to fund its general business requirements in accordance with the provisions of this Agreement, and not for personal, family, household or agricultural purposes.

5.10 Shares. Borrower has full power and authority to create a first lien on the Shares and no disability or contractual obligation exists that would prohibit Borrower from pledging the Shares pursuant to this Agreement. To Borrower's knowledge, there are no subscriptions, warrants, rights of first refusal or other restrictions on transfer relative to, or options exercisable with respect to the Shares. The Shares have been and will be duly authorized and validly issued, and are fully paid and non-assessable. To Borrower's knowledge, the Shares are not the subject of any present or threatened suit, action, arbitration, administrative or other proceeding, and Borrower knows of no reasonable grounds for the institution of any such proceedings.

5.11 Full Disclosure. No written representation, warranty or other statement of Borrower or any of its Subsidiaries in any certificate or written statement given to Collateral Agent or any Lender, as of the date such representation, warranty, or other statement was made, taken together with all such written certificates and written statements given to Collateral Agent or any Lender, contains any untrue statement of a material fact or omits to state a material fact necessary to make the statements contained in the certificates or statements not misleading (it being recognized that the projections and forecasts provided by Borrower in good faith and based upon reasonable assumptions are not viewed as facts and that actual results during the period or periods covered by such projections and forecasts may differ from the projected or forecasted results).

5.12 Definition of "**Knowledge.**" For purposes of the Loan Documents, whenever a representation or warranty is made to Borrower's knowledge or awareness, to the "best of" Borrower's knowledge, or with a similar qualification, knowledge or awareness means the actual knowledge, after reasonable investigation, of the Responsible Officers.

6. AFFIRMATIVE COVENANTS

Borrower shall, and shall cause each of its Subsidiaries to, do all of the following:

6.1 Government Compliance.

(a) Maintain its and all its Subsidiaries' legal existence and good standing in their respective jurisdictions of organization and maintain qualification in each jurisdiction in which the failure to so qualify could reasonably be expected to have a Material Adverse Change. Comply with all laws, ordinances and regulations to which Borrower or any of its Subsidiaries is subject, the noncompliance with which could reasonably be expected to have a Material Adverse Change.

(b) Obtain and keep in full force and effect, all of the material Governmental Approvals necessary for the performance by Borrower and its Subsidiaries of their respective businesses and obligations under the Loan Documents and the grant of a security interest to Collateral Agent for the ratable benefit of the Lenders, in all of the Collateral. Borrower shall promptly provide copies to Collateral Agent of any material Governmental Approvals obtained by Borrower or any of its Subsidiaries.

6.2 Financial Statements, Reports, Certificates.

(a) Deliver to each Lender:

(i) as soon as available, but no later than thirty (30) days after the last day of each month, a company prepared consolidated and consolidating balance sheet, income statement and cash flow statement covering the consolidated operations of Borrower and its Subsidiaries for such month certified by a Responsible Officer and in a form reasonably acceptable to Collateral Agent;

(ii) as soon as available, but no later than one hundred twenty (120) days after the last day of Borrower's fiscal year or within five (5) days of filing with the SEC, audited consolidated financial statements prepared under GAAP, consistently applied, together with an unqualified opinion on the financial statements from an independent certified public accounting firm acceptable to Collateral Agent in its reasonable discretion**;**

(iii) as soon as available after approval thereof by Borrower's Board of Directors, but no later than thirty (30) days after the last day of each of Borrower's fiscal years, Borrower's annual financial projections for the entire current fiscal year as approved by Borrower's Board of Directors, which such annual financial projections shall be set forth in a quarterly format (such annual financial projections as originally delivered to Collateral Agent and the Lenders are referred to herein as the "**Annual Projections**"; provided that, any revisions of the Annual Projections approved by Borrower's Board of Directors shall be delivered to Collateral Agent and the Lenders no later than ten (10) days after such approval);

(iv) within five (5) days of delivery, copies of all statements, reports and notices made available to Borrower's security holders or holders of Subordinated Debt;

(v) within five (5) days of filing, all reports on Form 10-K, 10-Q and 8-K filed with the Securities and Exchange Commission,

(vi) prompt notice of any amendments of or other material changes to the capitalization table of Borrower and to the Operating Documents of Borrower or any of its Subsidiaries, together with any copies reflecting such amendments or changes with respect thereto;

(vii) prompt notice of any event that could reasonably be expected to materially and adversely affect the value of the Intellectual Property;

(viii) as soon as available, but no later than thirty (30) days after the last day of each month, copies of the month-end account statements for each Collateral Account maintained by Borrower or its Subsidiaries, which statements may be provided to Collateral Agent and each Lender by Borrower or directly from the applicable institution(s), and

(ix) other information as reasonably requested by Collateral Agent or any Lender.

Notwithstanding the foregoing, documents required to be delivered pursuant to the terms hereof (to the extent any such documents are included in materials otherwise filed with the SEC) may be delivered electronically and if so delivered, shall be deemed to have been delivered on the date on which Borrower posts such documents, or provides a link thereto, on Borrower's website on the internet at Borrower's website address.

(b) Concurrently with the delivery of the financial statements specified in Section 6.2(a)(i) above but no later than thirty (30) days after the last day of each month, deliver to each Lender, a duly completed Compliance Certificate signed by a Responsible Officer.

(c) Keep proper books of record and account in accordance with GAAP in all material respects, in which full, true and correct entries shall be made of all dealings and transactions in relation to its business and activities. Borrower shall, and shall cause each of its Subsidiaries to, allow, at the sole reasonable cost of Borrower, Collateral Agent or any Lender, during regular business hours upon reasonable prior notice (provided that no notice shall be required when an Event of Default has occurred and is continuing), to visit and inspect any of its properties, to examine and make abstracts or copies from any of its books and records, and to conduct a collateral audit and analysis of its operations and the Collateral. Such audits shall be conducted no more often than once every year unless (and more frequently if) an Event of Default has occurred and is continuing.

6.3 Inventory; Returns. Keep all Inventory in good and marketable condition, free from material defects. Returns and allowances between Borrower, or any of its Subsidiaries, and their respective Account Debtors shall follow Borrower's, or such Subsidiary's, customary practices as they exist at the Effective Date. Borrower must promptly notify Collateral Agent and the Lenders of all returns, recoveries, disputes and claims that involve more than Two Hundred Fifty Thousand Dollars ($250,000.00) individually or in the aggregate in any calendar year.

6.4 Taxes; Pensions. Timely file and require each of its Subsidiaries to timely file, all required tax returns and reports or extensions therefor (which are timely filed and accepted and approved by the applicable Governmental Authority) and timely pay, and require each of its Subsidiaries to timely file, all foreign, federal, state, and local taxes, assessments, deposits and contributions owed by Borrower or its Subsidiaries, except for deferred payment of any taxes contested pursuant to the terms of Section 5.8 hereof, and shall deliver to Lenders, on demand, appropriate certificates attesting to such payments, and pay all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with the terms of such plans.

6.5 Insurance. Keep Borrower's and its Subsidiaries' business and the Collateral insured for risks and in amounts standard for companies in Borrower's and its Subsidiaries' industry and location and as Collateral Agent may reasonably request. Insurance policies shall be in a form, with companies, and in amounts that are reasonably satisfactory to Collateral Agent and Lenders. All property policies shall have a lender's loss payable endorsement showing Collateral Agent as lender loss payee and waive subrogation against Collateral Agent, and all liability policies shall show, or have endorsements showing, Collateral Agent, as additional insured. The Collateral Agent shall be named as lender loss payee and/or additional insured with respect to any such insurance providing coverage in respect of any Collateral, and each provider of any such insurance shall agree, by endorsement upon the policy or policies issued by it or by independent instruments furnished to the Collateral Agent, that it will give the Collateral Agent thirty (30) days prior written notice before any such policy or policies shall be materially altered or canceled. At Collateral Agent's request, Borrower shall deliver certified copies of policies and evidence of all premium payments. Proceeds payable under any policy shall, at Collateral Agent's option, be payable to Collateral Agent, for the ratable benefit of the Lenders, on account of the Obligations. Notwithstanding the foregoing, (a) so long as no Event of Default has occurred and is continuing, Borrower shall have the option of applying the proceeds of any casualty policy up to One Hundred Thousand Dollars ($100,000.00) with respect to any loss, but not exceeding One Hundred Thousand Dollars ($100,000.00), in the aggregate for all losses under all casualty policies in any one year, toward the replacement or repair of destroyed or damaged property; provided that any such replaced or repaired property (i) shall be of equal or like value as the replaced or repaired Collateral and (ii) shall be deemed Collateral in which Collateral Agent has been granted a first priority security interest, and (b) after the occurrence and during the continuance of an Event of Default, all proceeds payable under such casualty policy shall, at the option of Collateral Agent, be payable to Collateral Agent, for the ratable benefit of the Lenders, on account of the Obligations. If Borrower or any of its Subsidiaries fails to obtain insurance as required under this Section 6.5 or to pay any amount or furnish any required proof of payment to third persons, Collateral Agent and/or any Lender may make, at Borrower's expense, all or part of such payment or obtain such insurance policies required in this Section 6.5, and take any action under the policies Collateral Agent or such Lender deems prudent.

6.6 Operating Accounts.

(a) Maintain all of Borrower's and its Subsidiaries' Collateral Accounts in accounts which are subject to a Control Agreement in favor of Collateral Agent; provided, however, that Borrower may maintain an account with Square 1 Bank, a division of Pacific Western Bank, which is not subject to a Control Agreement so long as such account (i) is closed no later than ninety (90) days from the Effective Date and (ii) holds no more than Twenty-Five Thousand Dollars ($25,000) in cash and Cash Equivalents at any time.

(b) Borrower shall provide Collateral Agent five (5) days' prior written notice before Borrower or any of its Subsidiaries establishes any Collateral Account at or with any Person other than the institutions identified to Collateral Agent in the Perfection Certificate delivered by Borrower as of the Effective Date. In addition, for each Collateral Account that Borrower or any of its Subsidiaries, at any time maintains, Borrower or such Subsidiary shall cause the applicable bank or financial institution at or with which such Collateral Account is maintained to execute and deliver a Control Agreement or other appropriate instrument with respect to such Collateral Account to perfect Collateral Agent's Lien in such Collateral Account in accordance with the terms hereunder prior to the establishment of such Collateral Account, which Control Agreement may not be terminated without prior written consent of Collateral Agent. The provisions of the previous sentence shall not apply to deposit accounts exclusively used for payroll, payroll taxes and other employee wage and benefit payments to or for the benefit of Borrower's, or any of its Subsidiaries', employees and identified to Collateral Agent by Borrower as such in the Perfection Certificates. Collateral Agent agrees not to place a "hold" or deliver a notice of exclusive control, entitlement order, or other similar directions or instructions under any Control Agreement or similar agreements providing control of any Collateral unless an Event of Default has occurred.

(c) Neither Borrower nor any of its Subsidiaries shall maintain any Collateral Accounts except Collateral Accounts maintained in accordance with Sections 6.6(a) and (b).

6.7 Protection of Intellectual Property Rights. Borrower and each of its Subsidiaries shall: (a) use commercially reasonable efforts to protect, defend and maintain the validity and enforceability of its Intellectual Property that is material to Borrower's business; (b) promptly advise Collateral Agent in writing of material infringement by a third party of its Intellectual Property; and (c) not allow any Intellectual Property material to Borrower's business to be abandoned, forfeited or dedicated to the public without Collateral Agent's prior written consent.

6.8 Litigation Cooperation. Commencing on the Effective Date and continuing through the termination of this Agreement, make available to Collateral Agent and the Lenders, without expense to Collateral Agent or the Lenders, Borrower and each of Borrower's officers, employees and agents and Borrower's Books, to the extent that Collateral Agent or any Lender may reasonably deem them necessary to prosecute or defend any third-party suit or proceeding instituted by or against Collateral Agent or any Lender with respect to any Collateral or relating to Borrower.

6.9 Notices of Litigation and Default. Borrower will give prompt written notice to Collateral Agent and the Lenders of any litigation or governmental proceedings pending or threatened (in writing) against Borrower or any of its Subsidiaries, which could reasonably be expected to result in damages or costs to Borrower or any of its Subsidiaries of Two Hundred Fifty Thousand Dollars ($250,000.00) or more or which could reasonably be expected to have a Material Adverse Change. Without limiting or contradicting any other more specific provision of this Agreement, promptly (and in any event within three (3) Business Days) upon Borrower becoming aware of the existence of any Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default, Borrower shall give written notice to Collateral Agent and the Lenders of such occurrence, which such notice shall include a reasonably detailed description of such Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default.

6.10 [Intentionally Omitted.]

6.11 Landlord Waivers; Bailee Waivers. In the event that Borrower or any of its Subsidiaries, after the Effective Date, intends to add any new offices or business locations, including warehouses, or otherwise store any portion of the Collateral with, or deliver any portion of the Collateral to, a bailee, in each case pursuant to Section 7.2, then Borrower or such Subsidiary will provide written notice thereof to Collateral Agent and, in the event that the new location is the chief executive office of the Borrower or such Subsidiary or the Collateral at any such new location is valued in excess of Two Hundred Fifty Thousand ($250,000.00) in the aggregate, such bailee or landlord, as applicable, must execute and deliver a bailee waiver or landlord waiver, as applicable, in form and substance reasonably satisfactory to Collateral Agent prior to the addition of any new offices or business locations, or any such storage with or delivery to any such bailee, as the case may be.

6.12 Creation/Acquisition of Subsidiaries. In the event Borrower, or any of its Subsidiaries creates or acquires any Subsidiary, Borrower shall provide prior written notice to Collateral Agent and each Lender of the creation or acquisition of such new Subsidiary and take all such action as may be reasonably required by Collateral Agent or any Lender to cause each such Subsidiary to become a co-Borrower hereunder or to guarantee the Obligations of Borrower under the Loan Documents and, in each case, grant a continuing pledge and security interest in and to the assets of such Subsidiary (substantially as described on Exhibit A hereto); and Borrower (or its Subsidiary, as applicable) shall grant and pledge to Collateral Agent, for the ratable benefit of the Lenders, a perfected security interest in the Shares of each such newly created Subsidiary.

