# 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, 2017 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 (State or other jurisdiction of incorporation or organization)

350 Cambridge Avenue, Suite 350, Palo Alto, CA (Address of principal executive offices) 33-0971591 (I.R.S. Employer Identification No.) 94306 (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	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 Se	ection 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	on 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 fi	iled by Section 13 or 15(d) of the Securities Exchange Act of 1934 duri	

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  $\boxtimes$  No  $\square$ 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 ( $\frac{229.405}{240.405}$  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  $\boxtimes$  No  $\square$ 

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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act (Check one):

Large accelerated filer		Accelerated filer	
Non-accelerated filer	□ (Do not check if a smaller reporting company)	Smaller reporting company	X
Emerging growth company	X		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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, 2017 totaled approximately \$36,711,134 based on the closing price of \$7.90 as reported by the NASDAQ Global Market.

The number of outstanding shares of the registrant's common stock, par value \$0.001 per share, as of March 2, 2018 was 10,526,599.

# Eiger BioPharmaceuticals, Inc. Form 10-K For the Fiscal Year Ended December 31, 2017

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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, pegylated interferon lambda (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; 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 late stage biopharmaceutical company focused on bringing to market novel product candidates for the treatment of rare diseases. Since our founding in 2008, we have worked with investigators at Stanford University, or Stanford, 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 development programs addressing three distinct rare 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 HDV, exendin 9-39 for Post-Bariatric Hypoglycemia, or PBH, and ubenimex for lymphedema. Our lead program in HDV has been discussed with the FDA in respect to a proposal to progress into Phase 3 with a single, pivotal clinical trial planned for initiation in the second half of 2018. We currently plan to deliver data from three ongoing Phase 2 clinical trials with Lambda, exendin 9-39 and ubenimex over the next twelve 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** 

Product Indication	2018	
Lonafarnib Hepatitis Delta Virus	Ph 2	Ph 3
PEG IFN Lambda (Lambda) Hepatitis Delta Virus	Ph 2	
Exendin 9-39 Post-Bariatric Hypoglycemia	Ph 2	
Ubenimex Lymphedema	Ph 2	

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

Our product candidate pipeline includes four Phase 2 programs:

# 1. Lonafarnib (LNF)

Lonafamib, 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 farmesylation, in the virus life cycle. To date, 129 HDV infected patients have been dosed with LNF across five 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 greater or equal to 2 log decline or PCR-negativity in 50% of patients at 24 weeks of treatment. LNF boosted with RTV and combined with pegylated interferon alfa, or PEG-IFN-alfa, has demonstrated greater or equal to 2 log decline or PCR-negativity in 71% of patients at 24 weeks of treatment. In addition, the majority of patients normalize alanine transferase levels at 24 weeks of treatment. The most common gastrointestinal-related adverse events experienced with LNF were mild to moderate 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

Pegylated interferon lambda (Lambda) is our second 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 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 develop Lambda as a monotherapy and in a combination therapy with lonafamib. Currently, we are conducting a Phase 2 monotherapy study using Lambda to treat HDV and are have completed recruitment of 33 patients. Dosing is ongoing at four international sites with final dosing expected in the second half of 2018, and end of study expected in first quarter of 2019. In April 2017, we filed a U.S. IND for Lambda in HDV. In July 2017, the FDA granted Fast Track designation for Lambda a potential treatment for HDV infection, and in September 2017, the FDA granted orphan designation for Lambda in HDV infection.

# 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.

We have demonstrated clinical proof of concept in 36 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. Pharmacokinetics from these Phase 2 SC study indicate that the SC formulation could enable once or twice a day pre-prandial dosing. We developed a proprietary SC liquid formulation and completed a Phase 1 dose-ranging pharmacokinetics trial in healthy humans. We have initiated PREVENT, our Phase 2, 28-day trial in affected patients with our exendin 9-39 proprietary SC formulation in the first quarter of 2018 and expect to have data from this study in the second half of 2018.

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

Our fourth 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.

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.

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. Eiger is developing ubenimex for lymphedema based on its distinct mechanism of action impacting lymphangiogenesis as published in Science Translation Medicine (Tian *et al*, May 2017). We are currently conducting a Phase 2 clinical trial, or the ULTRA Study, treating subjects with both primary lymphedema and secondary lymphedema with ubenimex. We completed enrollment of 54 patients in the ULTRA Study in January 2018 and expect results from this multi-center international Phase 2 clinical trial in the second half of 2018.

Ubenimex was exclusively licensed from Nippon Kayaku, for use in the United States, Europe and certain other countries for inflammatory diseases involving LTB4, including lymphedema. 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.

In January 2018, Phase 2 LIBERTY study results in PAH demonstrated no improvement overall or in key subgroups for both the primary efficacy endpoint of pulmonary vascular resistance (PVR) and the secondary endpoint of 6-minute walk distance (6MWD). No safety signals attributed to ubenimex were identified in the preliminary analysis. Further analysis of data, including biomarkers is ongoing, although we will discontinue development of ubenimex in PAH based on these results. We plan to continue to study ubenimex in lymphedema.

#### **Business Model and Management Team**

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 rare 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.

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, Bristol-Meyers Squibb, Arena Pharmaceuticals, Alza (Johnson and Johnson), Halozyme, Clinical Data Inc., New River Pharmaceuticals, Genentech, Achillion Pharmaceuticals, Schering-Plough, and Globe Immune

#### **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 rare 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

Lonafamib, or LNF, is a small molecule that we in-licensed from Merck in 2010 and that we are advancing for the treatment of HDV infection. LNF is a wellcharacterized, orally active inhibitor of famesyl 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 129 HDV-infected patients in Phase 2 trials, across international study sites, demonstrating rapid decreases in HDV viral loads and no measurable levels of resistance. We have completed five Phase 2 clinical trials including Proof of Concept (NIH), LOWR HDV – 1 (Ankara, Turkey), LOWR HDV – 2 study (Ankara, Turkey), LOWR HDV – 3 (NIH) and LOWR HDV – 4 (Hannover, Germany) in over 129 HDV-infected patients, across international study sites, demonstrating rapid decreases in HDV viral loads and no resistance. In February 2018, we met with the FDA and, subject to agreement on a proposed Phase 3 clinical trial design, have an opportunity for a potentially pivotal single Phase 3 trial as the basis for an NDA filing.

# Lambda in HDV

Lambda is a well-characterized, late-stage, first in class, type III interferon, or 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 are developing Lambda as both a monotherapy and a combination therapy with lonafamib. Currently, we are conducting a Phase 2 monotherapy study using Lambda to treat HDV and have completed recruitment of 33 patients and are currently dosing at four international sites.

As part of the FDA meeting in February 2018, Eiger discussed the potential regulatory pathways for a Lonafarnib / Ritonavir / Lambda combination regimen including possible study designs and clinical endpoints. The current status of discussion with the FDA is as follows:

- Eiger had a very positive meeting with the agency on February 14th.
- Agency has agreed that the next Eiger study can be a single, registration trial in HDV.
- Eiger expects written minutes from the agency (by the end of March 2018) and plans to announce additional details on its clinical development efforts in HDV during the second quarter of this year.

# 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 superinfection (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 has been available in Europe (Robogene®) since 2015. A commercial assay for quantitative HDV RNA was made available in the United States in October 2016. Both of these assays are calibrated using the World Health Organization HDV standard provided by the Paul Erhlich Institute in Germany.

Our initial discussions with payors 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. 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 achieve PCR HDV RNA negativity 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. In addition, rebound of HBV RNA is common. HBV nucleoside analogs that inhibit HBV genome replication are ineffective against HDV since they are ineffective in suppressing the expression HBsAg. Other classic antiviral therapies have been tested, but none have shown to be effective against HDV infection.

#### HDV Replication and Farsenylation

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 farsenylated by a host enzyme which covalently attaches a 15-carbon prenyl lipid (farmesyl-moiety) to the cysteine of the CXXX box. Farsenylation 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 farsenylation, or protein farmesylation, 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 farsenylation 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 demonstrate that farmesyltransferase inhibitors block HDV viral production both in cellular experiments and in HDV transgenic mice. Targeting farsenylation or farmesyl 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 farsenylation which HDV requires to complete packaging. Thus, targeting a host farsenylation process provides what we believe to be a higher barrier to resistance. Identification of clinic-ready farmesylation inhibitors has allowed us to move rapidly into proof-of-concept studies in humans.

# **Our Lead HDV Opportunity: LNF**

LNF is a well-characterized, orally active inhibitor of famesyl transferase. LNF inhibits the farsenylation step of HDV replication inside liver cells and blocks the ability of the virus to multiply. Since farsenylation is a host process, not under control of HDV, and LNF inhibits farsenylation, 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 five Phase 2 clinical trials including Proof of Concept (NIH), LOWR HDV – 1 (Ankara, Turkey), LOWR HDV – 2 study (Ankara, Turkey), LOWR HDV – 3 (NIH) and LOWR HDV – 4 (Hannover, Germany). LNF has never been approved or commercialized for any indication.

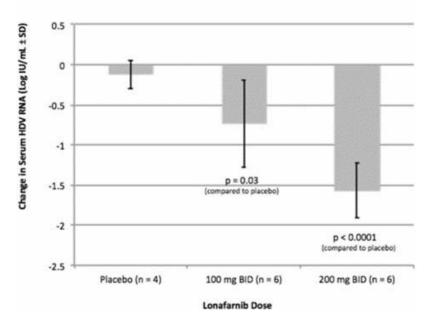
#### LNF Clinical Data

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.

LNF has been tested in five Phase 2 trials (POC, LOWR HDV - 1, LOWR HDV - 2, LOWR HDV - 3, LOWR HDV - 4) in 129 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.



# Change in Serum HDV RNA after Lonafarnib Treatment (Day 28)

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 Adverse Events, or 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 (Lonafamib With Ritonavir in HDV) Phase 2 Program. The objective of this program is to identify dose(s) and regimen(s) for registration. To date, 129 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  $\pm$  PEG IFN- $\alpha$ )
- LOWR HDV 3 Study (QD Dosing: LNF + RTV)
- LOWR HDV 4 Study (Dose-Escalation: LNF + RTV)

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

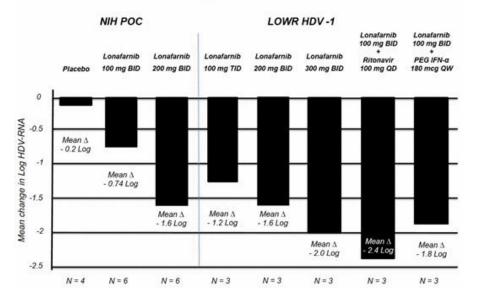
The LOWR HDV—1 trial studied LNF in 21 subjects who were enrolled into one of seven groups for durations of 4-12 weeks (three patients in each group): LNF 200 mg BID (12 weeks), LNF 300 mg BID (12 weeks), LNF 100 mg TID (5 weeks), LNF 100 mg BID + RTV 100 mg QD (8 weeks), LNF 100 mg BID + PEG-IFN-alfa 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.