6.13 Further Assurances.

(a) Execute any further instruments and take further action as Collateral Agent or any Lender reasonably requests to perfect or continue Collateral Agent's Lien in the Collateral or to effect the purposes of this Agreement.

(b) Deliver to Collateral Agent and Lenders, within five (5) days after the same are sent or received, copies of all material correspondence, reports, documents and other filings with any Governmental Authority that could reasonably be expected to have a material adverse effect on any of the Governmental Approvals material to Borrower's business or otherwise could reasonably be expected to have a Material Adverse Change.

7. NEGATIVE COVENANTS

Borrower shall not, and shall not permit any of its Subsidiaries to, do any of the following without the prior written consent of the Required Lenders:

7.1 Dispositions. Convey, sell, lease, transfer, assign, or otherwise dispose of (collectively, "**Transfer**"), or permit any of its Subsidiaries to Transfer, all or any part of its business or property, except for Transfers (a) of Inventory in the ordinary course of business; (b) of worn out, surplus or obsolete Equipment; and (c) in connection with Permitted Liens, Permitted Investments and Permitted Licenses; and (d) in addition to those specifically enumerated above, expenditures reflected in the Annual Projections, as such Annual Projections may be amended from time to time pursuant to the terms of Section 6.2 hereof.

7.2 Changes in Business, Management, Ownership, or Business Locations. (a) Engage in or permit any of its Subsidiaries to engage in any business other than the businesses engaged in by Borrower as of the Effective Date or reasonably related thereto; (b) liquidate or dissolve; or (c) (i) any Key Person shall cease to be actively engaged in the management of Borrower unless written notice thereof is provided to Collateral Agent within five (5) days of such change, or (ii) enter into any transaction or series of related transactions in which the stockholders of Borrower who were not stockholders immediately prior to the first such transaction own more than forty nine percent (49%) of the voting stock of Borrower immediately after giving effect to such transaction or related series of such transactions (other than by the sale of Borrower's equity securities in a public offering, a private placement of public equity or to venture capital investors so long as Borrower identifies to Collateral Agent the venture capital investors prior to the closing of the transaction). Borrower shall not, without at least thirty (30) days' prior written notice to Collateral Agent: (A) add any new offices or business locations, including warehouses (unless such new offices or business locations (ii) contain less than One Hundred Thousand Dollars ($100,000.00) in assets or property of Borrower or any of its Subsidiaries and (ii) are not Borrower's or its Subsidiaries' chief executive office); (B) change its jurisdiction of organization, (C) change its organizational structure or type, (D) change its legal name, or (E) change any organizational number (if any) assigned by its jurisdiction of organization.

7.3 Mergers or Acquisitions. Merge or consolidate, or permit any of its Subsidiaries to merge or consolidate, with any other Person, or acquire, or permit any of its Subsidiaries to acquire, all or substantially all of the capital stock, shares or property of another Person other than pursuant to a Permitted Acquisition. A Subsidiary (including each of EB Pharma and EBPI) may merge or consolidate into another Subsidiary (provided such surviving Subsidiary is a "co-Borrower" hereunder or has provided a secured Guaranty of Borrower's Obligations hereunder) or with (or into) Borrower provided Borrower is the surviving legal entity, and as long as no Event of Default is occurring prior thereto or arises as a result therefrom. Without limiting the foregoing, Borrower shall not, without Collateral Agent's prior written consent, enter into any binding contractual arrangement with any Person to attempt to facilitate a merger or acquisition of Borrower, unless (i) no Event of Default exists when such agreement is entered into by Borrower, (ii) such agreement does not give such Person the right to claim any fees, payments or damages from Borrower in excess of Two Hundred Fifty Thousand Dollars ($250,000.00), and (iii) Borrower notifies Collateral Agent in advance of entering into such an agreement.

7.4 Indebtedness. Create, incur, assume, or be liable for any Indebtedness, or permit any Subsidiary to do so, other than Permitted Indebtedness.

7.5 Encumbrance. Create, incur, allow, or suffer any Lien on any of its property, or assign or convey any right to receive income, including the sale of any Accounts, or permit any of its Subsidiaries to do so, except for Permitted Liens, or permit any Collateral not to be subject to the first priority security interest granted herein (except for Permitted Liens that are permitted by the terms of this Agreement to have priority over Collateral Agent's Lien), or enter into any agreement, document, instrument or other arrangement (except with or in favor of Collateral Agent, for the ratable benefit of the Lenders) with any Person which directly or indirectly prohibits or has the effect of prohibiting Borrower, or any of its Subsidiaries, from assigning, mortgaging, pledging, granting a security interest in or upon, or encumbering any of Borrower's or such Subsidiary's Intellectual Property, except as is otherwise permitted in Section 7.1 hereof and the definition of "**Permitted Liens**" herein.

7.6 Maintenance of Collateral Accounts. Maintain any Collateral Account except pursuant to the terms of Section 6.6 hereof.

7.7 Distributions; Investments. (a) Pay any dividends (other than dividends payable solely in capital stock) or make any distribution or payment in respect of or redeem, retire or purchase any capital stock (other than repurchases pursuant to the terms of employee stock purchase plans, employee restricted stock agreements, stockholder rights plans, director or consultant stock option plans, or similar plans, provided such repurchases do not exceed Two Hundred Fifty Thousand Dollars ($250,000.00) in the aggregate per fiscal year) or (b) directly or indirectly make any Investment other than Permitted Investments, or permit any of its Subsidiaries to do so.

7.8 Transactions with Affiliates. Directly or indirectly enter into or permit to exist any material transaction with any Affiliate of Borrower or any of its Subsidiaries, except for (a) transactions that are in the ordinary course of Borrower's or such Subsidiary's business, upon fair and reasonable terms that are no less favorable to Borrower or such Subsidiary than would be obtained in an arm's length transaction with a non-affiliated Person, (b) Subordinated Debt or equity investments by Borrower's investors in Borrower or its Subsidiaries, (c) any transaction contemplated in Section 7.1, (d) compensation and indemnification of, and other employment arrangements with, directors, officers and employees of Borrower or any Subsidiary, in each case, entered into in the ordinary course of business in accordance with Borrower's Annual Projections and corporate governance practices, and (e) loans and advances otherwise explicitly permitted hereunder to be made to the applicable Affiliate.

7.9 Subordinated Debt. (a) Make or permit any payment on any Subordinated Debt, except under the terms of the subordination, intercreditor, or other similar agreement to which such Subordinated Debt is subject, or (b) amend any provision in any document relating to the Subordinated Debt which would increase the maximum amount thereof or adversely affect the subordination thereof to Obligations owed to the Lenders.

7.10 Compliance. Become an "investment company" or a company controlled by an "investment company", under the Investment Company Act of 1940, as amended, or undertake as one of its important activities extending credit to purchase or carry margin stock (as defined in Regulation U of the Board of Governors of the Federal Reserve System), or use the proceeds of any Credit Extension for that purpose; fail to meet the minimum funding requirements of ERISA, permit a Reportable Event or Prohibited Transaction, as defined in ERISA, to occur; fail to comply with the Federal Fair Labor Standards Act or violate any other law or regulation, if the violation could reasonably be expected to have a Material Adverse Change, or permit any of its Subsidiaries to do so; withdraw or permit any Subsidiary to withdraw from participation in, permit partial or complete termination of, or permit the occurrence of any other event with respect to, any present pension, profit sharing and deferred compensation plan which could reasonably be expected to result in any liability of Borrower or any of its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

7.11 Compliance with Anti-Terrorism Laws. Collateral Agent hereby notifies Borrower and each of its Subsidiaries that pursuant to the requirements of Anti-Terrorism Laws, and Collateral Agent's policies and practices, Collateral Agent is required to obtain, verify and record certain information and documentation that identifies Borrower and each of its Subsidiaries and their principals, which information includes the name and address of Borrower and each of its Subsidiaries and their principals and such other information that will allow Collateral Agent to identify such party in accordance with Anti-Terrorism Laws. Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries permit any Affiliate to, directly or indirectly, knowingly enter into any documents, instruments, agreements or contracts with any Person listed on the OFAC Lists. Borrower and each of its Subsidiaries shall immediately notify Collateral Agent if Borrower or such Subsidiary has knowledge that Borrower, or any Subsidiary or Affiliate of Borrower, is listed on the OFAC Lists or (a) is convicted on, (b) pleads *nolo contendere* to, (c) is indicted on, or (d) is arraigned and held over on charges involving money laundering or predicate crimes to money laundering. Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries, permit any Affiliate to, directly or indirectly, (i) conduct any business or engage in any transaction or dealing with any Blocked Person, including, without limitation, the making or receiving of any contribution of funds, goods or services to or for the benefit of any Blocked Person, (ii) deal in, or otherwise engage in any transaction relating to, any property or interests in property blocked pursuant to Executive Order No. 13224 or any similar executive order or other Anti-Terrorism Law, or (iii) engage in or conspire to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the prohibitions set forth in Executive Order No. 13224 or other Anti-Terrorism Law.

8. EVENTS OF DEFAULT

Any one of the following shall constitute an event of default (an "**Event of Default**") under this Agreement:

8.1 Payment Default. Borrower fails to (a) make any payment of principal or interest on any Credit Extension on its due date, or (b) pay any other Obligations within three (3) Business Days after such Obligations are due and payable (which three (3) Business Day grace period shall not apply to payments due on the Maturity Date or the date of acceleration pursuant to Section 9.1 (a) hereof). During the cure period, the failure to cure the payment default is not an Event of Default (but no Credit Extension will be made during the cure period);

8.2 Covenant Default.

(a) Borrower or any of its Subsidiaries fails or neglects to perform any obligation in Sections 6.2 (Financial Statements, Reports, Certificates), 6.4 (Taxes), 6.5 (Insurance), 6.6 (Operating Accounts), 6.7 (Protection of Intellectual Property Rights), 6.9 (Notice of Litigation and Default), 6.11 (Landlord Waivers; Bailee Waivers), 6.12 (Creation/Acquisition of Subsidiaries) or 6.13 (Further Assurances) or Borrower violates any covenant in Section 7; or

(b) Borrower, or any of its Subsidiaries, fails or neglects to perform, keep, or observe any other term, provision, condition, covenant or agreement contained in this Agreement or any Loan Documents, and as to any default (other than those specified in this Section 8) under such other term, provision, condition, covenant or agreement that can be cured, has failed to cure the default within ten (10) days after the occurrence thereof; provided, however, that if the default cannot by its nature be cured within the ten (10) day period or cannot after diligent attempts by Borrower be cured within such ten (10) day period, and such default is likely to be cured within a reasonable time, then Borrower shall have an additional period (which shall not in any case exceed thirty (30) days) to attempt to cure such default, and within such reasonable time period the failure to cure the default shall not be deemed an Event of Default (but no Credit Extensions shall be made during such cure period). Grace periods provided under this Section shall not apply, among other things, to financial covenants or any other covenants, if any, set forth in subsection (a) above;

8.3 Material Adverse Change. A Material Adverse Change occurs;

8.4 Attachment; Levy; Restraint on Business.

(a) (i) The service of process seeking to attach, by trustee or similar process, any funds of Borrower or any of its Subsidiaries or of any entity under control of Borrower or its Subsidiaries on deposit with any Lender or any Lender's Affiliate or any bank or other institution at which Borrower or any of its Subsidiaries maintains a Collateral Account, or (ii) a notice of lien, levy, or assessment is filed against Borrower or any of its Subsidiaries or their respective assets by any government agency, and the same under subclauses (i) and (ii) hereof are not, within ten (10) days after the occurrence thereof, discharged or stayed (whether through the posting of a bond or otherwise); provided, however, no Credit Extensions shall be made during any ten (10) day cure period; and

(b) (i) any material portion of Borrower's or any of its Subsidiaries' assets is attached, seized, levied on, or comes into possession of a trustee or receiver, or (ii) any court order enjoins, restrains, or prevents Borrower or any of its Subsidiaries from conducting any part of its business;

8.5 Insolvency. (a) Borrower or any of its Subsidiaries is or becomes Insolvent; (b) Borrower or any of its Subsidiaries begins an Insolvency Proceeding; or (c) an Insolvency Proceeding is begun against Borrower or any of its Subsidiaries and not dismissed or stayed within forty-five (45) days (but no Credit Extensions shall be made while Borrower or any Subsidiary is Insolvent and/or until any Insolvency Proceeding is dismissed);

8.6 Other Agreements. There is a default in any agreement to which Borrower or any of its Subsidiaries is a party with a third party or parties resulting in a right by such third party or parties, whether or not exercised, to accelerate the maturity of any Indebtedness in an amount in excess of Two Hundred Fifty Thousand Dollars ($250,000.00) or that could reasonably be expected to have a Material Adverse Change;

8.7 **Judgments.** One or more judgments, orders, or decrees for the payment of money in an amount, individually or in the aggregate, of at least Two Hundred Fifty Thousand Dollars ($250,000.00) (not covered by independent third-party insurance as to which liability has been accepted by such insurance carrier) shall be rendered against Borrower or any of its Subsidiaries and shall remain unsatisfied, unvacated, or unstayed for a period of ten (10) days after the entry thereof (provided that no Credit Extensions will be made prior to the satisfaction, vacation, or stay of such judgment, order or decree);

8.8 **Misrepresentations.** Borrower or any of its Subsidiaries or any Person acting for Borrower or any of its Subsidiaries makes any representation, warranty, or other statement now or later in this Agreement, any Loan Document or in any writing delivered to Collateral Agent and/or Lenders or to induce Collateral Agent and/or the Lenders to enter this Agreement or any Loan Document, and such representation, warranty, or other statement is incorrect in any material respect when made;

8.9 **Subordinated Debt.** A default or breach occurs under any agreement between Borrower or any of its Subsidiaries and any creditor of Borrower or any of its Subsidiaries that signed a subordination, intercreditor, or other similar agreement with Collateral Agent or the Lenders, or any creditor that has signed such an agreement with Collateral Agent or the Lenders breaches any terms of such agreement;

8.10 **Guaranty.** (a) Any Guaranty terminates or ceases for any reason to be in full force and effect; (b) any Guarantor does not perform any obligation or covenant under any Guaranty; (c) any circumstance described in Sections 8.3, 8.4, 8.5, 8.7, or 8.8 occurs with respect to any Guarantor, or (d) the death, liquidation, winding up, or termination of existence of any Guarantor;

8.11 **Governmental Approvals.** Any Governmental Approval shall have been revoked, rescinded, suspended, modified in an adverse manner, or not renewed in the ordinary course for a full term *and* such revocation, rescission, suspension, modification or non-renewal has resulted in or could reasonably be expected to result in a Material Adverse Change; or

8.12 **Lien Priority**. Any Lien created hereunder or by any other Loan Document shall at any time fail to constitute a valid and perfected Lien on any of the Collateral purported to be secured thereby, subject to no prior or equal Lien, other than Permitted Liens which are permitted to have priority in accordance with the terms of this Agreement.