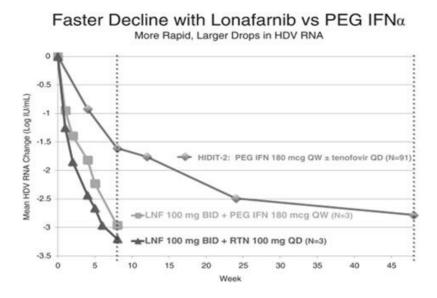
The addition of 100 mg of RTV once daily to 100 mg LNF BID led to a four- to five-fold increase in the serum concentration of LNF in treated patients compared to LNF 100 mg BID alone. This dose combination led to a mean viral load decrease of 2.4 logs after 28 days of treatment, which is a greater than 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 after 28 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, compared to the NIH results on combination led to a greater reduction in viral load, compared to the NIH results on given 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 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.

# Lonafarnib is Active Against HDV Week 4 Reduction in HDV-RNA with Lonafarnib



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.



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 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.

End of study results were presented at EASL 2017 in Amsterdam, Netherlands. Key findings were that in the all-oral LNF 50 mg BID + RTV 100 mg BID regimen, 7 of 14 (50%) patients demonstrated  $\geq$  2 log decline or PCR-negative at Week 24. Combination regimens of LNF 25 mg BID + RTV 100 mg BID + PEG IFN- $\alpha$  180 mcg QW resulted in the highest response rates of 5 of 7 (71%) patients achieving  $\geq$  2 log decline or PCR-negative at Week 24 and the majority of patients normalized ALT at Week 24. In addition, GI AEs predominantly were predominantly mild and moderate. Reported data used a research use only assay at Ankara University.

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

LOWR HDV - 3 was 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 was conducted at the National Institutes of Health (NIH) Bethesda, MD. This study has completed.

End of study results were presented at EASL 2017 in Amsterdam, Netherlands. After 12 weeks of therapy, the median log HDV RNA decline from baseline was 1.60 log IU/mL (LNF 50 mg), 1.33 (LNF 75 mg) and 0.83 (LNF 100 mg) (p=0.001). In subjects treated for 24 weeks, HDV RNA levels significantly differed from placebo (p=0.04). During the study, 6 patients achieved  $\geq 2$  log decline in HDV RNA; HDV RNA levels became undetectable in one subject and < LLOQ in three subjects. ALT normalization was achieved in 47% of patients. Adverse events were mild to moderate and included nausea, vomiting, dyspepsia, anorexia, diarrhea, and weight loss. There were no treatment discontinuations for adverse events.

The LOWR HDV-3 study demonstrated that the all-oral combination of once-daily ritonavir boosted lonafamib was safe and tolerable in patients for up to 6 months of therapy and demonstrated antiviral activity. Reported data used Robogene® HDV RNA Quantification Kit 2.0.

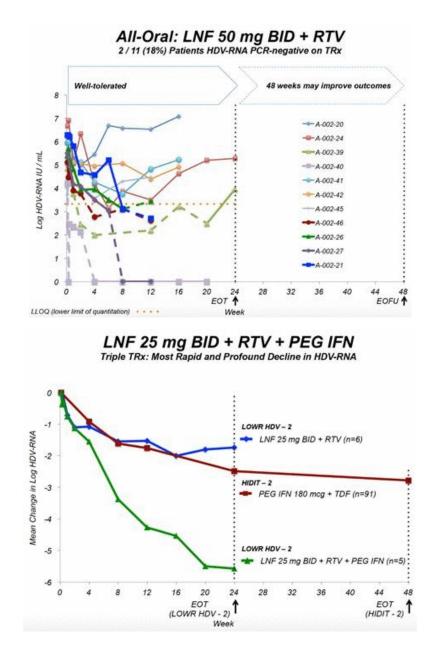
# LOWR HDV-4 (LOnafarnib With Ritonavir in HDV - 4) Phase 2 Study

LOWR HDV - 4 was 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 was conducted at Hannover Medical School in Hannover, Germany.

End of study results were presented at EASL 2017 in Amsterdam, Netherlands. At end of treatment, 5 of 15 (33%) patients reached and maintained LNF 100 mg BID + RTV through EOT; 1 of 5 (20%) patients achieved undetectable HDV-RNA, and 1 of 5 (20%) patients achieved HDV-RNA < LLOQ. ALT normalization was demonstrated in 53% patients.

In follow-up visits, 1 of 15 (7%) patients remained HDV-RNA < LLOQ and 3 of 15 (20%) patients dropped > 2 logs from baseline. Gastrointestinal AEs were mostly grade 1-2; 8 of 15 (53%) patients required dose reduction and 2 of 15 (13%) patients were discontinued. Reported data used Robogene<sup>®</sup> HDV RNA Quantification Kit 2.0.

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 posttreatment HDV-RNA clearance in a subset of patients, suggesting immune reactivation as a potential second mechanism to achieve HDV-RNA PCRnegativity.



#### Our Second HDV Therapeutic Approach: Lambda for HDV

Lambda is a well-characterized, late-stage, first in class, type III interferon, or 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, or SVR24, 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 dosing Lambda in 33 patients in the LIMT HDV, or 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 33 patients with chronic HDV. End of treatment, which is expected in the second half of 2018, 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 is being conducted at four international sites in New Zealand, Israel and Pakistan.

Interim Week 24 data was presented at AASLD 2017 in Washington, D.C. During this interim analysis, 10 of 33 patients had reached Week 24. Of these 10 patients, 5 (50%) achieved > 2 log decline and 4 (40%) achieved PCR-negativity.

Interim data shows that Lambda demonstrates comparable anti-HDV activity to historical PEG-alfa and that Lambda is well tolerated in the majority of patients. There were a few ALT flares that were associated with HDV viral load decline, suggesting a vigorous immune response to therapy rather than hepatotoxicity.

# 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 suppression of the virus to below the level of quantification (<LLOQ), the point where, upon withdrawal of the therapy, the infection does not return to quantifiable levels. 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.

We have demonstrated clinical proof of concept in 36 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. We have developed a novel liquid formulation for SC injection and have completed a Phase 1 PK study with this new formulation of exendin 9-39 in healthy volunteers in mid-2017. We completed a Phase 2 multiple ascending dosing trial (up to 3 days) in affected patients with our exendin 9-39 SC novel liquid formulation in 2017, and have initiated a Phase 2, 28 day study (PREVENT) in affected patients using of the new SC formulation in Q1 2018. We continue to expect data from the PREVENT study in the second half of 2018.

#### 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. Surgicallyaltered 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<sup>TM</sup> (exenatide), Victoza<sup>TM</sup> (liraglutide), and Trulicity<sup>TM</sup> (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 200,000 bariatric surgical procedures are performed each year in the United States, and another 100,000 are performed each year in Europe. Approximately 30% of these bariatric surgeries are Roux-en-Y gastric bypass procedures.

# Our Next Product Candidate: 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<sup>TM</sup> 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, is a new molecular entity and has never been approved nor commercialized for any indication.

#### Clinical Data to Date

We have demonstrated in three 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. We believe that exendin 9-39 may represent the first targeted medical treatment for patients with PBH. In the three completed studies, there were no adverse drug reactions attributed to exendin 9-39. These single-dose and multiple-dose Phase 1/2 studies were conducted under two investigator INDs for the study of exendin 9-39 for PBH.

The first exendin 9-39 study 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.

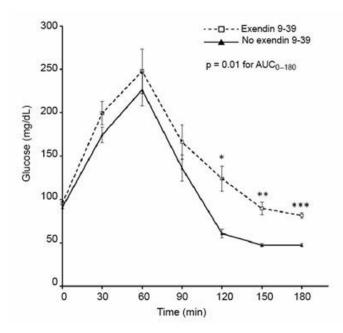
In this trial, IV infusion of exendin 9-39 raised the postprandial glucose nadir by over 70% and lowered the area under the curve insulin by 57%, normalizing both parameters relative to healthy nonsurgical controls, and preventing hypoglycemia in all eight participants. In contrast, during placebo infusion 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, and 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).

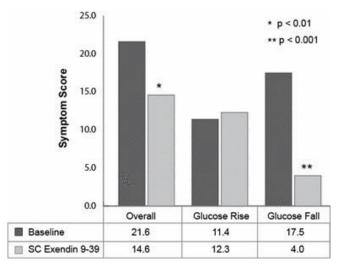
In all eight patients undergoing the OGTT, exendin 9-39 administration prevented hypoglycemia and reduced symptoms of hypoglycemia. The baseline OGTT resulted in a high peak in plasma glucose concentration for all eight patients, followed by a rapid, steep decline, with all patients requiring rescue 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 < 0.0001 for PBH patients with SC exendin 9-39 injection vs no injection. Source: Craig et al, ADA 2016.

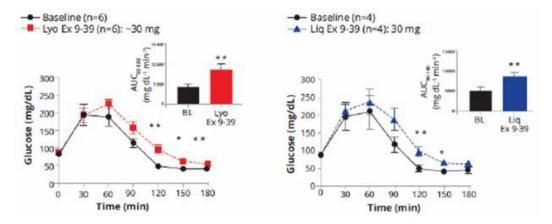
Symptoms of PBH were assessed using the Edinburgh Hypoglycemia Symptom Scale, which was completed by patients every 30 minutes during each 180minute OGTT. Patients used the scale to report the presence and severity of autonomic or neuroglycopenic symptoms or symptoms of malaise. SC exendin 9-39 reduced 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.



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

A third study with exendin 9-39 completed in June 2017. This was 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. A liquid and a lyophilized formulation of SC exendin 9-39 were evaluated in the MAD study.

Key findings from this study demonstrated that\_both SC exendin 9-39 liquid and lyophilized formulations reduced postprandial hyperinsulinemic hypoglycemia, reduced hypoglycemic symptoms and were well tolerated with no related adverse events. In addition, SC exendin 9-39 liquid formulation improved postprandial metabolic and clinical parameters with comparable or greater activity versus the lyophilized formulation. The liquid formulation produced a pharmacokinetic profile which may confer a longer duration of action versus the lyophilized formulation.

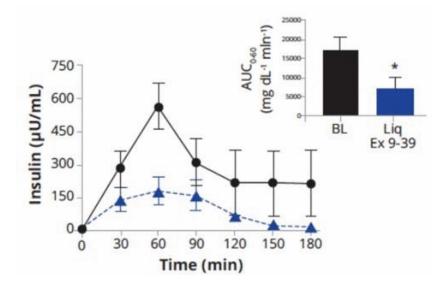


Exendin 9-39 SC Injection MAD Study Glycemic Results

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

Source: Craig et al ADA Poster, June 2017.

#### **Exendin 9-39 SC Injection MAD Study Results**



Source: Craig et al ADA Poster, June 2017.

#### 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.

#### 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 initiated a clinical study to explore if blocking the effects of LTB4 may be useful as a new treatment for lymphedema. 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  $\mu$ g/mL at one hour, 2.5  $\mu$ g/mL at three hours, and 7.4  $\mu$ g/mL at two hours, respectively.

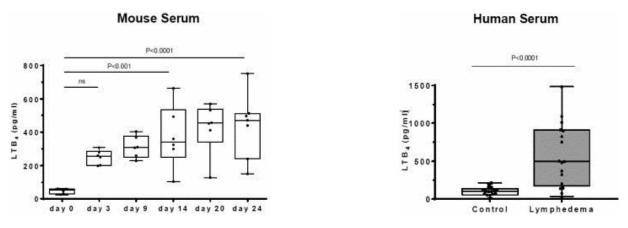
In the metabolism and excretion study, 84% to 94% of the administered doses of ubenimex was recovered in urine within 24 hours of dosing.

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  $\alpha$ -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.

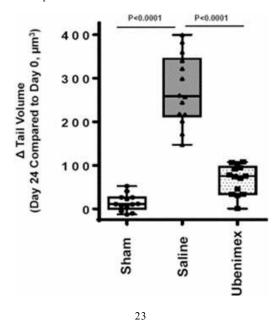
In a Phase 1b study performed in bone marrow transplant lymphoma patients in the United States, PK evaluation was performed in groups of ten patients receiving 10 mg of ubenimex QD, 30 mg of ubenimex QD, 30 mg of ubenimex three times a day, or TID, or 60 mg of ubenimex TID, in each case for up to 60 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.

#### Preclinical LTB4 Data in Lymphedema

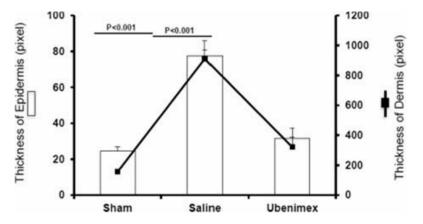
An animal model of lymphedema was used to mimic the physiological changes seen in lymphedema patients. In this model, acquired lymphedema was surgically induced in the tails of mice through the ablation of lymphatic trunks. As the tail volume increases, there is an accumulation of fibroblasts, fat cells 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 filed an. IND for Ubenimex for the treatment of 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), and is designed to assess efficacy as well as safety. As of December 31, 2017, the trial was fully enrolled with a total of 54 patients enrolled across 4 international sites. 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 ULTRA trial is six months, which we believe represents sufficient time to demonstrate activity.

## **Ubenimex for Pulmonary Arterial Hypertension**

In January 2018, topline results for the Phase 2 LIBERTY study results in PAH were announced. Ubenimex demonstrated no improvement overall or in key subgroups for both the primary efficacy endpoint of PVR and the secondary endpoint of 6-minute walk. No safety signals attributed to ubenimex were identified in the preliminary analysis. Further analysis of data, including biomarkers is ongoing, although we will discontinue development of ubenimex in PAH based on these results.

#### 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 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 completed the first FMP drug product manufacturing campaign in 2017 at a new manufacturing facility. 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. In 2017, we completed the process of transferring the drug substance process from Nippon Kayaku to our CMO. Since then, we have successfully manufactured a new formulation for the drug product which is intended to improve dosing compliance and reduce capsule burden.

# **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, or NCE, and Biologic License Application, or 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 or a patent office 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 in which 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. 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 disclosed 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.

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.

#### 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 filed one US application and two PCT applications that claim the use of LNF in combination with RTV and/or optionally other drugs for the treatment of HDV infection.

One PCT application claiming the use of LNF in combination with RTV is pending and one has matured into patent applications in the European Patent Office (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 five years is available in the United States, and we expect LNF to be eligible for this additional protection. In addition, provided it is the first indication in which LNF is approved, we expect LNF to be eligible for NCE status, which if granted provides five years of regulatory exclusivity. In addition, LNF has been granted orphan drug designation by the FDA and the EMA in this indication, which respectively provide seven and ten years of regulatory exclusivity.

We have filed an additional PCT application for LNF/RTV combination drug products useful for treating HDV and this application is pending. Any patents that issue from this application will expire in 2036.

We have not yet determined the countries in which we will pursue potential patent protection from our currently pending PCT applications, 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, or Lambda. The key United States composition of matter patent in this portfolio expires in 2025, but we expect to be eligible for the full five 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. The PCT applications have matured into patent applications in the United States, the European Patent Office (EPO), Australia, Brazil, Canada, and Chile. Any patents that issue from these applications will expire in 2036 without extension and up to five years of patent term extension will be available in the United States. We also expect exendin 9-39 to be eligible for orphan drug designation in this indication, which provides seven years and ten years of regulatory exclusivity in the United States and Europe, respectively.

# Ubenimex.

*Lymphedema*. We have also in-licensed from Stanford applications pending in the U.S and EPO that claim the use of ubenimex and other agents in the treatment of lymphedema. Any patents that issue in the U.S. and EPO will expire in 2036. Any US patent may be eligible for patent term extension of up to five years in the United States.

*Regulatory Exclusivity and Patent Term Extension.* If ubenimex is approved, it would be entitled to NCE exclusivity, which would provide 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 (commonly referred to as a SPC), if granted, may extend certain patent rights for up to five years. In addition, in Europe, marketing approval obtained through the 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 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)

- Hypoglycemia associated with bariatric surgery: Xeris Pharmaceuticals (Phase 2);
- Lymphedema: Novartis (Phase 2).

There are other therapies that are used or may be used for our targeted indications, and these 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 lonafamib. 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 the first half of 2018; 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. No additional milestone payments were incurred during the years ended December 31, 2017 and 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 famesyl 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 with Janssen Pharmaceutica NV, or Janssen, dated December 19, 2014, or the Janssen License Agreement.

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, 2017, 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 the 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 manufacturing 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 development milestone payments in aggregate up to \$1.0 million to each of the Sellers and a low, singledigit 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 as consultants pursuant to consulting agreements, each with a term of one year, subject to annual renewal. The consulting agreement with Dr. Tracey McLaughlin was extended to go through December 31, 2017. The consulting agreement with Dr. Colleen Craig expired in the year ended December 31, 2016. During the year ended December 31, 2017, upon the successful completion of the Phase 2 trials, the development milestone was achieved and we paid the related milestone payment of \$0.1 million to each of the Sellers.

# 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 between Eiccose and the Board of Trustees of Stanford dated October 27, 2015, or the Stanford Lymphedema Agreement.

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, 2017, 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.

#### License Agreement with Bristol-Myers Squibb Company

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

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, 2017, 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 facilities are adequate to assure consistent production of the product within required specifications. 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 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. An orphan drug designation also 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 prevent 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 \$29.5 million, \$33.0 million and \$8.1 million for the years ended December 31, 2017, 2016 and 2015, respectively.

### Employees

As of December 31, 2017, we had a total of 16 full-time employees in the United States, eight of whom were primarily engaged in manufacturing, and research and development activities and eight of whom were engaged in general management and administration. Five 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, Celladon reincorporated in Delaware and had its 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 \$1.1 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, 2017, 2016 and 2015, we reported a net loss of \$42.4 million, \$47.1 million and \$13.3 million, respectively. As of December 31, 2017, we had an accumulated deficit of \$118.8 million. Our prior losses, combined with expected future losses, have had and may continue to have an adverse effect on our stockholders' equity (deficit) 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, manufacturing efforts, 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 manufacturing of clinical supplies, 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 and debt facilities. 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 four Phase 2 clinical development programs for potentially three indications. In addition, our recent meeting with the FDA in February 2018 may allow us to initiate a single potentially pivotal Phase 3 study as the basis for the filing of an NDA, in which case we would need significant additional resources in order to fund the conduct of that potentially pivotal study. 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 advance these compounds to potential 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 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 lonafarnib for HDV, lambda for HDV, exendin 9-39 for PBH and ubenimex for lymphedema;
- 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 such as the loan and security agreement we entered into with Oxford Finance LLC, or Oxford Finance, in December 2016, or the Oxford Loan. This was a \$25.0 million debt financing arrangement with Oxford Finance wherein we borrowed the first tranche of \$15.0 million upon closing in December 2016. Our ability to access the final \$10.0 million under the Oxford Loan 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. The Oxford 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 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 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.

# 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.

The Oxford Loan provides for up to \$25.0 million in term loans due on July 1, 2021, of which \$15.0 million in term loans have 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 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 four Phase 2 development programs focused on three separate indications. For one of our product candidates, 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 and most of the data has been developed for a dose lower than in our current studies. In January 2018, we announced that Phase 2 LIBERTY study results in pulmonary arterial hypertension (PAH) demonstrated no improvement overall or in key subgroups for both the primary efficacy endpoint of pulmonary vascular resistance (PVR) and the secondary endpoint of 6-minute walk distance. The company has discontinued development of ubenimex in PAH based on these results.

We provide our geographically diverse clinical sites with good clinical practice protocols. We review and monitor the execution of our protocols at our various sites in an effort to understand those protocols are being followed. There can be no assurance that the data we develop for our product candidates in our planned indications will be sufficient or complete enough 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. Although our February 2018 discussions with the FDA with respect to the entry of lonafamib into a single potentially pivotal clinical trial have been positive, there can be no assurance that we would be able to design a single clinical trial that would enable an NDA filing if successful and in any event the timing of our discussions with the FDA are uncertain and may not meet our timelines for the planned initiation of a Phase 3 study of lonafamib by the end of 2018.

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. 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. Although we already obtained orphan drug designation for four of our product candidates in three targeted indications, failure to demonstrate significant benefit over existing approved drugs in pivotal clinical trials may lead to marketing approval but without qualifying for orphan drug protection in some regions, such as in Europe.

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, we identified significant good clinical practice, or GCP, violations in the LOWR HDV 1 and LOWR HDV 2 studies. We alerted the FDA to the discovery of GCP violations. These findings may bring into question the validity of the data set and may require repeat clinical studies to confirm the observations in question. Further studies may be needed to confirm the rigor, robustness and validity of any problematic safety and efficacy data identified;
- 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 four 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.