8.13 **Delisting**. The shares of common stock of Borrower are delisted from NASDAQ Capital Market because of failure to comply with continued listing standards thereof or due to a voluntary delisting which results in such shares not being listed on any other nationally recognized stock exchange in the United States having listing standards at least as restrictive as the NASDAQ Capital Market.

9. RIGHTS AND REMEDIES

9.1 Rights and Remedies.

(a) Upon the occurrence and during the continuance of an Event of Default, Collateral Agent may, and at the written direction of Required Lenders shall, without notice or demand, do any or all of the following: (i) deliver notice of the Event of Default to Borrower, (ii) by notice to Borrower declare all Obligations immediately due and payable (but if an Event of Default described in Section 8.5 occurs all Obligations shall be immediately due and payable without any action by Collateral Agent or the Lenders) or (iii) by notice to Borrower suspend or terminate the obligations, if any, of the Lenders to advance money or extend credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Collateral Agent and/or the Lenders (but if an Event of Default described in Section 8.5 occurs all obligations, if any, of the Lenders to advance money or extend credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Collateral Agent and/or the Lenders shall be immediately terminated without any action by Collateral Agent or the Lenders).

(b) Without limiting the rights of Collateral Agent and the Lenders set forth in Section 9.1(a) above, upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall have the right at the written direction of the Required Lenders, without notice or demand, to do any or all of the following:

(i) foreclose upon and/or sell or otherwise liquidate, the Collateral;

(ii) apply to the Obligations any (a) balances and deposits of Borrower that Collateral Agent or any Lender holds or controls, or (b) any amount held or controlled by Collateral Agent or any Lender owing to or for the credit or the account of Borrower; and/or

(iii) commence and prosecute an Insolvency Proceeding or consent to Borrower commencing any Insolvency Proceeding.

(c) Without limiting the rights of Collateral Agent and the Lenders set forth in Sections 9.1(a) and (b) above, upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall have the right, without notice or demand, to do any or all of the following:

(i) settle or adjust disputes and claims directly with Account Debtors for amounts on terms and in any order that Collateral Agent considers advisable, notify any Person owing Borrower money of Collateral Agent's security interest in such funds, and verify the amount of such account;

(ii) make any payments and do any acts it considers necessary or reasonable to protect the Collateral and/or its security interest in the Collateral. Borrower shall assemble the Collateral if Collateral Agent requests and make it available in a location as Collateral Agent reasonably designates. Collateral Agent may enter premises where the Collateral is located, take and maintain possession of any part of the Collateral, and pay, purchase, contest, or compromise any Lien which appears to be prior or superior to its security interest and pay all expenses incurred. Borrower grants Collateral Agent a license to enter and occupy any of its premises, without charge, to exercise any of Collateral Agent's rights or remedies;

(iii) ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, and/or advertise for sale, the Collateral. Collateral Agent is hereby granted a non-exclusive, royalty-free license or other right to use, without charge, Borrower's and each of its Subsidiaries' labels, patents, copyrights, mask works, rights of use of any name, trade secrets, trade names, trademarks, service marks, and advertising matter, or any similar property as it pertains to the Collateral, in completing production of, advertising for sale, and selling any Collateral and, in connection with Collateral Agent's exercise of its rights under this Section 9.1, Borrower's and each of its Subsidiaries' rights under all licenses and all franchise agreements inure to Collateral Agent, for the benefit of the Lenders;

(iv) place a "hold" on any account maintained with Collateral Agent or the Lenders and/or deliver a notice of exclusive control, any entitlement order, or other directions or instructions pursuant to any Control Agreement or similar agreements providing control of any Collateral;

(v) demand and receive possession of Borrower's Books;

(vi) appoint a receiver to seize, manage and realize any of the Collateral, and such receiver shall have any right and authority as any competent court will grant or authorize in accordance with any applicable law, including any power or authority to manage the business of Borrower or any of its Subsidiaries; and

(vii) subject to clauses 9.1(a) and (b), exercise all rights and remedies available to Collateral Agent and each Lender under the Loan Documents or at law or equity, including all remedies provided under the Code (including disposal of the Collateral pursuant to the terms thereof).

Notwithstanding any provision of this Section 9.1 to the contrary, upon the occurrence of any Event of Default, Collateral Agent shall have the right to exercise any and all remedies referenced in this Section 9.1 without the written consent of Required Lenders following the occurrence of an Exigent Circumstance. As used in the immediately preceding sentence, "**Exigent Circumstance**" means any event or circumstance that, in the reasonable judgment of Collateral Agent, imminently threatens the ability of Collateral Agent to realize upon all or any material portion of the Collateral, such as, without limitation, fraudulent removal, concealment, or abscondment thereof, destruction or material waste thereof, or failure of Borrower or any of its Subsidiaries after reasonable demand to maintain or reinstate adequate casualty insurance coverage, or which, in the judgment of Collateral Agent, could reasonably be expected to result in a material diminution in value of the Collateral.

9.2 Power of Attorney. Borrower hereby irrevocably appoints Collateral Agent as its lawful attorney-in-fact, exercisable upon the occurrence and during the continuance of an Event of Default, to: (a) endorse Borrower's or any of its Subsidiaries' name on any checks or other forms of payment or security; (b) sign Borrower's or any of its Subsidiaries' name on any invoice or bill of lading for any Account or drafts against Account Debtors; (c) settle and adjust disputes and claims about the Accounts directly with Account Debtors, for amounts and on terms Collateral Agent determines reasonable; (d) make, settle, and adjust all claims under Borrower's insurance policies; (e) pay, contest or settle any Lien, charge, encumbrance, security interest, and adverse claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; and (f) transfer the Collateral into the name of Collateral Agent or a third party as the Code or any applicable law permits. Borrower hereby appoints Collateral Agent as its lawful attorney-in-fact to sign Borrower's or any of its Subsidiaries' name on any documents necessary to perfect or continue the perfection of Collateral Agent's security interest in the Collateral regardless of whether an Event of Default has occurred until all Obligations (other than inchoate indemnity obligations) have been satisfied in full and Collateral Agent and the Lenders are under no further obligation to make Credit Extensions hereunder. Collateral Agent's foregoing appointment as Borrower's or any of its Subsidiaries' attorney in fact, and all of Collateral Agent's rights and powers, coupled with an interest, are irrevocable until all Obligations (other than inchoate indemnity obligations) have been fully repaid and performed and Collateral Agent's and the Lenders' obligation to provide Credit Extensions terminates.

9.3 Protective Payments. If Borrower or any of its Subsidiaries fail to obtain the insurance called for by Section 6.5 or fails to pay any premium thereon or fails to pay any other amount which Borrower or any of its Subsidiaries is obligated to pay under this Agreement or any other Loan Document, Collateral Agent may obtain such insurance or make such payment, and all amounts so paid by Collateral Agent are Lenders' Expenses and immediately due and payable, bearing interest at the Default Rate, and secured by the Collateral. Collateral Agent will make reasonable efforts to provide Borrower with notice of Collateral Agent obtaining such insurance or making such payment at the time it is obtained or paid or within a reasonable time thereafter. No such payments by Collateral Agent are deemed an agreement to make similar payments in the future or Collateral Agent's waiver of any Event of Default.

9.4 Application of Payments and Proceeds. Notwithstanding anything to the contrary contained in this Agreement, upon the occurrence and during the continuance of an Event of Default, (a) Borrower irrevocably waives the right to direct the application of any and all payments at any time or times thereafter received by Collateral Agent from or on behalf of Borrower or any of its Subsidiaries of all or any part of the Obligations, and, as between Borrower on the one hand and Collateral Agent and Lenders on the other, Collateral Agent shall have the continuing and exclusive right to apply and to reapply any and all payments received against the Obligations in such manner as Collateral Agent may deem advisable notwithstanding any previous application by Collateral Agent, and (b) the proceeds of any sale of, or other realization upon all or any part of the Collateral shall be applied: first, to the Lenders' Expenses; second, to accrued and unpaid interest on the Obligations (including any interest which, but for the provisions of the United States Bankruptcy Code, would have accrued on such amounts); third, to the principal amount of the Obligations outstanding; and fourth, to any other indebtedness or obligations of Borrower owing to Collateral Agent or any Lender under the Loan Documents. Any balance remaining shall be delivered to Borrower or to whoever may be lawfully entitled to receive such balance or as a court of competent jurisdiction may direct. In carrying out the foregoing, (x) amounts received shall be applied in the numerical order provided until exhausted prior to the application to the next succeeding category, and (y) each of the Persons entitled to receive a payment in any particular category shall receive an amount equal to its pro rata share of amounts available to be applied pursuant thereto for such category. Any reference in this Agreement to an allocation between or sharing by the Lenders of any right, interest or obligation "ratably," "proportionally" or in similar terms shall refer to Pro Rata Share unless expressly provided otherwise. Collateral Agent, or if applicable, each Lender, shall promptly remit to the other Lenders such sums as may be necessary to ensure the ratable repayment of each Lender's portion of any Term

Loan and the ratable distribution of interest, fees and reimbursements paid or made by Borrower. Notwithstanding the foregoing, a Lender receiving a scheduled payment shall not be responsible for determining whether the other Lenders also received their scheduled payment on such date; provided, however, if it is later determined that a Lender received more than its ratable share of scheduled payments made on any date or dates, then such Lender shall remit to Collateral Agent or other Lenders such sums as may be necessary to ensure the ratable payment of such scheduled payments, as instructed by Collateral Agent. If any payment or distribution of any kind or character, whether in cash, properties or securities, shall be received by a Lender in excess of its ratable share, then the portion of such payment or distribution in excess of such Lender's ratable share shall be received by such Lender in trust for and shall be promptly paid over to the other Lender for application to the payments of amounts due on the other Lenders' claims. To the extent any payment for the account of Borrower is required to be returned as a voidable transfer or otherwise, the Lenders shall contribute to one another as is necessary to ensure that such return of payment is on a pro rata basis. If any Lender shall obtain possession of any Collateral, it shall hold such Collateral for itself and as agent and bailee for Collateral Agent and other Lenders for purposes of perfecting Collateral Agent's security interest therein.

9.5 Liability for Collateral. So long as Collateral Agent and the Lenders comply with reasonable banking practices regarding the safekeeping of the Collateral in the possession or under the control of Collateral Agent and the Lenders, Collateral Agent and the Lenders shall not be liable or responsible for: (a) the safekeeping of the Collateral; (b) any loss or damage to the Collateral; (c) any diminution in the value of the Collateral; or (d) any act or default of any carrier, warehouseman, bailee, or other Person. Subject to the immediately preceding sentence, Borrower bears all risk of loss, damage or destruction of the Collateral.

9.6 No Waiver; Remedies Cumulative. Failure by Collateral Agent or any Lender, at any time or times, to require strict performance by Borrower of any provision of this Agreement or any other Loan Document shall not waive, affect, or diminish any right of Collateral Agent or any Lender thereafter to demand strict performance and compliance herewith or therewith. No waiver hereunder shall be effective unless signed by Collateral Agent and the Required Lenders and then is only effective for the specific instance and purpose for which it is given. The rights and remedies of Collateral Agent and the Lenders under this Agreement and the other Loan Documents are cumulative. Collateral Agent and the Lenders have all rights and remedies provided under the Code, any applicable law, by law, or in equity. The exercise by Collateral Agent or any Lender of one right or remedy is not an election, and Collateral Agent's or any Lender's waiver of any Event of Default is not a continuing waiver. Collateral Agent's or any Lender's delay in exercising any remedy is not a waiver, election, or acquiescence.

9.7 Demand Waiver. Borrower waives, to the fullest extent permitted by law, demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by Collateral Agent or any Lender on which Borrower or any Subsidiary is liable.

10. NOTICES

All notices, consents, requests, approvals, demands, or other communication (collectively, "**Communication**") by any party to this Agreement or any other Loan Document must be in writing and shall be deemed to have been validly served, given, or delivered: (a) upon the earlier of actual receipt and three (3) Business Days after deposit in the U.S. mail, first class, registered or certified mail return receipt requested, with proper postage prepaid; (b) upon transmission, when sent by electronic mail (if an email address is specified herein) or facsimile transmission; (c) one (1) Business Day after deposit with a reputable overnight courier with all charges prepaid; or (d) when delivered, if hand-delivered by messenger, all of which shall be addressed to the party to be notified and sent to the address, facsimile number, or email address indicated below. Any of Collateral Agent, Lender or Borrower may change its mailing address or facsimile number by giving the other party written notice thereof in accordance with the terms of this Section 10.