### 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 for the LOWR HDV 1 and LOWR HDV 2 studies, where we have in the past identified significant GCP violations that may impact the data set and information that we plan to submit to the FDA and may require repeat studies to confirm the rigor, robustness and validity of safety and efficacy signals seen in these studies;
- failure to perform the clinical studies in accordance with the FDA's GCP 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. 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, or unforeseen side effects due to incomplete or inadequate safety data collection from LOWR HDV - 1 and LOWR HDV - 2 clinical studies, 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.

For example, our lonafamib 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. There is no guarantee that additional or more severe side effects will not be identified through ongoing clinical studies by other uses of lonafamib for other indications or our own clinical trials. Additionally, while we have a license to another famesyltransferase inhibitor compound, tipifamib, from Janssen Pharmaceutica, N.V., or Janssen, Janssen has granted rights to tipifamib 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 lonafamib 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, we identified significant GCP violations in the LOWR HDV – 1 and LOWR HDV – 2 studies. We alerted the FDA to the discovery or GCP violations. These findings may call into question the validity of the data set and may require repeat clinical studies to confirm the observations in question 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 the requirements or the target of the data set and may require to comply with these laws, regulatory authority will determine that efforts, including any of our clinical studies, comply with applicable applicable and may require us to repeat clinical studies or conduct the requirements. Our failure to comply with these laws, regulatory aut

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 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 lonafamib program, we procured an inventory of product from Merck to supply our initial clinical study needs. In 2016, we 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. During 2017 we transferred the manufacturing technology to our third-party

vendors. With respect to our ubenimex programs, we have relied on Nippon Kayaku to provide us with product to conduct our trials in 2016 and 2017 and have now completed the process of transferring the manufacturing of ubenimex to our third-party vendors in the United States and such drug product will be adequate to complete ongoing and future clinical studies.

## 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 manufactures 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; and
- 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 conducted appropriately and test data is not reliable, patients could be put at risk of serious harm and could result in product liability suits.

The manufacturing 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, or otherwise fail to comply with their contractual obligations, our ability to provide our product candidates to include 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 rare 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 lonafamib 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 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 Sciences, Merck, Roche, Holding AG, Actelion Pharmaceuticals US, Inc., Johnson & Johnson, Replicor, Inc., Hepatera, Arrowhead Pharmaceuticals, Novartis International AG, and Xeris Pharmaceuticals 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, thirdparty 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.

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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

lonafamib 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 lonafamib 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 lonafamib expires before the anticipated launch date. Likewise, most of the patents or applications 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, lonafamib, 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 are deemed inadequate, we 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 using or exploiting 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. Even if we conduct freedom to operate analyses, we would expect to do so only with respect to certain of our product candidates as they move

through development. Accordingly, there may be third-party patents that would impair our ability to commercialize product candidates and we cannot assure you that we could obtain a license, or even if available, whether such license might be obtained on commercially reasonable terms. Even in those situations where we conduct a freedom to operate analysis, there can be no assurance that we would identify all relevant or necessary patents and patent applications that may apply to the manufacture and 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, and if patents issue with respect to any such application and we become aware of such issuance, we would have to determine its impact on our efforts to develop and commercialize our product candidates and the strategy for obtaining a license or contesting any such issued patent.

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.

If we fail to obtain a license, then 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 lonafamib 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 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 in the United States and/or in other countries 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**

### 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, 2017, we had 16 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. Some of the provisions of the Affordable Care Act have yet to be fully implemented, and since its enactment, there have been judicial and Congressional challenges to numerous provisions of the ACA, as well as recent efforts by the

Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of any certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. The Trump administration has also announced that it will discontinue the payment of cost-sharing reduction, or CSR, payments to insurance companies until Congress approves the appropriation of funds for the CSR payments. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. A bipartisan bill to appropriate funds for CSR payments has been introduced in the Senate, but the future of that bill is uncertain. Further, each chamber of Congress has put forth multiple bills designed to repeal or repeal and replace portions of the ACA. Although none of these measures has been enacted by Congress to date, Congress may consider other legislation to repeal and replace elements of the ACA. Any repeal and replace legislation or repeal of all or parts of the ACA or the implementation of new health care legislation could result in significant changes to the health care system, which may prevent us from being able to generate revenue, attain profitability or commercialize our drugs. 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.

In the United States, the European Union and other potentially significant markets for our product candidates, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. For example, in the United States, there have been several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. Furthermore, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general.

### 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 begin 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 noncompliance 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 claims 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 have conducted in the past and are currently conducting clinical trials in the United States; Canada; Sydney, Australia; Ankara, Turkey; Hannover, Germany; Karachi, Pakistan; Auckland, New Zealand and Jerusalem and 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, both Turkey and Pakistan are key regions for clinical activity relating to Hepatitis Delta, and further outbracks of violence and political instability in the region could disrupt our clinical operations or otherwise limit our ability to access or conduct clinical studies in those regions. 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. On May 5, 2017, the lead plaintiff filed his opening brief. On July 5, 2017, the defendants filed their appellate brief response. On August 18, 2017, the lead plaintiff filed his reply appellate brief.

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. 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 our 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 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.

#### The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new tax legislation, or the Tax Act, which significantly changes the Internal Revenue Code of 1986, as amended. The Tax Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%; limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses); for net operating losses generated after 2017, limitation of the deduction to 80% of current year taxable income, indefinite carryforward of net operating losses and elimination of net operating loss carrybacks; changes in the treatment of offshore earnings regardless of whether they are repatriated; mandatory capitalization of research and development expenses beginning in 2022; immediate deductions for certain new investments instead of



deductions for depreciation expense over time; further deduction limits on executive compensation; and modifying, repealing and creating many other business deductions and credits, including the reduction in the orphan drug credit from 50% to 25% of qualifying expenditures. We continue to examine the impact this tax reform legislation may have on our business. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. This annual report does not discuss any such tax legislation or the manner in which it might affect us or our stockholders in the future. We urge our stockholders to consult with their legal and tax advisors with respect to such legislation.

### Because the 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 Merger resulted in an ownership change and, accordingly, Celladon's and Eiger's 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, that 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 3,877 square feet of office space. The lease for this office space expires in March 2018, has one two-year renewal option prior to expiration and includes rent escalation clauses through the lease term.

In March 2017, we entered into a non-cancelable facility lease agreement for an office facility at 366 Cambridge Avenue in Palo Alto, California 94306. The lease commenced on April 1, 2017 and expires 12 months after the commencement date. The lease has one twelve-month renewal option prior to expiration and includes rent escalation clauses through the lease term.

In October 2017, we entered into a non-cancelable facility lease agreement for 8,029 square feet of office space located at 2171 Park Blvd in Palo Alto, California 94306. The lease commences on March 1, 2018 and expires five years after the commencement date. The lease has one three-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. On May 5, 2017, the lead plaintiff filed his opening brief. On July 5, 2017, the defendants filed their appellate brief response. The Plaintiff subsequently filed their response to the Company's July 5, 2017 filing on August 19, 2017. Upon these filings, the next step in the process would be to wait for oral arguments to be scheduled by the 9<sup>th</sup> Circuit Court of Appeals.

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. 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 15-for-1 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			
	H	ligh		Low
Year Ended December 31, 2017				
First Quarter	\$	12.65	\$	10.15
Second Quarter	\$	11.60	\$	6.10
Third Quarter	\$	12.05	\$	7.13
Fourth Quarter	\$	14.50	\$	10.26
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

### **Holders of Record**

As of March 2, 2018, there were approximately 28 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 rare 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 three distinct rare 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 lonafamib for Hepatitis Delta Virus, or HDV, lambda for HDV, exendin 9-39 for PBH and ubenimex for lymphedema. We plan to deliver data from three ongoing Phase 2 clinical trials over the course of the next twelve months.

In January 2018, Phase 2 LIBERTY study results in PAH demonstrated no improvement overall or in key subgroups for both the primary efficacy endpoints of PVR and 6-minute walk distance. Further analysis of data, including biomarkers is ongoing, although we plan to discontinue development of ubenimex in PAH based on the LIBERTY study results

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, and we do not anticipate that we will achieve profitability in the near term. Our net losses were \$42.4 million, \$47.1 million and \$13.3 million for the years ended December 31, 2017, 2016 and 2015, respectively. As of December 31, 2017, we had an accumulated deficit of \$118.8 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 merger with Celladon in March 2016, and we have and 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 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, contract research organizations 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 trial 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 manufacturing capabilities and 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, 2017, 2016 and 2015 (in thousands):

	Year Ended December 31,						
	2017		2016		2015		
Product candidates:							
Lonafamib HDV	\$ 4,284	\$	5,237	\$	2,052		
Lambda HDV	3,892		7,244		_		
Exendin 9-39 PBH	3,173		2,984		115		
Ubenimex PAH (terminated in January 2018)	9,789		10,393		648		
Ubenimex Lymphedema	2,132		2,271		198		
Internal research and development costs	6,249		4,885		5,104		
Total research and development expense	\$ 29,519	\$	33,014	\$	8,117		

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 clinical trial material 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, insurance costs and costs associated with being a public company. 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. As a result of becoming a public company following completion of the Merger, expenses include costs related to compliance with the rules and regulations of the SEC and NASDAQ, additional insurance, investor relations, bank fees and other administrative expenses and professional services.

# Interest Expense

Interest expense for the year ended December 31, 2017, consists of interest and amortization of the debt discount related to our borrowing under the Oxford Loan executed in December 2016. Interest expense for the year ended December 31, 2016, consists of interest and amortization of the debt discount related to the outstanding convertible promissory notes issued in November 2015, which were converted into common stock in March 2016, or the Notes.

#### **Interest Income**

Interest income consists of interest earned on our investments in marketable securities and cash equivalents.

#### Other Income (Expense), Net

Other income (expense), net in 2017 primarily consists of the \$0.2 million payment received for MYDICAR sale.

Other income (expense), net in 2016 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 96,300 fully vested shares of our common stock to Eiccose 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 income (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 (deficit).

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 (deficit), 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. 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 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 and prior to adoption of ASU 2016-09 in the first quarter of 2017, we estimated our forfeiture rate based on actual forfeiture experience, analysis of employee turnover behavior, and other factors. The impact from any forfeiture rate adjustment was recognized in full in the period of adjustment and if the actual number of future forfeitures differed from our estimates, we were required to record adjustments to stock-based compensation in future periods. Following the adoption of ASU 2016-09 we made an accounting policy election to account for forfeitures as they occur. This change did not have a material impact to the consolidated financial statements.

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, 2017 and 2016

The following table summarizes results of operations for the years ended December 31, 2017 and 2016 (in thousands):

	 Years Er Decembe		 Increase / (Decrease)	% Change
	2017 2016			
Operating expenses:				
Research and development	\$ 29,519	33,014	\$ (3,495)	(11)%
General and administrative	12,001	13,106	\$ (1,105)	(8)%
Total operating expenses	 41,520	46,120	(4,600)	
Loss from operations	 (41,520)	(46,120)	 4,600	
Interest expense	(1,524)	(690)	(834)	121%
Interest income	410	97	313	323%
Other income (expense), net	186	(374)	560	(150)%
Net loss	\$ (42,448)	\$ (47,087)	\$ 4,639	

## Research and development expenses

Research and development expenses decreased by \$3.5 million to \$29.5 million for the year ended December 31, 2017, from \$33.0 million for the same period in 2016. The decrease was primarily due to a \$5.2 million upfront payment under our License Agreement with Bristol Myers Squibb Company in 2016. There were no similar payments in 2017. The decrease was partially offset by a \$0.7 million increase in compensation and personnel related expenses due to an increase in headcount, a \$0.5 million increase in stock-based compensation expense due to an increase in headcount, \$0.3 million increase in facility and insurance expenses and \$0.2 million in milestone payments to two Stanford University inventors for the asset purchase agreement.

#### General and administrative expenses

General and administrative expenses decreased by \$1.1 million to \$12.0 million for the year ended December 31, 2017, from \$13.1 million for the same period in 2016. The decrease was due to a \$2.5 million decrease in legal, consulting, advisory and accounting services due to the incremental expenses incurred as a result of the Merger in the first quarter 2016. The decrease was partially offset by a \$0.6 million increase in stock-based compensation expense, a \$0.5 million increase in compensation and personnel related expenses due to an increase in headcount and a \$0.3 million increase in facility and insurance expenses.

#### Interest expense

Interest expense increased by \$0.8 million to \$1.5 million for the year ended December 31, 2017, from \$0.7 million for the same period in 2016. Interest expense in 2017 consisted of interest and amortization of the debt discount related to the Oxford Loan borrowings in December 2016. Interest expense in 2016 consisted of interest and amortization of the debt discount related to the Notes outstanding prior to their conversion into common stock in March 2016.

#### Interest income

Interest income increased by \$0.3 million to \$0.4 million for the year ended December 31, 2017, from \$0.1 million for the year ended December 31, 2016. The increase was primarily due to the interest earned on our investments in marketable securities and cash equivalents being for the entire year of 2017, compared to 2016 only being for one quarter as the funds were not invested until the fourth quarter of 2016.



# Other income (expense), net

Other income (expense), net changed by \$0.6 million to \$0.2 million of other income for the year ended December 31, 2017, from \$0.4 million of other expense for same period in 2016. Other income in 2017 consisted of the \$0.2 million payment received from Theragene for MYDICAR sale. Other expense in 2016 primarily consisted of the change in fair value of the obligation to issue common stock to Eiccose and the change in fair value of warrant liability, that were settled upon the Merger.

# 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%
Interest income	97		_	\$	97	100%
Other expense, net	(374)		—	\$	(374)	100%
Net loss	\$ (47,087)	\$	(13,322)	\$	(33,765)	

#### Research and development

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

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

Interest expense increased by \$0.3 million to \$0.7 million for the year ended December 31, 2016, from \$0.4 million for 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 expense, 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.

#### Sources of Liquidity

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 February and March 2017, pursuant to ATM, we completed our underwritten public offering of 4,537 shares of common stock for gross cash proceeds of \$53,000 under the shelf registration statement on Form S-3 (File No. 333-212114).

On October 31, 2017, we issued 2,132,961 shares of common stock pursuant to an underwriting agreement with BTIG, LLC at a public offering price of \$10.00 per share, for gross proceeds of \$21.3 million, which resulted in approximately \$19.8 million of net proceeds to the Company after deducting underwriting fees and offering expenses.

In December 2017, we filed a second shelf registration statement on Form S-3 (File No. 333-221972) 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.

In December 2017, pursuant to ATM, we completed our underwritten public offering of 6,027 shares of common stock for gross cash proceeds of \$73,000 under the shelf registration statement on Form S-3 (File No. 333-212114).

As of December 31, 2017, we had \$32.0 million of cash and cash equivalents, \$9.7 million of short-term marketable securities and an accumulated deficit of \$118.8 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.

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, which was achieved in the fourth quarter of 2016, plus 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.

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,						
		2017		2016		2015	
Net cash provided by (used in):							
Operating activities	\$	(38,372)	\$	(37,970)	\$	(9,134)	
Investing activities		22,657		(4,194)		(45)	
Financing activities		19,994		65,142		13,180	
Net increase in cash and cash equivalents	\$	4,279	\$	22,978	\$	4,001	

# Cash flows from operating activities

Cash used in operating activities for the year ended December 31, 2017 was \$38.4 million and primarily consisted of a net loss of \$42.4 million and gain on intellectual property sale of \$0.2 million from MYDICAR sale, which was partially offset by \$4.2 million of stock-based compensation expense and \$0.3 million of non-cash interest related to amortization of debt discount. Additionally, cash used in operating activities reflected changes in net operating assets due to an increase of \$0.2 million in other non-current assets primarily associated with the deposit paid for the new facility lease entered into in October 2017 and an increase of \$0.1 million in prepaid expenses and other current assets primarily associated with the timing of payments.

Cash used in operating activities for the year ended December 31, 2016 was \$38.0 million, and 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 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 and 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 flows from investing activities

Net cash provided by investing activities for the year ended December 31, 2017 was \$22.7 million. The net cash increase was primarily due to \$47.0 million of proceeds from maturities of marketable securities and a \$0.2 million payment received from Theragene for the sale of MYDICAR related assets, partially offset by \$24.5 million purchase of marketable securities.

Net cash used in investing activities for the year ended December 31, 2016 was \$4.2 million. The net cash increase was primarily due to \$34.2 million for the purchase of marketable securities, partially offset by \$28.0 million of proceeds received upon the consummation of the Merger and \$2.0 million of proceeds from maturities of marketable securities.

Cash used in investing activities for the year ended December 31, 2015 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, 2017 was \$20.0 million and consisted of \$19.8 million of proceeds from the issuance of common stock upon public offering, net of issuance costs, and \$0.2 million of proceeds received from the issuance of common stock upon ESPP purchase and options exercises.

Cash provided by financing activities for the year ended December 31, 2016 was \$65.1 million and 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, \$18.2 million of net proceeds from the issuance of common stock in the underwritten public offering, after deducting underwriting discounts and commissions and expenses payable by us, and \$14.8 million of proceeds 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.

# **Contractual Obligations and Commitments**

The following table summarizes our contractual obligations at December 31, 2017 (in thousands):

	Payments due by period									
		Less than Total 1 year				1 – 3 3 – 5 Years Years			More than 5 years	
Operating lease obligations (1)	\$	3,222	\$	634	\$	1,203	\$	1,276	\$	109
Term loan debt (2)	\$	15,000	\$	2,083	\$	10,000	\$	2,917	\$	_
Interest on term loan debt (3)	\$	3,641	\$	1,156	\$	1,284	\$	1,201	\$	
Total	\$	21,863	\$	3,873	\$	12,487	\$	5,394	\$	109

(1) Represents future rent payments under 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, 2017. 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, 2017, 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 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 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 adopted this ASU in the first quarter of 2017. As a result of adopting this standard, the Company made an accounting policy election to account for forfeitures as they occur. This change did not have a material impact to the consolidated financial statements.

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 does not expect the standard to have a material impact 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**

To the Stockholders and Board of Directors Eiger BioPharmaceuticals, Inc.

#### **Opinion on the Consolidated Financial Statements**

We have audited the accompanying consolidated balance sheets of Eiger BioPharmaceuticals, Inc. and subsidiaries (the Company) as of December 31, 2017 and 2016, 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, 2017, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2017, in conformity with U.S. generally accepted accounting principles.

#### Basis for Opinion

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 are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

#### /s/ KPMG LLP

We have served as the Company's auditor since 2015.

San Francisco, California March 9, 2018



# **Consolidated Balance Sheets**

(In thousands, except share and per share amounts)

	December 31,				
	 2017		2016		
Assets					
Current assets:					
Cash and cash equivalents	\$ 32,035	\$	27,756		
Short-term marketable securities	9,744		32,180		
Prepaid expenses and other current assets	 712		581		
Total current assets	42,491		60,517		
Property and equipment, net	79		76		
Other assets	312		143		
Total assets	\$ 42,882	\$	60,736		
Liabilities and Stockholders' Equity	 				
Current liabilities:					
Accounts payable	\$ 3,183	\$	2,639		
Accrued liabilities	2,084		2,649		
Current portion of long term debt	2,002				
Total current liabilities	7,269		5,288		
Long term debt, net	13,091		14,727		
Total liabilities	\$ 20,360	\$	20,015		
Commitments and contingencies (Note 15)					
Stockholders' equity:					
Common stock, \$0.001 par value, 200,000,000 shares authorized as of December 31, 2017 and 2016; 10,526,599 and 8,356,659 shares issued					
and outstanding as of December 31, 2017 and 2016, respectively	11		8		
Additional paid-in capital	141,320		117,086		
Accumulated other comprehensive loss	(3)		(15)		
Accumulated deficit	 (118,806)		(76,358)		
Total stockholders' equity	22,522		40,721		
Total liabilities and stockholders' equity	\$ 42,882	\$	60,736		

See accompanying notes to the consolidated financial statements.

# **Consolidated Statements of Operations**

(In thousands, except share and per share amounts)

	Year Ended December 31,					
	2017		2016		2015	
Operating expenses:						
Research and development	\$ 29,519	\$	33,014	\$	8,117	
General and administrative	 12,001		13,106		4,855	
Total operating expenses	41,520		46,120		12,972	
Loss from operations	(41,520)		(46,120)		(12,972)	
Interest expense	(1,524)		(690)		(350)	
Interest income	410		97		—	
Other income (expense), net	 186		(374)			
Net loss	\$ (42,448)	\$	(47,087)	\$	(13,322)	
Net loss per share, basic and diluted	\$ (4.86)	\$	(7.84)	\$	(62.19)	
Weighted-average common shares outstanding, basic and diluted	8,727,935		6,007,027		214,228	

See accompanying notes to the consolidated financial statements.