If to Borrower:	EIGER BIOPHARMACEUTICALS, INC. 350 Cambridge Ave. Suite 350 Palo Alto, CA 94306 Attn: Chief Financial Officer Fax: (650) 618-1621 Email: jwelch@eigerbio.com
with a copy (which shall not constitute notice) to:	Cooley LLP 3175 Hanover Street Palo Alto, CA 94304-1130 Attn: Glen Sato Fax: (650) 849 7400 Email: gsato@cooley.com
If to Collateral Agent:	OXFORD FINANCE LLC 133 North Fairfax Street Alexandria, Virginia 22314 Attention: Legal Department Fax: (703) 519-5225 Email: LegalDepartment@oxfordfinance.com
with a copy (which shall not constitute notice) to:	DLA Piper LLP (US) 4365 Executive Drive, Suite 1100 San Diego, California 92121-2133 Attn: Troy Zander Fax: (858) 638-5086 Email: troy.zander@dlapiper.com

11. CHOICE OF LAW, VENUE AND JURY TRIAL WAIVER

New York law governs the Loan Documents without regard to principles of conflicts of law. Borrower, Lenders and Collateral Agent each submit to the exclusive jurisdiction of the State and Federal courts in the City of New York, Borough of Manhattan. NOTWITHSTANDING THE FOREGOING, COLLATERAL AGENT AND THE LENDERS SHALL HAVE THE RIGHT TO BRING ANY ACTION OR PROCEEDING AGAINST BORROWER OR ITS PROPERTY IN THE COURTS OF ANY OTHER JURISDICTION WHICH COLLATERAL AGENT AND THE LENDERS (IN ACCORDANCE WITH THE PROVISIONS OF SECTION 9.1) DEEM NECESSARY OR APPROPRIATE TO REALIZE ON THE COLLATERAL OR TO OTHERWISE ENFORCE COLLATERAL AGENT'S AND THE LENDERS' RIGHTS AGAINST BORROWER OR ITS PROPERTY. Borrower expressly submits and consents in advance to such jurisdiction in any action or suit commenced in any such court, and Borrower hereby waives any objection that it may have based upon lack of personal jurisdiction, improper venue, or forum non conveniens and hereby consents to the granting of such legal or equitable relief as is deemed appropriate by such court. Borrower hereby waives personal service of the summons, complaints, and other process issued in such action or suit and agrees that service of such summons, complaints, and other process may be made by registered or certified mail addressed to Borrower at the address set forth in, or subsequently provided by Borrower in accordance with, Section 10 of this Agreement and that service so made shall be deemed completed upon the earlier to occur of Borrower's actual receipt thereof or three (3) days after deposit in the U.S. mails, first class, registered or certified mail return receipt requested, proper postage prepaid.

TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, BORROWER, COLLATERAL AGENT, AND THE LENDERS EACH WAIVE THEIR RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION ARISING OUT OF OR BASED UPON THIS AGREEMENT, THE LOAN DOCUMENTS OR ANY CONTEMPLATED TRANSACTION, INCLUDING CONTRACT, TORT, BREACH OF DUTY AND ALL OTHER CLAIMS. THIS WAIVER IS A MATERIAL INDUCEMENT FOR EACH PARTY TO ENTER INTO THIS AGREEMENT. EACH PARTY HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.

12. GENERAL PROVISIONS

12.1 Successors and Assigns. This Agreement binds and is for the benefit of the successors and permitted assigns of each party. Borrower may not transfer, pledge or assign this Agreement or any rights or obligations under it without Collateral Agent's and each Lender's prior written consent (which may be granted or withheld in Collateral Agent's and each Lender's discretion, subject to Section 12.6). The Lenders have the right, without the consent of or notice to Borrower, to sell, transfer, assign, pledge, negotiate, or grant participation in **(any** such sale, transfer, assignment, negotiation**,** or grant of a participation, a **"Lender Transfer")** all or any part of, or any interest in, the Lenders' obligations, rights, and benefits under this Agreement and the other Loan Documents; *provided*, *however*, that any such Lender Transfer (other than a transfer, pledge, sale or assignment to an Eligible Assignee) of its obligations, rights, and benefits under this Agreement and the other Loan Documents shall require the prior written consent of the Required Lenders (such approved assignee, an "**Approved Lender**")**.** Borrower and Collateral Agent shall be entitled to continue to deal solely and directly with such Lender in connection with the interests so assigned until Collateral Agent shall have received and accepted an effective assignment agreement in form satisfactory to Collateral Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such Eligible Assignee or Approved Lender as Collateral Agent reasonably shall require. Notwithstanding anything to the contrary contained herein, so long as no Event of Default has occurred and is continuing, no Lender Transfer (other than a Lender Transfer (i) in respect of the Warrants or (ii) in connection with (x) assignments by a Lender due to a forced divestiture at the request of any regulatory agency; or (y) upon the occurrence of a default, event of default or similar occurrence with respect to a Lender's own financing or securitization transactions) shall be permitted, without Borrower's consent, to any Person which is an Affiliate or Subsidiary of Borrower, a direct competitor of Borrower or a vulture hedge fund, each as determined by Collateral Agent in its reasonable good faith business discretion.

12.2 Indemnification. Borrower agrees to indemnify, defend and hold Collateral Agent and the Lenders and their respective directors, officers, employees, agents, attorneys, or any other Person affiliated with or representing Collateral Agent or the Lenders (each, an "**Indemnified Person**") harmless against: (a) all obligations, demands, claims, and liabilities (collectively, "**Claims**") asserted by any other party in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents; and (b) all losses or Lenders' Expenses incurred, or paid by Indemnified Person in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents between Collateral Agent, and/or the Lenders and Borrower (including reasonable attorneys' fees and expenses), except for Claims and/or losses directly caused by such Indemnified Person's gross negligence or willful misconduct. Borrower hereby further indemnifies, defends and holds each Indemnified Person harmless from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements of any kind or nature whatsoever (including the fees and disbursements of counsel for such Indemnified Person) in connection with any investigative, response, remedial, administrative or judicial matter or proceeding, whether or not such Indemnified Person shall be designated a party thereto and including any such proceeding initiated by or on behalf of Borrower, and the reasonable expenses of investigation by engineers, environmental consultants and similar technical personnel and any commission, fee or compensation claimed by any broker (other than any broker retained by Collateral Agent or Lenders) asserting any right to payment for the transactions contemplated hereby which may be imposed on, incurred by or asserted against such Indemnified Person as a result of or in connection with the transactions contemplated hereby and the use or intended use of the proceeds of the loan proceeds except for liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements directly caused by such Indemnified Person's gross negligence or willful misconduct.

12.3 Time of Essence. Time is of the essence for the performance of all Obligations in this Agreement.

12.4 Severability of Provisions. Each provision of this Agreement is severable from every other provision in determining the enforceability of any provision.

12.5 Correction of Loan Documents. Collateral Agent and the Lenders may correct patent errors and fill in any blanks in this Agreement and the other Loan Documents consistent with the agreement of the parties, so long as Collateral Agent provides Borrower with written notice of such correction and allows the Borrower at least ten (10) days to object to such correction. In the event of such objection, such correction shall not be made except by and amendment signed by Lenders, Collateral Agent and Borrower.

12.6 Amendments in Writing; Integration. (a) No amendment, modification, termination or waiver of any provision of this Agreement or any other Loan Document, no approval or consent thereunder, or any consent to any departure by Borrower or any of its Subsidiaries therefrom, shall in any event be effective unless the same shall be in writing and signed by Borrower, Collateral Agent and the Required Lenders provided that:

(i) no such amendment, waiver or other modification that would have the effect of increasing or reducing a Lender's Term Loan Commitment or Commitment Percentage shall be effective as to such Lender without such Lender's written consent;

(ii) no such amendment, waiver or modification that would affect the rights and duties of Collateral Agent shall be effective without Collateral Agent's written consent or signature;

(iii) no such amendment, waiver or other modification shall, unless signed by all the Lenders directly affected thereby, (A) reduce the principal of, rate of interest on or any fees with respect to any Term Loan or forgive any principal, interest (other than default interest) or fees (other than late charges) with respect to any Term Loan (B) postpone the date fixed for, or waive, any payment of principal of any Term Loan or of interest on any Term Loan (other than default interest) or any fees provided for hereunder (other than late charges or for any termination of any commitment); (C) change the definition of the term "**Required Lenders**" or the percentage of Lenders which shall be required for the Lenders to take any action hereunder; (D) release all or substantially all of any material portion of the Collateral, authorize Borrower to sell or otherwise dispose of all or substantially all or any material portion of the Collateral or release any Guarantor of all or any portion of the Obligations or its guaranty obligations with respect thereto, except, in each case with respect to this clause (D), as otherwise may be expressly permitted under this Agreement or the other Loan Documents (including in connection with any disposition permitted hereunder); (E) amend, waive or otherwise modify this Section 12.6 or the definitions of the terms used in this Section 12.6 insofar as the definitions affect the substance of this Section 12.6; (F) consent to the assignment, delegation or other transfer by Borrower of any of its rights and obligations under any Loan Document or release Borrower of its payment obligations under any Loan Document, except, in each case with respect to this clause (F), pursuant to a merger or consolidation permitted pursuant to this Agreement; (G) amend any of the provisions of Section 9.4 or amend any of the definitions of Pro Rata Share, Term Loan Commitment, Commitment Percentage or that provide for the Lenders to receive their Pro Rata Shares of any fees, payments, setoffs or proceeds of Collateral hereunder; (H) subordinate the Liens granted in favor of Collateral Agent securing the Obligations; or (I) amend any of the provisions of Section 12.10. It is hereby understood and agreed that all Lenders shall be deemed directly affected by an amendment, waiver or other modification of the type described in the preceding clauses (C), (D), (E), (F), (G) and (H) of the preceding sentence;

(iv) the provisions of the foregoing clauses (i), (ii) and (iii) are subject to the provisions of any interlender or agency agreement among the Lenders and Collateral Agent pursuant to which any Lender may agree to give its consent in connection with any amendment, waiver or modification of the Loan Documents only in the event of the unanimous agreement of all Lenders.

(b) Other than as expressly provided for in Section 12.6(a)(i)-(iii), Collateral Agent may, if requested by the Required Lenders, from time to time designate covenants in this Agreement less restrictive by notification to a representative of Borrower.

(c) This Agreement and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Agreement and the Loan Documents merge into this Agreement and the Loan Documents.

12.7 Counterparts. This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Agreement.

12.8 Survival. All covenants, representations and warranties made in this Agreement continue in full force and effect until this Agreement has terminated pursuant to its terms and all Obligations (other than inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) have been satisfied. The obligation of Borrower in Section 12.2 to indemnify each Lender and Collateral Agent, as well as the confidentiality provisions in Section 12.9 below, shall survive until the statute of limitations with respect to such claim or cause of action shall have run.

12.9 Confidentiality. In handling any confidential information of Borrower, the Lenders and Collateral Agent shall exercise the same degree of care that it exercises for their own proprietary information, but disclosure of information may be made: (a) subject to the terms and conditions of this Agreement, to the Lenders' and Collateral Agent's Subsidiaries or Affiliates, or in connection with a Lender's own financing or securitization transactions and upon the occurrence of a default, event of default or similar occurrence with respect to such financing or securitization transaction; (b) to prospective transferees (other than those identified in (a) above) or purchasers of any interest in the Credit Extensions (provided, however, the Lenders and Collateral Agent shall, except upon the occurrence and during the continuance of an Event of Default, obtain such prospective transferee's or purchaser's agreement to the terms of this provision or to similar confidentiality terms); (c) as required by law, regulation, subpoena, or other order; (d) to Lenders' or Collateral Agent's regulators or as otherwise required in connection with an examination or audit; (e) as Collateral Agent reasonably considers appropriate in exercising remedies under the Loan Documents; and (f) to third party service providers of the Lenders and/or Collateral Agent so long as such service providers have executed a confidentiality agreement with the Lenders and Collateral Agent with terms no less restrictive than those contained herein. Confidential information does not include information that either: (i) is in the public domain or in the Lenders' and/or Collateral Agent's possession when disclosed to the Lenders and/or Collateral Agent, or becomes part of the public domain after disclosure to the Lenders and/or Collateral Agent; or (ii) is disclosed to the Lenders and/or Collateral Agent by a third party, if the Lenders and/or Collateral Agent does not know that the third party is prohibited from disclosing the information. Collateral Agent and the Lenders may use confidential information for any purpose, including, without limitation, for the development of client databases, reporting purposes, and market analysis, in each case so long as Collateral Agent does not disclose Borrower's identity or the identity of any person associated with Borrower unless otherwise expressly permitted by this Agreement. The provisions of the immediately preceding sentence shall survive the termination of this Agreement. The agreements provided under this Section 12.9 supersede all prior agreements, understanding, representations, warranties, and negotiations between the parties about the subject matter of this Section 12.9.

12.10 Right of Set Off. Borrower hereby grants to Collateral Agent and to each Lender, a lien, security interest and right of set off as security for all Obligations to Collateral Agent and each Lender hereunder, whether now existing or hereafter arising upon and against all deposits, credits, collateral and property, now or hereafter in the possession, custody, safekeeping or control of Collateral Agent or the Lenders or any entity under the control of Collateral Agent or the Lenders (including a Collateral Agent affiliate) or in transit to any of them. At any time after the occurrence and during the continuance of an Event of Default, without demand or notice, Collateral Agent or the Lenders may set off the same or any part thereof and apply the same to any liability or obligation of Borrower even though unmatured and regardless of the adequacy of any other collateral securing the Obligations. ANY AND ALL RIGHTS TO REQUIRE COLLATERAL AGENT TO EXERCISE ITS RIGHTS OR REMEDIES WITH RESPECT TO ANY OTHER COLLATERAL WHICH SECURES THE OBLIGATIONS, PRIOR TO EXERCISING ITS RIGHT OF SETOFF WITH RESPECT TO SUCH DEPOSITS, CREDITS OR OTHER PROPERTY OF BORROWER ARE HEREBY KNOWINGLY, VOLUNTARILY AND IRREVOCABLY WAIVED.

12.11 Cooperation of Borrower. If necessary, Borrower agrees to (i) execute any documents (including new Secured Promissory Notes) reasonably required to effectuate and acknowledge each assignment of a Term Loan Commitment or Loan to an assignee in accordance with Section 12.1 (provided such assignment is in accordance with section 12.1), (ii) make Borrower's management available to meet with Collateral Agent and prospective participants and assignees of Term Loan Commitments or Credit Extensions (which meetings shall be conducted no more often than twice every twelve months unless an Event of Default has occurred and is continuing), and (iii) assist Collateral Agent or the Lenders in the preparation of information relating to the financial affairs of Borrower as any prospective participant or assignee of a Term Loan Commitment or Term

Loan reasonably may request in accordance with section 11.1 and subject to Section 11.9. Subject to the provisions of Sections 12.1 and 12.9, Borrower authorizes each Lender to disclose to any prospective participant or assignee of a Term Loan Commitment, any and all information in such Lender's possession concerning Borrower and its financial affairs which has been delivered to such Lender by or on behalf of Borrower pursuant to this Agreement, or which has been delivered to such Lender by or on behalf of Borrower in connection with such Lender's credit evaluation of Borrower prior to entering into this Agreement.