# **Consolidated Statements of Comprehensive Loss**

# (In thousands)

	Year Ended December 31,						
	2017		2016		2015		
Net loss	\$ (42,448)	\$	(47,087)	\$	(13,322)		
Other comprehensive loss:							
Unrealized gain (loss) on marketable securities, net	12		(15)		—		
Comprehensive loss	\$ (42,436)	\$	(47,102)	\$	(13,322)		

 $See\ accompanying\ notes\ to\ the\ consolidated\ financial\ statements.$ 

# Eiger BioPharmaceuticals, Inc. Consolidated Statements of Stockholders' Equity (Deficit) (In thousands, except share amounts)

	Conve Preferre		Commo	n Stock	Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Loss	Deficit	Equity (Deficit)
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	_	_	_	_	227	_	(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	2,009,102	22,307	1,954,390	2	32.106		(29,271)	32,108
Issuance of common stock upon conversion of convertible promissory note			350,040	2	6,129			6,129
Issuance of common stock upon			550,040		0,129			0,129
exercise of common stock upon Issuance of common stock to	_	_	61,254	_	1,057	_	_	1,057
Eiccose upon private placement Conversion of preferred stock into	_	_	96,300	_	1,661	_	—	1,661
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 Unrealized loss on marketable	—	—	_	—	3,190	—	—	3,190
securities, net	_		_	_		(15)	(47,087)	(15) (47,087)
Balance at December 31, 2016			8,356,659	8	117,086	(15)	(76,358)	40,721
Issuance of common stock upon public offering, net of \$376 issuance costs		_	2,143,525	3	19,797	(10)	(10,550)	19,800
Issuance of common stock upon ESPP purchase	_	_	16,186	_	142	_	_	142
Issuance of common stock upon stock option exercise	_	_	10,229	_	52	_	_	52
Stock-based compensation expense	_	_		_	4,243	_	_	4,243
Unrealized gain on marketable securities, net	_	_	_	_	_	12	_	12
Net loss	_	_		_	_	_	(42,448)	(42,448)
Balance at December 31, 2017		\$	10,526,599	\$ 11	\$ 141,320	\$ (3)	\$ (118,806)	\$ 22,522

See accompanying notes to the consolidated financial statements.

# **Consolidated Statements of Cash Flows**

# (In thousands)

	Year Ended December 31,					
	2017		2016		2015	
Operating Activities						
Net loss	\$ (42,44	8) \$	(47,087)	\$	(13,322)	
Adjustments to reconcile net loss to net cash used in operating activities:						
Depreciation	4	1	23		11	
Amortization of premiums on marketable securities	(5	3)	(41)		—	
Stock-based compensation	4,24	3	3,190		227	
Non-cash interest expense	36	6	685		350	
Gain on intellectual property sale	(20	0)	_		_	
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	(13	,	326		(685)	
Other non-current assets	(16	,	(89)		(46)	
Accounts payable	54	4	699		1,881	
Accrued liabilities	(56	5)	783		782	
Net cash used in operating activities	(38,37	2)	(37,970)		(9,134)	
Investing Activities		_				
Purchase of marketable securities	(24,52	4)	(34,154)		_	
Proceeds from maturities of marketable securities	47,02	5	2,000		_	
Proceeds from intellectual property sale	20	0	_		_	
Cash received from merger transaction	-	_	28,018		_	
Purchase of property and equipment	(4	4)	(58)		(45)	
Net cash provided by (used in) investing activities	22,65	7	(4,194)		(45)	
Financing Activities			/			
Proceeds from issuance of common stock upon public offering,						
net of issuance cost	19,80	0	18,229		_	
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 ESPP purchase	14	2	_		_	
Proceeds from issuance of common stock upon options exercises	5	2	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	
Net cash provided by financing activities	19,99	4	65,142		13,180	
Net increase in cash and cash equivalents	4,27	_	22,978		4,001	
Cash and cash equivalents at beginning of period	27,75		4,778		777	
Cash and cash equivalents at end of period	\$ 32,03		27,756	\$	4,778	
	\$ 52,05	J 3	27,750	φ	4,778	
Supplemental disclosure of cash flow information						
Non-cash 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		_	
Non-cash net liabilities assumed in reverse merger	-	_	671		_	
Conversion of convertible promissory note to common stock upon			( 120			
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.

#### Notes to Consolidated Financial Statements

#### 1. Description of Business

Eiger BioPharmaceuticals, Inc. (the "Company" or "Eiger") 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 rare 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 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 consumation 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

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, 2017, the Company had \$32.0 million of cash and cash equivalents and \$9.7 million of short-term marketable securities. In addition, the Company had an accumulated deficit of \$118.8 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, focused on completing its three ongoing Phase 2 development programs and initial preparations for advancing its lead program into Phase 3, 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 will 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 subsidiary EB Pharma LLC, 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 accrued research and development expenses, 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.

## Short-Term Marketable Securities

Short-term securities 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 short-term marketable securities 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 income (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

Computer equipment and software

## 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, 2017, the Company has not impaired any long-lived assets.

5 years

3 years

# Accrued Research and Development Expenses

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.

# **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). 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.

## **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,	
	2017	2016	2015
Options to purchase common stock	1,467,051	1,212,044	254,058
Warrants to purchase common stock	10,180	10,180	_
Convertible preferred stock	—		2,609,102
Total	1,477,231	1,222,224	2,863,160

# **Recent Accounting Pronouncements**

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 adopted this ASU in the first quarter of 2017. As a result of adopting this standard, the Company made an accounting policy election to account for forfeitures as they occur. This change did not have a material impact on the Company's consolidated financial statements.

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 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 does not expect the standard to have a material impact 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, 2017 and 2016, the carrying amount of prepaid expenses and other current assets, accounts payable and accrued liabilities approximated their estimate fair value due to their relatively short maturities. Management believes the terms of long term debt reflects 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.

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, 2017							
	Level 1		Level 2		Level 3		Total	
Financial Assets:								
Money market funds	\$ 19,612	\$	_	\$	_	\$	19,612	
Corporate debt securities			6,501		_		6,501	
Commercial paper	—		3,243		—		3,243	
Total	\$ 19,612	\$	9,744	\$		\$	29,356	
			Decembe	r 31, 201	6			
	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	

There were no financial liabilities as of December 31, 2017.

Total

The following table provides a reconciliation of liabilities measured at fair value using Level 3 significant unobservable inputs as of December 31, 2016 (in thousands):

34,360

44,017

9,657

	Year Ended Dec 2016	ember 31,
Balance at December 31, 2015	\$	2,342
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 at December 31, 2016	\$	_

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

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

		December 31, 2017						
	Amo	rtized cost	Unr	ealized gain	τ	<b>Unrealized loss</b>	Esti	mated Fair Value
Cash equivalents:								
Money market funds	\$	19,612	\$	—	\$	_	\$	19,612
Total cash equivalents	\$	19,612	\$		\$		\$	19,612
Marketable securities:								
Corporate debt securities	\$	6,503	\$	_	\$	(2)	\$	6,501
Commercial paper		3,244		_		(1)		3,243
Total marketable securities	\$	9,747	\$	_	\$	(3)	\$	9,744

		December 31, 2016						
	Amo	rtized 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, 2017, the contractual maturity of the available-for-sale marketable securities is less than one year. The Company periodically reviews the available-for-sale investments for other-than-temporary impairment loss. The Company considers factors such as the duration, severity and the reason for the decline in value, the potential recovery period and its intent to sell. For debt securities, it also considers whether (i) it is more likely than not that the Company will be required to sell the debt securities before recovery of their amortized cost basis, and (ii) the amortized cost basis cannot be recovered as a result of credit losses. As of December 31, 2017, the Company did not recognize any other-than-temporary impairment losses. All marketable securities with unrealized losses have been in a loss position for less than twelve months.

# 4. Balance Sheet Components

# Property and Equipment, Net

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

		December 31,		
	2017			2016
Lab equipment	\$	36	\$	35
Computer equipment and software		150		107
Total property and equipment		186		142
Less: accumulated depreciation		(107)		(66)
Property and equipment, net	\$	79	\$	76

Depreciation expense for the years ended December 31, 2017, 2016 and 2015 was \$41,000, \$23,000 and \$11,000, respectively.

# Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	 December 31,		
	2017		2016
Compensation and related benefits	\$ 1,262	\$	1,299
Contract research costs	634		834
Consulting costs	87		106
Franchise tax	56		97
Contract manufacturing costs	4		122
Other	41		191
Total accrued liabilities	\$ 2,084	\$	2,649

# 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 for 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 required the Company to make an upfront payment of \$2.0 million in cash and issue \$3.0 million in Company common stock (see below) 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 issued BMS \$3.0 million in common stock as an element of the upfront payment. The BMS Purchase Agreement provided 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 lonafamib 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 is estimated to be in the first half of 2018; 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 milestones have been achieved during the years 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 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, 2017, 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 farmesyl transferase inhibitors as anti-viral agents and methods to treat viral infections 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, 2017, 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, 2017, 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, 2017, 2016 and 2015, the Company recognized \$44,000, \$0.3 million and \$15,000 of non-employee compensation expense related to the time-vested options, respectively. No expense was recognized for the milestone vested options during the years ended December 31, 2015.

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"). 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, 2017, upon the successful completion of the Phase 2 trials, the development milestone was achieved and the Company paid the related milestone payment of \$0.1 million to each of the Sellers.

#### 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 income (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 (deficit).

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, 2017, the product has not reached commercialization and no milestones have been paid. In June 2017, Eiccose was disbanded. The



Company's commercial milestone obligations and sales royalties remain, however have been transferred to the previous shareholders of Eiccose.

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 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 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 years ended December 31, 2017 and 2016, no amounts have been recorded 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 (the "Oxford Loan"). The loan matures on July 1, 2021. The Company borrowed \$15.0 million in December 2016 ("Tranche A"). The remaining \$10.0 million ("Tranche B") will be available to the Company upon achievement of positive top line data from the lonafarnib Phase 2 trial in HDV, which was achieved in the fourth quarter of 2016, plus positive top line Phase 2 data from at least one of the following programs: (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 as a debt discount. 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 defaults 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, 2017 and 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 \$1.1 million and \$5,000 for the years ended December 31, 2017 and 2016, respectively. Long-term debt and unamortized discount balances are as follows (in thousands):

	December 31,		
	 2017	2016	
Face value of long term debt	\$ 15,000 \$	15,000	
Exit fee	1,125	1,125	
Unamortized debt discount associated with exit fee, debt issuance costs and loan			
origination fees	(1,032)	(1,398	
Total long term debt	15,093	14,727	
Less: current portion of long term debt	 (2,002)		
Long term debt, net	\$ 13,091 \$	14,727	

As of December 31, 2017, future minimum payments of principal, exit fee and interest expense under the Oxford Loan were as follows (in thousands):

#### Year ending December 31,

Tear thang betember try	
2018	\$ 3,239
2019	5,839
2020	5,445
2021	 4,118
Total future payments	18,641
Less: unamortized interest	(2,516)
Less: 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 (deficit), 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. Sale of Assets

In May 2017, the Company and Theragene Pharmaceuticals, Inc. ("Theragene") entered into an asset purchase agreement ("Theragene APA"), whereby the Company sold all of the assets related to MYDICAR including any related intellectual property for a cash payment of \$0.2 million and 475,000 shares of common stock of Theragene. At any time after the Theragene APA execution date and until Theragene has received cumulative gross proceeds of \$4.0 million ("Proceeds Date") from all equity financing transactions occurring after the Theragene APA execution date, if Theragene issues additional shares of its common stock without consideration or for a consideration per share less than \$6.00 per share then Theragene will issue additional shares of its common stock to the Company concurrently with such issue, in an amount such that the per share consideration multiplied by the aggregate number of common stock shares issued to the Company, Theragene will repurchase the 225,000 shares of its common stock held by the Company ("Option Shares") at an aggregate purchase price equal to the greater of \$1.35 million or the aggregate fair market value of the Option Shares as of the date of the receipt notice. The Company is also eligible to receive contingent consideration up to a maximum \$45.0 million in cash, based upon Theragene achieving certain specified future milestones. In addition, the Company is also eligible to receive up to 8% royalties on net sales of any future Theragene products covered by or involving the related patents or know-how until the 20<sup>th</sup> anniversary of the Theragene APA.

The Company has determined that the sale of the MYDICAR assets qualify as an asset sale and not a business.

During the year ended December 31, 2017, the Company received a cash payment of \$0.2 million, which was recognized as other income (expense), net in the consolidated statement of operations. Concurrently with the execution of the Theragene APA, the Company became an owner of 475,000 shares of common stock of Theragene and a put option for 225,000 shares of common stock of Theragene, which were recognized as a cost method investment with carrying value of zero. As of December 31, 2017, there was no change in the fair value of our equity investment in Theragene.

## 11. Stockholders' Equity

#### **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, 2017, no dividends had been declared by the Board of Directors.

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

	December 3	31,
	2017	2016
Options issued and outstanding	1,467,051	1,212,044
Options available for future grants	799,375	646,778
Warrants to purchase common stock issued and outstanding	10,180	10,180
Total	2,276,606	1,869,002

# Warrants

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' equity (deficit). The change in fair value of the warrant liability was recognized as a component of other income (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 per share and expire in October 2018.

#### 12. 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 years ended December 31, 2017 and 2016 (in thousands, except share and per share data):

	Shares Available for Grant	Number of Options	1	Veighted- Average Exercise Price er Option	Weighted- Average Remaining Contractual Life (in Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2016	646,778	1,212,044	\$	14.06	9.00	\$ 2,414
Additional options authorized	417,833	—		—		
Granted	(652,200)	652,200	\$	10.91		
Exercised		(10,229)	\$	5.04		
Forfeited or cancelled	386,964	(386,964)	\$	14.13		
Outstanding as of December 31, 2017	799,375	1,467,051	\$	12.70	8.41	\$ 4,511
Vested and exercisable as of December 31, 2017		630,727	\$	13.82	8.01	\$ 2,117

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 closing price of the Company's common stock of \$13.95 as of December 31, 2017.

The aggregate intrinsic value of stock options exercised in 2017, 2016 and 2015 was \$0.1 million, \$0.1 million and \$0.9 million, respectively.

# Stock Options Granted to Employees

During the years ended December 31, 2017, 2016 and 2015, the Company granted employees stock options for the purchase of 579,700, 902,028 and 166,793 shares, respectively, with a weighted-average grant date fair value of \$7.66, \$10.40 and \$1.09 per share, respectively. The total grant date fair value of employee options that vested during the years ended December 31, 2017, 2016 and 2015 was \$5.0 million, \$2.0 million and \$6,000, 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 straightline basis. The fair value of employee stock options was estimated using the following weighted-average assumptions:

		Year Ended December 31,	
	2017	2016	2015
Expected term (in years)	5.27 - 6.08	5.27 - 6.08	5.00 - 6.08
Volatility	79.00% - 80.00%	73.91% - 78.00%	77.58% - 97.62%
Risk free interest rate	1.63% - 2.23%	1.21% - 2.27%	1.44% - 1.75%
Dividend yield	_		_

Each of these inputs is subjective and generally requires 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, 2017, 2016 and 2015, the Company granted to non-employees stock options for 72,500, 48,544 and 46,134 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,	
	2017	2016	2015
Remaining contractual term (in years)	6.00 - 10.00	6.75 - 10.00	7.75 - 10.00
Volatility	83.62%-106.13%	84.42% - 98.13%	85.83% - 90.50%
Risk-free interest rate	1.90% - 2.43%	1.37% - 2.50%	1.73% - 2.24%
Dividend vield	_	_	_

#### 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,					
	2017		2016		2015	
Research and development	\$ 1,214	\$	737	\$	64	
General and administrative	3,029		2,453		163	
Total stock-based compensation expense	\$ 4,243	\$	3,190	\$	227	

As of December 31, 2017, the total unrecognized compensation expense related to unvested employee options was \$6.8 million, which the Company expects to recognize over an estimated weighted average period of 2.7 years.

# 13. Income Taxes

No provision for income taxes was recorded for the years ended December 31, 2017, 2016 and 2015. 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:

	Yea	Year Ended December 31,			
	2017	2016	2015		
Federal statutory income tax rate	34.00%	34.00%	34.00%		
State income taxes, net of federal benefit	0.36	(0.21)	6.11		
Federal and state tax credits	5.10	4.68	2.54		
Change in valuation allowance	(8.04)	(36.67)	(42.14)		
Stock-based compensation	(1.06)	(1.26)	(0.49)		
Other, net	_	(0.54)	(0.02)		
Change in tax law	(30.36)				
Provision (benefit) for income taxes	%	%	%		

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

		December 31,			
	2	2017		2016	
Deferred tax assets:					
Net operating loss carryforwards	\$	20,230	\$	19,882	
Tax credits		9,514		5,344	
Depreciation and amortization		1,700		3,025	
Accruals and reserves		1,158		936	
Gross deferred tax assets		32,602		29,187	
Valuation allowance		(32,602)		(29,187)	
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, 2017 and 2016. The valuation allowance increased by \$3.4 million and \$17.3 million during the years ended December 31, 2017 and 2016, respectively.

As of December 31, 2017, the Company had approximately \$88.4 million and \$25.5 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, 2017, the Company also had research and development tax credit carryforwards of approximately \$0.2 million and \$0.9 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, 2017, the Company had orphan drug tax credit carryforwards of approximately \$11.8 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, 2017. 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, 2017, 2016 and 2015 is as follows (in thousands):

	Year Ended December 31,			
	2017		2016	2015
Balance at beginning of year	\$ 1,831	\$	404	\$ 99
Additions based on tax positions related to prior				
year	_		19	46
Additions based on tax positions related to				
current year	1,387		1,408	259
Balance at end of year	\$ 3,218	\$	1,831	\$ 404

If the \$3.2 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, 2017, 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, 2017, 2016 and 2015.

# 14. 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. On May 5, 2017, the lead plaintiff filed his opening brief. On July 5, 2017, the defendants filed their appellate brief response. The Plaintiff subsequently filed their response to the Company's July 5, 2017 filing on August 19, 2017. Upon these filings, the next step in the process would be to wait for oral arguments to be scheduled by the 9<sup>th</sup> Circuit Court of Appeals.

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. The Company is not able to predict or reasonably estimate the ultimate outcome or possible losses relating to these claims.

# 15. 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.

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 to \$49,000, which is included in other assets in the Company's consolidated balance sheet as of December 31, 2017 and 2016.

In March 2017, the Company entered into a non-cancelable facility lease agreement for an office facility in Palo Alto, California. The lease commenced on April 1, 2017 and expires 12 months after the commencement date. The lease has one twelve-month renewal option prior to expiration and includes rent escalation clauses through the lease term. In April 2017, the Company provided a security deposit of \$27,000 as collateral for the lease, which is included in other assets in the Company's consolidated balance sheet as of December 31, 2017.

In October 2017, the Company entered into a non-cancelable facility lease agreement for 8,029 square feet of office space located at 2171 Park Blvd in Palo Alto, California 94306. The lease commences on March 1, 2018 and expires five years after the commencement date. The lease has one three-year renewal option prior to expiration and includes rent escalation clauses through the lease term. In October 2017, the Company provided a security deposit of \$0.3 million, which is included in other assets in the Company's consolidated balance sheet as of December 31, 2017.

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

Year ending December 31,	Amounts	
2018	\$	634
2019		593
2020		610
2021		629
2022		647
Thereafter		109
Total minimum payments	\$	3,222

Rent expense was \$0.6 million, \$0.3 million and \$0.1 million for the years ended December 31, 2017, 2016 and 2015, 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.

# 16. Related Party Transactions

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, in 2015 the Company entered into an asset purchase agreement with Eiccose, for which the Company's chief executive officer was the sole managing member and significant equity interest holder. In June 2017, Eiccose was disbanded. The Company's commercial milestone obligations and sales royalties remain, however have been transferred to the previous shareholders of Eiccose.

# 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, 2017, 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 principals generally accepted in the United States of America.

As of December 31, 2017, 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, 2017, 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, 2017, 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 2018 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2017.

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 <a href="http://www.eigerbio.com">www.eigerbio.com</a>.

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 2018 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2017.

# 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 2018 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2017.

# 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 2018 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2017.

# 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 2018 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2017.



# 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.
  - 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

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 the Current Report on Form 8-K, filed with the SEC on March 23, 2016).
3.4	<u>Certificate of Amendment of Amended and Restated Certificate of Incorporation of Celladon Corporation (incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K, filed with the SEC on March 23, 2016).</u>
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	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+	<u>Celladon Corporation 2001 Stock Option Plan and Form of Notice of Grant of Stock Option, Stock Option Agreement and Stock Option</u> <u>Exercise Notice thereunder (incorporated by reference to Exhibit 10.2 to the Registration Statement on Form S-1, as amended (File No.</u> <u>333-191688), originally filed with the SEC on October 11, 2013).</u>
10.3+	<u>Celladon Corporation 2012 Equity Incentive Plan and Form of Stock Option Grant Notice, Option Agreement and Notice of Exercise</u> <u>thereunder (incorporated by reference to Exhibit 10.3 to the Registration Statement on Form S-1, as amended (File No. 333-191688),</u> <u>originally filed with the SEC on October 11, 2013).</u>

Exhibit Number	Description of Document
10.4+	Celladon Corporation Non-Employee Director Compensation Policy, amended on April 12, 2017 (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q (File No. 001-36183), filed with the SEC on May 12, 2017).
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).
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).