12.12 Borrower Liability. Either Borrower may, acting singly, request Credit Extensions hereunder. Each Borrower hereby appoints the other as agent for the other for all purposes hereunder, including with respect to requesting Credit Extensions hereunder. Each Borrower hereunder shall be jointly and severally obligated to repay all Credit Extensions made hereunder, regardless of which Borrower actually receives said Credit Extension, as if each Borrower hereunder directly received all Credit Extensions. Each Borrower waives (a) any suretyship defenses available to it under the Code or any other applicable law, and (b) any right to require Collateral Agent or any Lender to: (i) proceed against any Borrower or any other person; (ii) proceed against or exhaust any security; or (iii) pursue any other remedy. Collateral Agent and or any Lender may exercise or not exercise any right or remedy it has against any Borrower or any security it holds (including the right to foreclose by judicial or non-judicial sale) without affecting any Borrower's liability. Notwithstanding any other provision of this Agreement or other related document, each Borrower irrevocably waives all rights that it may have at law or in equity (including, without limitation, any law subrogating Borrower to the rights of Collateral Agent and the Lenders under this Agreement) to seek contribution, indemnification or any other form of reimbursement from any other Borrower, or any other Person now or hereafter primarily or secondarily liable for any of the Obligations, for any payment made by Borrower with respect to the Obligations in connection with this Agreement or otherwise and all rights that it might have to benefit from, or to participate in, any security for the Obligations as a result of any payment made by Borrower with respect to the Obligations in connection with this Agreement or otherwise. Any agreement providing for indemnification, reimbursement or any other arrangement prohibited under this Section shall be null and void. If any payment is made to a Borrower in contravention of this Section, such Borrower shall hold such payment in trust for Collateral Agent and the Lenders and such payment shall be promptly delivered to Collateral Agent for application to the Obligations, whether matured or unmatured.

13. DEFINITIONS

13.1 Definitions. As used in this Agreement, the following terms have the following meanings:

"**Account**" is any "account" as defined in the Code with such additions to such term as may hereafter be made, and includes, without limitation, all accounts receivable and other sums owing to Borrower.

"**Account Debtor**" is any "account debtor" as defined in the Code with such additions to such term as may hereafter be made.

"**Affiliate**" of any Person is a Person that owns or controls directly or indirectly the Person, any Person that controls or is controlled by or is under common control with the Person, and each of that Person's senior executive officers, directors, partners and, for any Person that is a limited liability company, that Person's managers and members.

"**Agreement**" is defined in the preamble hereof.

"**Amortization Date**" is August 1, 2018; provided that, if Borrower draws the Term B Loan, the Amortization Date shall be February 1, 2019.

"**Annual Projections**" is defined in Section 6.2(a).

"**Anti-Terrorism Laws**" are any laws relating to terrorism or money laundering, including Executive Order No. 13224 (effective September 24, 2001), the USA PATRIOT Act, the laws comprising or implementing the Bank Secrecy Act, and the laws administered by OFAC.

"**Approved Fund**" is any (i) investment company, fund, trust, securitization vehicle or conduit that is (or will be) engaged in making, purchasing, holding or otherwise investing in commercial loans and similar extensions of credit in the ordinary course of its business or (ii) any Person (other than a natural person) which temporarily warehouses loans for any Lender or any entity described in the preceding clause (i) and that, with respect to each of the preceding clauses (i) and (ii), is administered or managed by (a) a Lender, (b) an Affiliate of a Lender or (c) a Person (other than a natural person) or an Affiliate of a Person (other than a natural person) that administers or manages a Lender.

"**Approved Lender**" is defined in Section 12.1.

"**Basic Rate**" is the per annum rate of interest (based on a year of three hundred sixty (360) days) equal to the sum of (a) the greater of (i) thirty (30) day U.S. LIBOR rate reported in The Wall Street Journal on the last Business Day of the month that immediately precedes the month in which the interest will accrue, or (ii) fifty-four one hundredths percent (0.54%), plus (b) six and forty-one hundredths percent (6.41%). Notwithstanding the foregoing, (x) the Basic Rate for the Term Loan for the period from the Effective Date through and including December 31, 2016 shall be seven and three thousand, three hundred sixty-seven hundred-thousandths percent (7.03367%); and (y) the Basic Rate shall not reset below seven and three thousand, three hundred sixty-seven hundred-thousandths percent (7.03367%).

"**Blocked Person**" is any Person: (a) listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (b) a Person owned or controlled by, or acting for or on behalf of, any Person that is listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (c) a Person with which any Lender is prohibited from dealing or otherwise engaging in any transaction by any Anti-Terrorism Law, (d) a Person that commits, threatens or conspires to commit or supports "terrorism" as defined in Executive Order No. 13224, or (e) a Person that is named a "specially designated national" or "blocked person" on the most current list published by OFAC or other similar list.

"**Borrower**" is defined in the preamble hereof.

"**Borrower's Books**" are Borrower's or any of its Subsidiaries' books and records including ledgers, federal, and state tax returns, records regarding Borrower's or its Subsidiaries' assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

"**Business Day**" is any day that is not a Saturday, Sunday or a day on which Collateral Agent is closed.

"**Cash Equivalents**" are (a) marketable direct obligations issued or unconditionally guaranteed by the United States or any agency or any State thereof having maturities of not more than one (1) year from the date of acquisition; (b) commercial paper maturing no more than one (1) year after its creation and having the highest rating from either Standard & Poor's Ratings Group or Moody's Investors Service, Inc., and (c) certificates of deposit maturing no more than one (1) year after issue provided that the account in which any such certificate of deposit is maintained is subject to a Control Agreement in favor of Collateral Agent. For the avoidance of doubt, the direct purchase by Borrower or any of its Subsidiaries of any Auction Rate Securities, or purchasing participations in, or entering into any type of swap or other derivative transaction, or otherwise holding or engaging in any ownership interest in any type of Auction Rate Security by Borrower or any of its Subsidiaries shall be conclusively determined by the Lenders as an ineligible Cash Equivalent, and any such transaction shall expressly violate each other provision of this Agreement governing Permitted Investments. Notwithstanding the foregoing, Cash Equivalents does not include and Borrower, and each of its Subsidiaries, are prohibited from purchasing, purchasing participations in, entering into any type of swap or other equivalent derivative transaction, or otherwise holding or engaging in any ownership interest in any type of debt instrument, including, without limitation, any corporate or municipal bonds with a long-term nominal maturity for which the interest rate is reset through a dutch auction and more commonly referred to as an auction rate security (each, an "**Auction Rate Security**").

"**Claims**" are defined in Section 12.2.

"**Code**" is the Uniform Commercial Code, as the same may, from time to time, be enacted and in effect in the State of New York; provided, that, to the extent that the Code is used to define any term herein or in any Loan Document and such term is defined differently in different Articles or Divisions of the Code, the definition

of such term contained in Article or Division 9 shall govern; provided further, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection, or priority of, or remedies with respect to, Collateral Agent's Lien on any Collateral is governed by the Uniform Commercial Code in effect in a jurisdiction other than the State of New York, the term "Code" shall mean the Uniform Commercial Code as enacted and in effect in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority, or remedies and for purposes of definitions relating to such provisions.

"**Collateral**" is any and all properties, rights and assets of Borrower described on Exhibit A.

"**Collateral Account**" is any Deposit Account, Securities Account, or Commodity Account, or any other bank account maintained by Borrower or any Subsidiary at any time.

"**Collateral Agent**" is, Oxford, not in its individual capacity, but solely in its capacity as agent on behalf of and for the benefit of the Lenders.

"**Commitment Percentage**" is set forth in Schedule 1.1, as amended from time to time.

"**Commodity Account**" is any "commodity account" as defined in the Code with such additions to such term as may hereafter be made.

"**Communication**" is defined in Section 10.

"**Compliance Certificate**" is that certain certificate in the form attached hereto as Exhibit C.

"**Contingent Obligation**" is, for any Person, any direct or indirect liability, contingent or not, of that Person for (a) any indebtedness, lease, dividend, letter of credit or other obligation of another such as an obligation directly or indirectly guaranteed, endorsed, co-made, discounted or sold with recourse by that Person, or for which that Person is directly or indirectly liable; (b) any obligations for undrawn letters of credit for the account of that Person; and (c) all obligations from any interest rate, currency or commodity swap agreement, interest rate cap or collar agreement, or other agreement or arrangement designated to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices; but "Contingent Obligation" does not include endorsements in the ordinary course of business. The amount of a Contingent Obligation is the stated or determined amount of the primary obligation for which the Contingent Obligation is made or, if not determinable, the maximum reasonably anticipated liability for it determined by the Person in good faith; but the amount may not exceed the maximum of the obligations under any guarantee or other support arrangement.

"**Control Agreement**" is any control agreement entered into among the depository institution at which Borrower or any of its Subsidiaries maintains a Deposit Account or the securities intermediary or commodity intermediary at which Borrower or any of its Subsidiaries maintains a Securities Account or a Commodity Account, Borrower and such Subsidiary, and Collateral Agent pursuant to which Collateral Agent obtains control (within the meaning of the Code) for the benefit of the Lenders over such Deposit Account, Securities Account, or Commodity Account.

"**Copyrights**" are any and all copyright rights, copyright applications, copyright registrations and like protections in each work or authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret.

"**Credit Extension**" is any Term Loan or any other extension of credit by Collateral Agent or Lenders for Borrower's benefit.

"**Default Rate**" is defined in Section 2.3(b).

"**Deposit Account**" is any "deposit account" as defined in the Code with such additions to such term as may hereafter be made.

"**Designated Deposit Account**" is Borrower's deposit account, account number 203241930, maintained with Citibank, N.A.

"**Disbursement Letter**" is that certain form attached hereto as Exhibit B.

"**Dollars**," "**dollars**" and "$" each mean lawful money of the United States. "**Effective Date**" is defined in the preamble of this Agreement.

"**Eligible Assignee**" is (i) a Lender, (ii) an Affiliate of a Lender, (iii) an Approved Fund and (iv) any commercial bank, savings and loan association or savings bank or any other entity which is an "accredited investor" (as defined in Regulation D under the Securities Act of 1933, as amended) and which extends credit or buys loans as one of its businesses, including insurance companies, mutual funds, lease financing companies and commercial finance companies, in each case, which either (A) has a rating of BBB or higher from Standard & Poor's Rating Group and a rating of Baa2 or higher from Moody's Investors Service, Inc. at the date that it becomes a Lender or (B) has total assets in excess of Five Billion Dollars ($5,000,000,000.00), and in each case of clauses (i) through (iv), which, through its applicable lending office, is capable of lending to Borrower without the imposition of any withholding or similar taxes; provided that notwithstanding the foregoing, "Eligible Assignee" shall not include, unless an Event of Default has occurred and is continuing, (i) Borrower or any of Borrower's Affiliates or Subsidiaries or (ii) a direct competitor of Borrower or a vulture hedge fund, each as determined by Collateral Agent in its reasonable good faith business discretion. Notwithstanding the foregoing, (x) in connection with assignments by a Lender due to a forced divestiture at the request of any regulatory agency, the restrictions set forth herein shall not apply and Eligible Assignee shall mean any Person or party and (y) in connection with a Lender's own financing or securitization transactions, the restrictions set forth herein shall not apply and Eligible Assignee shall mean any Person or party providing such financing or formed to undertake such securitization transaction and any transferee of such Person or party upon the occurrence of a default, event of default or similar occurrence with respect to such financing or securitization transaction; provided that no such sale, transfer, pledge or assignment under this clause (y) shall release such Lender from any of its obligations hereunder or substitute any such Person or party for such Lender as a party hereto until Collateral Agent shall have received and accepted an effective assignment agreement from such Person or party in form satisfactory to Collateral Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such Eligible Assignee as Collateral Agent reasonably shall require.

"**Equipment**" is all "equipment" as defined in the Code with such additions to such term as may hereafter be made, and includes without limitation all machinery, fixtures, goods, vehicles (including motor vehicles and trailers), and any interest in any of the foregoing.

"**ERISA**" is the Employee Retirement Income Security Act of 1974, as amended, and its regulations. "**Event of Default**" is defined in Section 8.

"**Final Payment**" is a payment (in addition to and not a substitution for the regular monthly payments of principal plus accrued interest) due on the earliest to occur of (a) the Maturity Date, or (b) the acceleration of any Term Loan, or (c) the prepayment of a Term Loan pursuant to Section 2.2(c) or (d), equal to the original principal amount of such Term Loan multiplied by the Final Payment Percentage, payable to Lenders in accordance with their respective Pro Rata Shares.

"**Final Payment Percentage**" is seven and one-half percent (7.50%).

"**Foreign Subsidiary**" is a Subsidiary that is not an entity organized under the laws of the United States or any territory thereof.

"**Funding Date**" is any date on which a Credit Extension is made to or on account of Borrower which shall be a Business Day.

"**GAAP**" is generally accepted accounting principles set forth in the opinions and pronouncements of the Accounting Principles Board of the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board or in such other statements by such other Person as may be approved by a significant segment of the accounting profession in the United States, which are applicable to the circumstances as of the date of determination.

"**General Intangibles**" are all "general intangibles" as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation, all copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work, whether published or unpublished, any patents, trademarks, service marks and, to the extent permitted under applicable law, any applications therefor, whether registered or not, any trade secret rights, including any rights to unpatented inventions, payment intangibles, royalties, contract rights, goodwill, franchise agreements, purchase orders, customer lists, route lists, telephone numbers, domain names, claims, income and other tax refunds, security and other deposits, options to purchase or sell real or personal property, rights in all litigation presently or hereafter pending (whether in contract, tort or otherwise), insurance policies (including without limitation key man, property damage, and business interruption insurance), payments of insurance and rights to payment of any kind.

"**Governmental Approval**" is any consent, authorization, approval, order, license, franchise, permit, certificate, accreditation, registration, filing or notice, of, issued by, from or to, or other act by or in respect of, any Governmental Authority.

"**Governmental Authority**" is any nation or government, any state or other political subdivision thereof, any agency, authority, instrumentality, regulatory body, court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative functions of or pertaining to government, any securities exchange and any self-regulatory organization.

"**Guarantor**" is any Person providing a Guaranty in favor of Collateral Agent.

"**Guaranty**" is any guarantee of all or any part of the Obligations, as the same may from time to time be amended, restated, modified or otherwise supplemented.

"**Indebtedness**" is (a) indebtedness for borrowed money or the deferred price of property or services, such as reimbursement and other obligations for surety bonds and letters of credit, (b) obligations evidenced by notes, bonds, debentures or similar instruments, (c) capital lease obligations, and (d) Contingent Obligations.

"**Indemnified Person**" is defined in Section 12.2.

"**Insolvency Proceeding**" is any proceeding by or against any Person under the United States Bankruptcy Code, or any other bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions, extensions generally with its creditors, or proceedings seeking reorganization, arrangement, or other relief.

"**Insolvent**" means not Solvent.

"**Intellectual Property**" means all of Borrower's or any Subsidiary's right, title and interest in and to the following:

(a) its Copyrights, Trademarks and Patents;

(b) any and all trade secrets and trade secret rights, including, without limitation, any rights to unpatented inventions, know-how, operating manuals;

(c) any and all source code;

(d) any and all design rights which may be available to Borrower;

(e) any and all claims for damages by way of past, present and future infringement of any of the foregoing, with the right, but not the obligation, to sue for and collect such damages for said use or infringement of the Intellectual Property rights identified above; and

(f) all amendments, renewals and extensions of any of the Copyrights, Trademarks or

Patents.

"**Inventory**" is all "inventory" as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation all merchandise, raw materials, parts, supplies, packing and shipping materials, work in process and finished products, including without limitation such inventory as is temporarily out of any Person's custody or possession or in transit and including any returned goods and any documents of title representing any of the above.

"**Investment**" is any beneficial ownership interest in any Person (including stock, partnership interest or other securities), and any loan, advance, payment or capital contribution to any Person.

"**Key Person**" is each of Borrower's (i) Chief Executive Officer, who is David Corey as of the Effective Date, (ii) Chief Financial Officer, who is James Welch as of the Effective Date, (iii) Chief Business Officer, who is James Shaffer as of the Effective Date and (iv) Chief Medical Officer, who is Joanne Quan as of the Effective Date.

"**Lender**" is any one of the Lenders.

"**Lenders**" are the Persons identified on Schedule 1.1 hereto and each assignee that becomes a party to this Agreement pursuant to Section 12.1.

"**Lenders' Expenses**" are all audit fees and expenses, costs, and expenses (including reasonable attorneys' fees and expenses, as well as appraisal fees, fees incurred on account of lien searches, inspection fees, and filing fees) for preparing, amending, negotiating, administering, defending and enforcing the Loan Documents (including, without limitation, those incurred in connection with appeals or Insolvency Proceedings) or otherwise incurred by Collateral Agent and/or the Lenders in connection with the Loan Documents.

"**Lien**" is a claim, mortgage, deed of trust, levy, charge, pledge, security interest, or other encumbrance of any kind, whether voluntarily incurred or arising by operation of law or otherwise against any property.

"**Loan Documents**" are, collectively, this Agreement, the Warrants, the Perfection Certificates, each Compliance Certificate, each Disbursement Letter, the Post Closing Letter, any subordination agreements, any note, or notes or guaranties executed by Borrower or any other Person, and any other present or future agreement entered into by Borrower, any Guarantor or any other Person for the benefit of the Lenders and Collateral Agent in connection with this Agreement; all as amended, restated, or otherwise modified.

"**Material Adverse Change**" is (a) a material impairment in the perfection or priority of Collateral Agent's Lien in the Collateral or in the value of such Collateral; (b) a material adverse change in the business, operations or condition (financial or otherwise) of Borrower or any Subsidiary; or (c) a material impairment of the prospect of repayment of any portion of the Obligations.

"**Maturity Date**" is July 1, 2021.

"**Obligations**" are all of Borrower's obligations to pay when due any debts, principal, interest, Lenders' Expenses, the Prepayment Fee, the Final Payment, and other amounts Borrower owes the Lenders now or later, in connection with, related to, following, or arising from, out of or under, this Agreement or, the other Loan Documents (other than the Warrants), or otherwise, and including interest accruing after Insolvency Proceedings begin (whether or not allowed) and debts, liabilities, or obligations of Borrower assigned to the Lenders and/or Collateral Agent, and the performance of Borrower's duties under the Loan Documents (other than the Warrants).

"**OFAC**" is the U.S. Department of Treasury Office of Foreign Assets Control.

"**OFAC Lists**" are, collectively, the Specially Designated Nationals and Blocked Persons List maintained by OFAC pursuant to Executive Order No. 13224, 66 Fed. Reg. 49079 (Sept. 25, 2001) and/or any other list of terrorists or other restricted Persons maintained pursuant to any of the rules and regulations of OFAC or pursuant to any other applicable Executive Orders.

"**Operating Documents**" are, for any Person, such Person's formation documents, as certified by the Secretary of State (or equivalent agency) of such Person's jurisdiction of organization on a date that is no earlier than thirty (30) days prior to the Effective Date, and, (a) if such Person is a corporation, its bylaws in current form, (b) if such Person is a limited liability company, its limited liability company agreement (or similar agreement), and (c) if such Person is a partnership, its partnership agreement (or similar agreement), each of the foregoing with all current amendments or modifications thereto.

"**Patents**" means all patents, patent applications and like protections including without limitation improvements, divisions, continuations, renewals, reissues, extensions and continuations-in-part of the same.

"**Payment Date**" is the first (1st) calendar day of each calendar month, commencing on February 1, 2017. "**Perfection Certificate**" and "**Perfection Certificates**" is defined in Section 5.1.

"**Permitted Acquisition**" means an acquisition by Borrower of all or substantially all of the assets of, all of the ownership interests in, or a business line or unit or division of another Person and shall include any foreign corporations in the acceptable jurisdictions listed below in this definition; provided that (a) no Event of Default or event that with the passage of time would result in an Event of Default shall exist immediately before or immediately after the consummation of such acquisition, (b) such acquired Person or assets shall be in the same line of business as is conducted by Borrower as of the Effective Date (or a line of business reasonably related thereto), (c) such acquisition shall not cause the focus or locations of Borrower's and its Subsidiaries' operations (when taken as a whole) to be located outside of the United States, (d) such acquisition shall not constitute a hostile acquisition, (e) any Person acquired as a result of such acquisition shall, if requested by Collateral Agent become a secured guarantor or co-Borrower, (f) in connection with such acquisition, neither Borrower nor any of its Subsidiaries (including for this purpose, the target of the acquisition) shall acquire or be subject to any Indebtedness or Liens that are not otherwise permitted hereunder, (g) all of the consideration paid in connection with such acquisition shall be in the form of stock of Borrower, except that Borrower shall be permitted to pay reasonable closing costs, not to exceed One Hundred Thousand Dollars ($100,000.00) in the aggregate in cash, (h) Borrower has notified the Lenders at least ten (10) Business Days in advance of entering into such transaction, which notice shall include a reasonably detailed description of such transaction, (i) such transaction shall only involve assets and entities located in the United States, Canada and the United Kingdom, (j) Collateral Agent and the Lenders have received evidence, in form and substance reasonably satisfactory to them that Borrower has sufficient cash on hand to pay its projected expenses and all debt service when due for a period of twelve (12) months after the consummation of such transaction, (k) all transactions related to such acquisition shall be consummated in all material respects in accordance with applicable law; and (l) Borrower shall provide to the Lenders as soon as available but in any event not later than five (5) Business Days after the execution thereof, a copy of the executed purchase agreement or similar agreement with respect to any such acquisition.

"**Permitted Indebtedness**" is:

(a) Borrower's Indebtedness to the Lenders and Collateral Agent under this Agreement and the other Loan Documents;

(b) Indebtedness existing on the Effective Date and disclosed on the Perfection Certificate(s);

(c) Subordinated Debt;

(d) unsecured Indebtedness to trade creditors incurred in the ordinary course of business;

(e) Indebtedness consisting of capitalized lease obligations and purchase money Indebtedness, in each case incurred by Borrower or any of its Subsidiaries to finance the acquisition, repair, improvement or construction of fixed or capital assets of such person, provided that (i) the aggregate outstanding principal amount of all such Indebtedness does not exceed Five Hundred Thousand Dollars ($500,000.00) at any time and (ii) the principal amount of such Indebtedness does not exceed the lower of the cost or fair market value of the property so acquired or built or of such repairs or improvements financed with such Indebtedness (each measured at the time of such acquisition, repair, improvement or construction is made);

(f) Indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of Borrower's business;

(g) extensions, refinancings, modifications, amendments and restatements of any items of Permitted Indebtedness (a) through (e) above, provided that the principal amount thereof is not increased or the terms thereof are not modified to impose materially more burdensome terms upon Borrower, or its Subsidiary, as the case may be; and

(h) Other unsecured Indebtedness not to exceed Two Hundred Fifty Thousand Dollars ($250,000.00) at any time outstanding.

"**Permitted Investments**" are:

(a) Investments disclosed on the Perfection Certificate(s) and existing on the Effective Date;

(b) (i) Investments consisting of cash and Cash Equivalents, and (ii) any other Investments permitted by Borrower's investment policy, as amended from time to time, provided that such investment policy (and any such amendment thereto) has been approved in writing by Collateral Agent (and Collateral Agent acknowledges the investment policy delivered on or prior to the Effective Date is hereby approved);

(c) Investments consisting of the endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of Borrower;

(d) Investments consisting of deposit accounts in which Collateral Agent has a perfected security interest;

(e) Investments in connection with Transfers permitted by Section 7.1;

(f) Investments consisting of (i) travel advances and employee relocation loans and other employee loans and advances in the ordinary course of business, and (ii) loans to employees, officers or directors relating to the purchase of equity securities of Borrower or its Subsidiaries pursuant to employee stock purchase plans or agreements approved by Borrower's Board of Directors; not to exceed Two Hundred Fifty Thousand Dollars ($250,000.00) in the aggregate for (i) and (ii) in any fiscal year;

(g) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of business;

(h) Investments consisting of notes receivable of, or prepaid royalties and other credit extensions, to customers and suppliers who are not Affiliates, in the ordinary course of business; provided that this paragraph (h) shall not apply to Investments of Borrower in any Subsidiary;

(i) non-cash Investments in joint ventures or strategic alliances in the ordinary course of Borrower's business consisting of the non-exclusive licensing of technology, the development of technology or the providing of technical support;

(j) other Investments not otherwise permitted herein provided that the aggregate amount of all such Investments in any year shall not exceed One Hundred Fifty Thousand Dollars ($150,000.00); and

(k) Permitted Acquisitions, including any investments that are held by acquired Persons acquired pursuant to Permitted Acquisitions, to the extent permitted in accordance with the definition of such term "Permitted Acquisition".

"**Permitted Licenses**" are (A) licenses of over-the-counter software that is commercially available to the public, and (B) non-exclusive and exclusive licenses for the use of the Intellectual Property of Borrower or any of its Subsidiaries entered into in the ordinary course of business, provided, that, with respect to each such license described in clause (B), (i) no Event of Default has occurred or is continuing at the time of such license; (ii) the license constitutes an arms-length transaction, the terms of which, on their face, do not provide for a sale or assignment of any Intellectual Property and do not restrict the ability of Borrower or any of its Subsidiaries, as applicable, to pledge, grant a security interest in or lien on, or assign or otherwise Transfer any Intellectual Property; (iii) in the case of any exclusive license, (x) Borrower delivers ten (10) days' prior written notice and a brief summary of the terms of the proposed license to Collateral Agent and the Lenders and delivers to Collateral Agent and the Lenders copies of the final executed licensing documents in connection with the exclusive license promptly upon consummation thereof, and (y) any such license could not result in a legal

transfer of title of the licensed property but may be exclusive in respects other than territory and may be exclusive as to territory only as to discrete geographical areas outside of the United States; and (iv) all upfront payments, royalties, milestone payments or other proceeds arising from the licensing agreement that are payable to Borrower or any of its Subsidiaries are paid to a Deposit Account that is governed by a Control Agreement.

"**Permitted Liens**" are:

(a) Liens existing on the Effective Date and disclosed on the Perfection Certificates or arising under this Agreement and the other Loan Documents;

(b) Liens for taxes, fees, assessments or other government charges or levies, either (i) not due and payable or (ii) being contested in good faith and for which Borrower maintains adequate reserves on its Books, provided that no notice of any such Lien has been filed or recorded under the Internal Revenue Code of 1986, as amended, and the Treasury Regulations adopted thereunder;

(c) liens securing Indebtedness permitted under clause (e) of the definition of "**Permitted Indebtedness**," provided that (i) such liens exist prior to the acquisition of, or attach substantially simultaneous with, or within twenty (20) days after the, acquisition, lease, repair, improvement or construction of, such property financed or leased by such Indebtedness and (ii) such liens do not extend to any property of Borrower other than the property (and proceeds thereof) acquired, leased or built, or the improvements or repairs, financed by such Indebtedness;

(d) Liens of carriers, warehousemen, suppliers, or other Persons that are possessory in nature arising in the ordinary course of business so long as such Liens attach only to Inventory, securing liabilities in the aggregate amount not to exceed Twenty Five Thousand Dollars ($25,000.00), and which are not delinquent or remain payable without penalty or which are being contested in good faith and by appropriate proceedings which proceedings have the effect of preventing the forfeiture or sale of the property subject thereto;

(e) Liens to secure payment of workers' compensation, employment insurance, old-age pensions, social security and other like obligations incurred in the ordinary course of business (other than Liens imposed by ERISA);

(f) Liens incurred in the extension, renewal or refinancing of the indebtedness secured by Liens described in (a) through (c), but any extension, renewal or replacement Lien must be limited to the property encumbered by the existing Lien and the principal amount of the indebtedness may not increase;

(g) leases or subleases of real property granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), and leases, subleases, non-exclusive licenses or sublicenses of personal property (other than Intellectual Property) granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), if the leases, subleases, licenses and sublicenses do not prohibit granting Collateral Agent or any Lender a security interest therein;

(h) banker's liens, rights of setoff and Liens in favor of financial institutions incurred in the ordinary course of business arising in connection with Borrower's deposit accounts or securities accounts held at such institutions solely to secure payment of fees and similar costs and expenses and provided such accounts are maintained in compliance with Section 6.6(b) hereof;

(i) Liens arising from judgments, decrees or attachments in circumstances not constituting an Event of Default under Section 8.4 or 8.7; and

(j) Liens consisting of Permitted Licenses.

"**Person**" is any individual, sole proprietorship, partnership, limited liability company, joint venture, company, trust, unincorporated organization, association, corporation, institution, public benefit corporation, firm, joint stock company, estate, entity or government agency.

"**Post Closing Letter**" is that certain Post Closing Letter dated as of the Effective Date by and between Collateral Agent and Borrower.

"**Prepayment Fee**" is, with respect to any Term Loan subject to prepayment prior to the Maturity Date, whether by mandatory or voluntary prepayment, acceleration or otherwise, an additional fee payable to the Lenders in amount equal to:

(i) for a prepayment made on or after the Funding Date of such Term Loan through and including the first anniversary of the Funding Date of such Term Loan, three percent (3.00%) of the principal amount of such Term Loan prepaid;

(ii) for a prepayment made after the date which is after the first anniversary of the Funding Date of such Term Loan through and including the second anniversary of the Funding Date of such Term Loan, two percent (2.00%) of the principal amount of the Term Loans prepaid; and

(iii) for a prepayment made after the date which is after the second anniversary of the Funding Date of such Term Loan and prior to the Maturity Date, one percent (1.00%) of the principal amount of the Term Loans prepaid.

"**Pro Rata Share**" is, as of any date of determination, with respect to each Lender, a percentage (expressed as a decimal, rounded to the ninth decimal place) determined by dividing the outstanding principal amount of Term Loans held by such Lender by the aggregate outstanding principal amount of all Term Loans.

"**Registered Organization**" is any "registered organization" as defined in the Code with such additions to such term as may hereafter be made.

"**Required Lenders**" means (i) for so long as all of the Persons that are Lenders on the Effective Date (each an "**Original Lender**") have not assigned or transferred any of their interests in their Term Loan, Lenders holding one hundred percent (100%) of the aggregate outstanding principal balance of the Term Loan, or (ii) at any time from and after any Original Lender has assigned or transferred any interest in its Term Loan, Lenders holding at least sixty six percent (66%) of the aggregate outstanding principal balance of the Term Loan and, in respect of this clause (ii), (A) each Original Lender that has not assigned or transferred any portion of its Term Loan, (B) each assignee or transferee of an Original Lender's interest in the Term Loan, but only to the extent that such assignee or transferee is an Affiliate or Approved Fund of such Original Lender, and (C) any Person providing financing to any Person described in clauses (A) and (B) above; provided, however, that this clause (C) shall only apply upon the occurrence of a default, event of default or similar occurrence with respect to such financing.

"**Requirement of Law**" is as to any Person, the organizational or governing documents of such Person, and any law (statutory or common), treaty, rule or regulation or determination of an arbitrator or a court or other Governmental Authority, in each case applicable to or binding upon such Person or any of its property or to which such Person or any of its property is subject.

"**Responsible Officer**" is any of the President, Chief Executive Officer, or Chief Financial Officer of Borrower acting alone.

"**Second Draw Period**" is the period commencing on the date of the occurrence of the Term B Milestones and ending on the earliest of (i) sixty (60) days from the occurrence of the Term B Milestones, (ii) March 31, 2018 and (iii) the occurrence of an Event of Default; provided, however, that the Second Draw Period shall not commence if on the date of the occurrence of the Term B Milestones an Event of Default has occurred and is continuing.

"**Secured Promissory Note**" is defined in Section 2.4.

"**Secured Promissory Note Record**" is a record maintained by each Lender with respect to the outstanding Obligations owed by Borrower to Lender and credits made thereto.

"**Securities Account**" is any "securities account" as defined in the Code with such additions to such term as may hereafter be made.

"**Shares**" is one hundred percent (100%) of the issued and outstanding capital stock, membership units or other securities owned or held of record by Borrower or Borrower's Subsidiary, in any Subsidiary; provided that, in the event Borrower, demonstrates to Collateral Agent's reasonable satisfaction, that a pledge of more than sixty five percent (65%) of the Shares of such Subsidiary which is a Foreign Subsidiary, creates a present and existing adverse tax consequence to Borrower under the U.S. Internal Revenue Code, "Shares" shall mean sixty-five percent (65%) of the issued and outstanding capital stock, membership units or other securities owned or held of record by Borrower or its Subsidiary in such Foreign Subsidiary.

"**Solvent**" is, with respect to any Person: the fair salable value of such Person's consolidated assets (including goodwill minus disposition costs) exceeds the fair value of such Person's liabilities; such Person is not left with unreasonably small capital after the transactions in this Agreement; and such Person is able to pay its debts (including trade debts) as they mature.

"**Success Fee**" is defined in the Success Fee Agreement.

"**Success Fee Agreement**" means that certain Success Fee Agreement, dated as of the Effective Date, by and among Borrower, the Collateral Agent and Lenders.

"**Subordinated Debt**" is indebtedness incurred by Borrower or any of its Subsidiaries subordinated to all Indebtedness of Borrower and/or its Subsidiaries to the Lenders (pursuant to a subordination, intercreditor, or other similar agreement in form and substance satisfactory to Collateral Agent and the Lenders entered into between Collateral Agent, Borrower, and/or any of its Subsidiaries, and the other creditor), on terms acceptable to Collateral Agent and the Lenders.

"**Subsidiary**" is, with respect to any Person, any Person of which more than fifty percent (50%) of the voting stock or other equity interests (in the case of Persons other than corporations) is owned or controlled, directly or indirectly, by such Person or through one or more intermediaries.

"**Term Loan**" is defined in Section 2.2(a)(ii) hereof.

"**Term A Loan**" is defined in Section 2.2(a)(i) hereof.

"**Term B Loan**" is defined in Section 2.2(a)(ii) hereof.

"**Term B Milestones**" means Borrower has achieved (1) positive final data from the lonafarnib Phase 2 LOWR-HDV-2,3,4 trials in hepatitis delta virus ("**HDV**"), achievement of which hereby is acknowledged by Collateral Agent, and (2) positive data from at least one of the following programs (i) pegylated interferon lambda 1a ("**PEG-IFN Lambda**") LIMT-HDV Phase 2 trial in HDV, (ii) Exendin Phase 2 trial in post-bariatric surgery associated hypoglycemia under Eider's own IND, (iii) ubenimex LIBERTY Phase 2 trial in pulmonary arterial hypertension ("**PAH**"), or (iv) ubenimex ULTRA Phase 2 trial in lymphedema; in each case, provided that Borrower has provided to Collateral Agent written evidence of the same, in form and content acceptable to Collateral Agent in its sole discretion.

"**Term Loan Commitment**" is, for any Lender, the obligation of such Lender to make a Term Loan, up to the principal amount shown on Schedule 1.1**.** "**Term Loan Commitments**" means the aggregate amount of such commitments of all Lenders.

"**Trademarks**" means any trademark and servicemark rights, whether registered or not, applications to register and registrations of the same and like protections, and the entire goodwill of the business of Borrower connected with and symbolized by such trademarks.

"**Transfer**" is defined in Section 7.1.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the Effective Date.

BORROWER:

EIGER BIOPHARMACEUTICALS, INC.

By: /s/ James Welch
Name: James Welch
Title: CFO

EB PHARMA, LLC

By: James P. Shaffer
Its:

By:
Name: James Shaffer
Title:

EBPI MERGER, INC.

By: /s/ James Welch
Name: James Welch
Title: CFO

COLLATERAL AGENT AND LENDER:

OXFORD FINANCE LLC

By: /s/ Mark Davis
Name: Mark Davis
Title: Vice President – Finance, Secretary & Treasurer

SCHEDULE 1.1

Lenders and Commitments

Term A Loans

Lender	Term Loan Commitment	Commitment Percentage
OXFORD FINANCE LLC	$15,000,000.00	100.00%
TOTAL	**$15,000,000.00**	**100.00%**

Term B Loans

Lender	Term Loan Commitment	Commitment Percentage
OXFORD FINANCE LLC	$10,000,000.00	100.00%
TOTAL	**$10,000,000.00**	**100.00%**

Aggregate (all Term Loans)

Lender	Term Loan Commitment	Commitment Percentage
OXFORD FINANCE LLC	$25,000,000.00	100.00%
TOTAL	**$25,000,000.00**	**100.00%**

EXHIBIT A

Description of Collateral

The Collateral consists of all of Borrower's right, title and interest in and to the following personal property:

All goods, Accounts (including health-care receivables), Equipment, Inventory, contract rights or rights to payment of money, leases, license agreements, franchise agreements, General Intangibles (except as noted below), commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts and other Collateral Accounts, all certificates of deposit, fixtures, letters of credit rights (whether or not the letter of credit is evidenced by a writing), securities, and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever located; and

All Borrower's Books relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing.

Notwithstanding the foregoing, the Collateral does not include any Intellectual Property; provided, however, the Collateral shall include all Accounts and all proceeds of Intellectual Property. If a judicial authority (including a U.S. Bankruptcy Court) would hold that a security interest in the underlying Intellectual Property is necessary to have a security interest in such Accounts and such property that are proceeds of Intellectual Property, then the Collateral shall automatically, and effective as of the Effective Date, include the Intellectual Property to the extent necessary to permit perfection of Collateral Agent's security interest in such Accounts and such other property of Borrower that are proceeds of the Intellectual Property; or (ii) more than 65% of the total combined voting power of all classes of stock entitled to vote the shares of capital stock (the "**Shares**") of any Foreign Subsidiary, if Borrower demonstrates to Collateral Agent's reasonable satisfaction that a pledge of more than sixty five percent (65%) of the Shares of such Subsidiary creates a present and existing adverse tax consequence to Borrower under the U.S. Internal Revenue Code.

Pursuant to the terms of a certain negative pledge arrangement with Collateral Agent and the Lenders, Borrower has agreed not to encumber any of its Intellectual Property.

EXHIBIT B

Form of Disbursement Letter

[see attached]

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DISBURSEMENT LETTER

December 30, 2016

The undersigned, being the duly elected and acting of EIGER BIOPHARMACEUTICALS, INC., a Delaware corporation with offices located at 350 Cambridge Ave. Suite 350, Palo Alto, CA 94306, for itself and on behalf of all Borrowers under the Loan Agreement (defined below) ("**Borrower**"), does hereby certify to **OXFORD FINANCE LLC** ("**Oxford**" and "**Lender**"), as collateral agent (the "**Collateral Agent**") in connection with that certain Loan and Security Agreement dated as of December 30, 2016, by and among Borrower, Collateral Agent and the Lenders from time to time party thereto (the "**Loan Agreement**"; with other capitalized terms used below having the meanings ascribed thereto in the Loan Agreement) that:

1. The representations and warranties made by Borrower in Section 5 of the Loan Agreement and in the other Loan Documents are true and correct in all material respects as of the date hereof.

2. No event or condition has occurred that would constitute an Event of Default under the Loan Agreement or any other Loan Document.

3. Borrower is in compliance with the covenants and requirements contained in Sections 4, 6 and 7 of the Loan Agreement.

4. All conditions referred to in Section 3 of the Loan Agreement to the making of the Loan to be made on or about the date hereof have been satisfied or waived by Collateral Agent.

5. No Material Adverse Change has occurred.

6. The undersigned is a Responsible Officer.

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7. The proceeds of the Term A Loan shall be disbursed as follows:

Disbursement from Oxford:	
Loan Amount	$15,000,000.00
Plus:	
--Deposit Received	$50,000.00
Less:	
--Facility Fee	($75,000.00)
[--Interim Interest	($_____)]
--Lender's Legal Fees	($_____)*
TOTAL TERM A LOAN NET PROCEEDS FROM OXFORD:	**$_____**

8. The Term A Loan shall amortize in accordance with the Amortization Table attached hereto.

9. The aggregate net proceeds of the Term Loans shall be transferred to the Designated Deposit Account as follows:

Account Name:	EIGER BIOPHARMACEUTICALS, INC.
Bank Name:	[_____]
Bank Address:	[_____]
Account Number:	_____
ABA Number:	[_____]

[Balance of Page Intentionally Left Blank]

* Legal fees and costs are through the Effective Date. Post-closing legal fees and costs, payable after the Effective Date, to be invoiced and paid post-closing.

Dated as of the date first set forth above.

BORROWER:

EIGER BIOPHARMACEUTICALS, INC.,
for itself and on behalf of all Borrowers under the Loan Agreement

By _____
Name: _____
Title: _____

COLLATERAL AGENT AND LENDER:

OXFORD FINANCE LLC

By _____
Name: _____
Title: _____

AMORTIZATION TABLE
(Term A Loan)

[see attached]

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EXHIBIT C

Compliance Certificate

TO: OXFORD FINANCE LLC, as Collateral Agent and Lender

FROM: EIGER BIOPHARMACEUTICALS, INC.,
for itself and on behalf of all Borrowers under the Loan Agreement

The undersigned authorized officer ("**Officer**") of EIGER BIOPHARMACEUTICALS, INC., for itself and on behalf of all Borrowers under the Loan Agreement (as defined below) ("**Borrower**"), hereby certifies that in accordance with the terms and conditions of the Loan and Security Agreement by and among Borrower, Collateral Agent, and the Lenders from time to time party thereto (the "**Loan Agreement**;" capitalized terms used but not otherwise defined herein shall have the meanings given them in the Loan Agreement),

(a) Borrower is in complete compliance for the period ending with all required covenants except as noted below;

(b) There are no Events of Default, except as noted below;

(c) Except as noted below, all representations and warranties of Borrower stated in the Loan Documents are true and correct in all material respects on this date and for the period described in (a), above; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date.

(d) Borrower, and each of Borrower's Subsidiaries, has timely filed, or filed for extensions,all required tax returns and reports, Borrower, and each of Borrower's Subsidiaries, has timely paid all foreign, federal, state, and local taxes, assessments, deposits and contributions owed by Borrower, or Subsidiary, except as otherwise permitted pursuant to the terms of Section 5.8 of the Loan Agreement;

(e) No Liens have been levied or claims made against Borrower or any of its Subsidiaries relating to unpaid employee payroll or benefits of which Borrower has not previously provided written notification to Collateral Agent and the Lenders in accordance with the Loan Agreement.

Attached are the required documents, if any, supporting our certification(s). The Officer, on behalf of Borrower, further certifies that the attached financial statements are prepared in accordance with Generally Accepted Accounting Principles (GAAP) and are consistently applied from one period to the next except as explained in an accompanying letter or footnotes and except, in the case of unaudited financial statements, for the absence of footnotes and subject to year-end audit adjustments as to the interim financial statements.

Please indicate compliance status since the last Compliance Certificate by circling Yes, No, or N/A under "Complies" column.

	Reporting Covenant	Requirement	Actual	Complies		
1)	Financial statements	Monthly within 30 days		Yes	No	N/A
2)	Annual (CPA Audited) statements	Within 120 days after FYE		Yes	No	N/A
3)	Annual Financial Projections/Budget (prepared on a monthly basis)	Annually (within 30 days of FYE), and when revised		Yes	No	N/A
4)	A/R & A/P agings	If applicable		Yes	No	N/A
5)	8-K, 10-K and 10-Q Filings	If applicable, within 5 days of filing		Yes	No	N/A
6)	Compliance Certificate	Monthly within 30 days		Yes	No	N/A
7)	IP Report	When required		Yes	No	N/A
8)	Total amount of Borrower's cash and cash equivalents at the last day of the measurement period		$	Yes	No	N/A
9)	Total amount of Borrower's Subsidiaries' cash and cash equivalents at the last day of the measurement period		$	Yes	No	N/A

Deposit and Securities Accounts
(Please list all accounts; attach separate sheet if additional space needed)

	Institution Name	Account Number	New Account?		Account Control	Agreement in place?
1)			Yes	No	Yes	No
2)			Yes	No	Yes	No
3)			Yes	No	Yes	No
4)			Yes	No	Yes	No

Financial Covenants

None

Other Matters

1)	Have there been any changes in management since the last Compliance Certificate?	Yes	No
2)	Have there been any transfers/sales/disposals/retirement of Collateral or IP prohibited by the Loan Agreement?	Yes	No
3)	Have there been any new or pending claims or causes of action against Borrower that involve more than Two Hundred Fifty Thousand Dollars ($250,000.00)?	Yes	No
4)	Have there been any material changes to the capitalization table of Borrower or any amendments or other changes to the Operating Documents of Borrower or any of its Subsidiaries? If yes, provide copies of any such amendments or changes with this Compliance Certificate.	Yes	No

Exceptions

Please explain any exceptions with respect to the certification above: (If no exceptions exist, state “No exceptions.” Attach separate sheet if additional space needed.)

EIGER BIOPHARMACEUTICALS, INC.,
for itself and on behalf of all Borrowers under the Loan Agreement

By _____
Name: _____
Title: _____

Date: _____

LENDER USE ONLY

Received by: _____ Date: _____

Verified by: _____ Date: _____

Compliance Status: Yes No

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EXHIBIT D

Form of Secured Promissory Note

[see attached]

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SECURED PROMISSORY NOTE
(Term A Loan)

$15,000,000.00 Dated: December 30, 2016

FOR VALUE RECEIVED, the undersigned, EIGER BIOPHARMACEUTICALS, INC., a Delaware corporation ("**Parent**"), EB Pharma, LLC, a Delaware limited liability company ("**EB Pharma**") and EBPI Merger, Inc. ("**EBPI**"), each with offices located at 350 Cambridge Ave. Suite 350, Palo Alto, CA 94306 (Parent, EB Pharma and EBPI, individually and collectively, jointly and severally, "**Borrower**"), HEREBY PROMISES TO PAY to the order of OXFORD FINANCE LLC ("**Lender**") the principal amount of FIFTEEN MILLION DOLLARS ($15,000,000.00) or such lesser amount as shall equal the outstanding principal balance of the Term A Loan made to Borrower by Lender, plus interest on the aggregate unpaid principal amount of such Term A Loan, at the rates and in accordance with the terms of the Loan and Security Agreement dated December 30, 2016 by and among Borrower, Lender, Oxford Finance LLC, as Collateral Agent, and the other Lenders from time to time party thereto (as amended, restated, supplemented or otherwise modified from time to time, the "**Loan Agreement**"). If not sooner paid, the entire principal amount and all accrued and unpaid interest hereunder shall be due and payable on the Maturity Date as set forth in the Loan Agreement. Any capitalized term not otherwise defined herein shall have the meaning attributed to such term in the Loan Agreement.

Principal, interest and all other amounts due with respect to the Term A Loan, are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Secured Promissory Note (this "**Note**"). The principal amount of this Note and the interest rate applicable thereto, and all payments made with respect thereto, shall be recorded by Lender and, prior to any transfer hereof, endorsed on the grid attached hereto which is part of this Note.

The Loan Agreement, among other things, (a) provides for the making of a secured Term A Loan by Lender to Borrower, and (b) contains provisions for acceleration of the maturity hereof upon the happening of certain stated events.

This Note may not be prepaid except as set forth in Section 2.2 (c) and Section 2.2(d) of the Loan Agreement.

This Note and the obligation of Borrower to repay the unpaid principal amount of the Term A Loan, interest on the Term A Loan and all other amounts due Lender under the Loan Agreement is secured under the Loan Agreement.

Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Note are hereby waived.

Borrower shall pay all reasonable fees and expenses, including, without limitation, reasonable attorneys' fees and costs, incurred by Lender in the enforcement or attempt to enforce any of Borrower's obligations hereunder not performed when due.

This Note shall be governed by, and construed and interpreted in accordance with, the internal laws of the State of New York.

The ownership of an interest in this Note shall be registered on a record of ownership maintained by Lender or its agent. Notwithstanding anything else in this Note to the contrary, the right to the principal of, and stated interest on, this Note may be transferred only if the transfer is registered on such record of ownership and the transferee is identified as the owner of an interest in the obligation. Borrower shall be entitled to treat the registered holder of this Note (as recorded on such record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to or interest in this Note on the part of any other person or entity.

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IN WITNESS WHEREOF, Borrower has caused this Note to be duly executed by one of its officers thereunto duly authorized on the date hereof.

BORROWER:

EIGER BIOPHARMACEUTICALS, INC.

By: _____
Name: _____
Title: _____

EB PHARMA, LLC

By: _____
Its: _____

By: _____
Name: _____
Title: _____

EBPI MERGER, INC.

By: _____
Name: _____
Title: _____

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LOAN INTEREST RATE AND PAYMENTS OF PRINCIPAL

Date	Principal Amount	Interest Rate	Scheduled Payment Amount	Notation By

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CORPORATE BORROWING CERTIFICATE
[agreed form to be "duplicated" for each Borrower]

BORROWER: EIGER BIOPHARMACEUTICALS, INC. **DATE:** December 30, 2016
LENDER: OXFORD FINANCE LLC, as Collateral Agent and Lender

I hereby certify as follows, as of the date set forth above:

1. I am the Secretary, Assistant Secretary or other officer of Borrower. My title is as set forth below.

2. Borrower's exact legal name is set forth above. Borrower is a corporation existing under the laws of the State of Delaware.

3. Attached hereto as Exhibit A and Exhibit B, respectively, are true, correct and complete copies of (i) Borrower's Certificate of Incorporation (including amendments), as filed with the Secretary of State of the state in which Borrower is incorporated as set forth in paragraph 2 above; and (ii) Borrower's Bylaws. Neither such Certificate of Incorporation nor such Bylaws have been amended, annulled, rescinded, revoked or supplemented, and such Certificate of Incorporation and such Bylaws remain in full force and effect as of the date hereof.

4. The following resolutions were duly and validly adopted by Borrower's Board of Directors at a duly held meeting of such directors (or pursuant to a unanimous written consent or other authorized corporate action). Such resolutions are in full force and effect as of the date hereof and have not been in any way modified, repealed, rescinded, amended or revoked, and the Lenders may rely on them until each Lender receives written notice of revocation from Borrower.

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RESOLVED, that **any one** of the following officers or employees of Borrower, whose names, titles and signatures are below, may act on behalf of Borrower:

Name	Title	Signature	Authorized to Add or Remove Signatories
			☐
			☐
			☐
			☐

RESOLVED FURTHER, that **any one** of the persons designated above with a checked box beside his or her name may, from time to time, add or remove any individuals to and from the above list of persons authorized to act on behalf of Borrower.

RESOLVED FURTHER, that such individuals may, on behalf of Borrower:

Borrow Money. Borrow money from the Lenders. **Execute Loan Documents**. Execute any loan documents any Lender requires. **Grant Security**. Grant Collateral Agent a security interest in any of Borrower's assets. **Negotiate Items**. Negotiate or discount all drafts, trade acceptances, promissory notes, or other indebtedness in which Borrower has an interest and receive cash or otherwise use the proceeds. **Further Acts**. Designate other individuals to request advances, pay fees and costs and execute other documents or agreements (including documents or agreement that waive Borrower's right to a jury trial) they believe to be necessary to effectuate such resolutions.

RESOLVED FURTHER, that all acts authorized by the above resolutions and any prior acts relating thereto are ratified.

[*Balance of Page Intentionally Left Blank*]

5. The persons listed above are Borrower's officers or employees with their titles and signatures shown next to their names.

By: _____

Name: _____

Title: _____

**** If the Secretary, Assistant Secretary or other certifying officer executing above is designated by the resolutions set forth in paragraph 4 as one of the authorized signing officers, this Certificate must also be signed by a second authorized officer or director of Borrower.*

I, the _____ of Borrower, hereby certify as to paragraphs 1 through 5 above, as
[print title]
of the date set forth above.

By: _____

Name: _____

Title: _____

[*Signature Page to Corporate Borrowing Certificate*]

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EXHIBIT A

Certificate of Incorporation (including amendments)

[see attached]

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EXHIBIT B

Bylaws

[see attached]

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DEBTOR: **EIGER BIOPHARMACEUTICALS, INC. EB PARMA, LLC**
EBPI MERGER, INC.

SECURED PARTY: **OXFORD FINANCE LLC,**
as Collateral Agent

EXHIBIT A TO UCC FINANCING STATEMENT

Description of Collateral

The Collateral consists of all of Debtor's right, title and interest in and to the following personal property:

All goods, Accounts (including health-care receivables), Equipment, Inventory, contract rights or rights to payment of money, leases, license agreements, franchise agreements, General Intangibles (except as noted below), commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts and other Collateral Accounts, all certificates of deposit, fixtures, letters of credit rights (whether or not the letter of credit is evidenced by a writing), securities, and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever located; and

All Debtor's Books relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing.

Notwithstanding the foregoing, the Collateral does not include any Intellectual Property; provided, however, the Collateral shall include all Accounts and all proceeds of Intellectual Property. If a judicial authority (including a U.S. Bankruptcy Court) would hold that a security interest in the underlying Intellectual Property is necessary to have a security interest in such Accounts and such property that are proceeds of Intellectual Property, then the Collateral shall automatically, and effective as of the Effective Date, include the Intellectual Property to the extent necessary to permit perfection of Collateral Agent's security interest in such Accounts and such other property of Borrower that are proceeds of the Intellectual Property; or (ii) more than 65% of the total combined voting power of all classes of stock entitled to vote the shares of capital stock (the "**Shares**") of any Foreign Subsidiary, if Borrower demonstrates to Collateral Agent's reasonable satisfaction that a pledge of more than sixty five percent (65%) of the Shares of such Subsidiary creates a present and existing adverse tax consequence to Borrower under the U.S. Internal Revenue Code.

Pursuant to the terms of a certain negative pledge arrangement with Collateral Agent and the Lenders, Debtor has agreed not to encumber any of its Intellectual Property.

Capitalized terms used but not defined herein have the meanings ascribed in the Uniform Commercial Code in effect in the State of New York as in effect from time to time (the "Code") or, if not defined in the Code, then in the Loan and Security Agreement by and between Debtor, Secured Party and the other Lenders party thereto (as modified, amended and/or restated from time to time).

Exhibit 21.1

Subsidiaries of Registrant

Name of Subsidiary	Jurisdiction of Incorporation
EBPI Merger, Inc.	Delaware

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Eiger BioPharmaceuticals, Inc.:

We consent to the incorporation by reference in registration statements (Nos. 333-203153 and 333-212114) on Form S-3 and registration statements (Nos. 333-203154, 333-193662, and 333-211009) on Form S-8 of Eiger BioPharmaceuticals, Inc. of our report dated March 22, 2017, with respect to the consolidated balance sheets of Eiger BioPharmaceuticals, Inc. as of December 31, 2016 and 2015, and the related consolidated statements of operations, comprehensive loss, stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2016, which report appears in the December 31, 2016 annual report on Form 10-K of Eiger BioPharmaceuticals, Inc.

/s/ KPMG LLP

San Francisco, California
March 22, 2017

Exhibit 31.1

Certification of the Chief Executive Officer
Pursuant to
Securities Exchange Act Rules 13A-14(A) and 15D-14(A)

I, David Cory, certify that:

1. I have reviewed this annual report on Form 10-K of Eiger BioPharmaceuticals, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: March 22, 2017

/s/ David Cory
David Cory
President and Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

Certification of Chief Financial Officer
Pursuant to
Securities Exchange Act Rules 13A-14(A) and 15D-14(A)

I, James Welch, certify that:

1. I have reviewed this annual report on Form 10-K of Eiger BioPharmaceuticals, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: March 22, 2017

/s/ James Welch
James Welch
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

Certification Pursuant to
18 U.S.C. Section 1350,
As Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of Eiger BioPharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2016 (the "Report"), David Cory, President and Chief Executive Officer of the Company, and James Welch, Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: March 22, 2017

/s/ David Cory
David Cory
President and Chief Executive Officer (Principal Executive Officer)

/s/ James Welch
James Welch
Chief Financial Officer (Principal Financial and Accounting Officer)

This certification accompanies the Annual Report on Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Eiger BioPharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.