Exhibit Number	Description of Document
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 or December 14, 2015).
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 or 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 Squib 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 (incorporate by reference to Exhibit 10.26 to the Annual report on Form 10-K (File No. 001-36183) filed with the SEC on March 23, 2017).
10.27	Standard Multi-Tenant Office Lease – Net, dated October 11, 2017, by and between Eiger BioPharmaceuticals, Inc. and the McDonald Family Co. LLC, and addendum thereto.
10.28	Offer Letter, dated as of December 12, 2017, by and between Eiger BioPharmaceuticals, Inc. and David Apelian, M.D., Ph.D.
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.

Exhibit Number	Description of Document
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
	tes management contract or compensatory plan. dential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

# 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: 9 March, 2018

By: /s/ David A. Cory

David A. Cory Director, President and Chief Executive Officer (Principal Executive Officer)

Eiger BioPharmaceuticals, Inc.

Date: 9 March, 2018

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)	9 March, 2018
/s/ James Welch James Welch	Chief Financial Officer (Principal Financial and Accounting Officer)	9 March, 2018
/s/ Thomas J. Dietz Thomas J. Dietz	Chairman of the Board of Directors	9 March, 2018
/s/ David Apelian David Apelian	Member of the Board of Directors	9 March, 2018
/s/ Evan Loh Evan Loh	Member of the Board of Directors	9 March, 2018
/s/ Jeffrey Glenn Jeffrey Glenn	Member of the Board of Directors	9 March, 2018
/s/ Eldon Mayer Eldon Mayer	Member of the Board of Directors	9 March, 2018

# Standard Multi-Tenant Office Lease - Net, dated October 11, 2017, by and between Eiger BioPharmaceuticals, Inc. and the McDonald Family Co. LLC, and addendum.



## **STANDARD MULTI-TENANT OFFICE LEASE - NET**

Basic Provisions ("Basic Provisions"). 1.

1.1 Parties. This Lease ("Lease"), dated for reference purposes only October 11, 2017, is made by and between McDonald Family Co. LLC ("Lessor") and Eiger BioPharmaceuticals Inc. ("Lessee"), (collectively the "Parties", or individually a "Party"),

1.2(a) Premises: That certain portion of the Project (as defined below), commonly known as (street address, suite, city, state): 2171 Park Blvd, Palo Alto, CA ("Premises"). The Premises are located in the County of Santa Clara, and consist of approximately 8, 029 rentable square feet and approximately 8,029 useable square feet. In addition to Lessee's rights to use and occupy the Premises as hereinafter specified, Lessee shall have non-exclusive rights to the Common Areas (as defined in Paragraph 2.7 below) as hereinafter specified, but shall not have any rights to the roof, the exterior walls, the area above the dropped ceilings, or the utility raceways of the building containing the Premises ("Building") or to any other buildings in the Project. The Premises, the Building, the Common Areas, the land upon which they are located, along with all other buildings and improvements thereon, are herein collectively referred to as the "Project." The Project consists of approximately rentable square feet. (See also Paragraph 2)

1.2(b) Parking: \_ unreserved and <u>17</u> reserved vehicle parking spaces at a monthly cost of per unreserved space and per reserved space. (See Paragraph 2.6)

1.3 Term: 5 years and \_\_\_\_\_ months ("Original Term") commencing <u>March 1, 2018</u> ("Commencement Date") and ending <u>February 28, 2023</u> ("Expiration Date"). (See also Paragraph 3) 1.4 Early Possession: If the Premises are available Lessee may have non-exclusive possession of the Premises commencing <u>February 1, 2018</u> ("Early Possession Date"). (See also Paragraph 3) Paragraphs 3.2 and 3.3)

1.5 Base Rent: <u>\$6.00</u> per month ("Base Rent"), payable on the <u>1st</u> day of each month commencing <u>March 1, 2018.</u> (See also Paragraph 4) The Base Rent shall increase annually by 3% If this box is checked, there are provisions in this Lease for the Base Rent to be adjusted. See Paragraph <u>51</u>.

1.6 Lessee's Share of Operating Expenses: fifty-five percent (55%) ("Lessee's Share"). In the event that that size of the Premises and/or the Project are modified during the term of this Lease, Lessor shall recalculate Lessee's Share to reflect such modification.

1.7 Base Rent and Other Monies Paid Upon Execution:

- (a)
- Base Rent: \$48,174.00 for the period March 1, 2018 March 31, 2018. Operating Expenses: \$7,627.65 for the period March 1, 2018 March 31, 2018. (b)
- Security Deposit: \$289,044.00 ("Security Deposit"). (See also Paragraph 5 and Addendum 58) (c)

<del>(d)</del> P<del>a</del>r<del>ki</del>ng÷ \_\_ for the period

(e) Other:

- (f) Total Due Upon Execution of this Lease: \$337,218.00.
- Agreed Use: <u>Professional, office, R&D uses and other permitted legal uses</u>. (See also Paragraph 6) Insuring Party. Lessor is the "Insuring Party". (See also Paragraph 8)

- 1.10 Real Estate Brokers. (See also Paragraph 15 and 25)
   (a) Representation: The following real estate brokers (the "Brokers") and brokerage relationships exist in this transaction (check applicable boxes):
- In <u>Newmark Cornish & Carey</u> represents Lessor exclusively ("Lessor's Broker");
- ☑ Jones Lang LaSalle represents Lessee exclusively ("Lessee's Broker"); or
  □ represents both Lessor and Lessee ("Dual Agency").
  - - Payment to Brokers. Upon execution and delivery of this Lease by both Parties, Lessor shall pay to the Brokers the brokerage fee agreed to in a separate written agreement (or if (b) t. the sum of or \_\_\_\_\_ % of the tota under this Lesse shall be guaranteed by % of the total Base Rent) for the brokerage services rende red by the
  - ("Guari also Parac

1.17 Business Hours for the Building: 8:00 a.m. to 6:00 p.m., Mondays through Fridays (except Building Holidays) and 9:00 a.m. to 1:00 p.m. on Saturdays (except Building Holidays). "Building Holidays" shall mean the dates of observation of New Year's Day, President's Day, Memorial Day, Independence Day, Labor Day, Thanksgiving Day, Christmas Day, and \_\_\_\_\_. 1.3 Lessor Supplied Services. Notwithstanding the provisions of Paragraph 11.1, Lessor is NOT obligated to provide the following within the Premises

Janitorial services

☑ Electricity

1.8

□ Other (specify):

- 1.14 Attachments. Attached hereto are the following, all of which constitute a part of this Lease:
- ☑ an Addendum consisting of Paragraphs 50 through 80;
- ☑ a plot plan depicting the Premises; Z a current set of the Rules and Regulations;
- □ a Work Letter;
- a janitorial schedule:
- ☑ other (specify): <u>Floor Plan</u>.

#### 2 Premises

2.1 Letting. Lessor hereby leases to Lessee, and Lessee hereby leases from Lessor, the Premises, for the term, at the rental, and upon all of the terms, covenants and conditions set forth in this Lease. While the approximate square footage of the Premises may have been used in the marketing of the Premises for purposes of comparison, the Base Rent stated herein is NOT tied to square footage and is not subject to adjustment should the actual size be determined to be different. NOTE: Lessee is advised to verify the actual size prior to executing this Lease

2.2 Condition. Lessor shall deliver the Premises to Lessee in a clean condition on the Commencement Date or the Early Possession Date, whichever first occurs ("Start Date"), and warrants that the existing electrical, plumbing, fire sprinkler, lighting, heating, ventilating and air conditioning systems ("HVAC"), and all other items which the Lessor is obligated to construct pursuant to the Work Letter attached hereto, if any, other than those constructed by Lessee, shall be in good operating condition on said date, that the structural elements of the roof, bearing walls and foundation of the Unit shall be free of material defects, and that the Premises do not contain hazardous levels of any mold or fungi defined as toxic under applicable state or federal law. Lessor also warrants, that unless otherwise specified in writing, Lessor is unaware of (i) any recorded Notices of Default affecting the Premise; (ii) any delinquent amounts due under any loan secured by the Premises; and (iii) any bankruptcy proceeding affecting the Premises.

Compliance. Lessor warrants that to the best of its knowledge the improvements on the Premises and the Common Areas comply with the building codes, applicable laws, covenants or restrictions of record, regulations, and ordinances ("Applicable Requirements") that were in effect at the time that each improvement, or portion thereof, was constructed. Said warranty does not apply to the use to which Lessee will put the Premises, modifications which may be required by the Americans with Disabilities Act or any similar laws as a result of Lessee's use (see Paragraph 49), or to any Alterations or Utility Installations (as defined in Paragraph 7.3(a)) made or to be made by Lessee. NOTE: Lessee is responsible for determining whether or not the zoning and other Applicable Requirements are appropriate for Lessee's intended use, and acknowledges that past uses of the Premises may no longer be allowed. If the Premises do not comply with said warranty, Lessor shall, except as otherwise provided, promptly after receipt of written notice from Lessee setting forth with specificity the nature and extent of such non-compliance, rectify the same. If the Applicable Requirements are hereafter changed so as to require during the term of this Lease the construction of an addition to or an alteration of the Premises, the remediation of any Hazardous Substance, or the reinforcement or other physical modification of the Premises ("Capital Expenditure"), Lessor and Lessee shall allocate the cost of such work as follows

(a) Subject to Paragraph 2.3(c) below, if such Capital Expenditures are required as a result of the specific and unique use of the Premises by Lessee as

compared with uses by tenants in general, Lessee shall be fully responsible for the cost thereof, provided, however, that if such Capital Expenditure is required during the last 2 years of this Lease and the cost thereof exceeds 6 months' Base Rent. Lessee may instead terminate this Lease unless Lessor notifies Lessee, in writing, within 10 days after receipt of Lessee's termination notice that Lessor has elected to pay the difference between the actual cost thereof and the amount equal to 6 months' Base Rent. If Lessee elects termination, Lessee shall immediately cease the use of the Premises which requires such Capital Expenditure and deliver to Lessor written notice specifying a termination date at least 90 days thereafter. Such termination date shall, however, in no event be earlier than the last day that Lessee could legally utilize the Premises without commencing such Capital Expenditure.

(b) If such Capital Expenditure is not the result of the specific and unique use of the Premises by Lessee (such as, governmentally mandated seismic modifications), then Lessor shall pay for such Capital Expenditure and Lessee shall only be obligated to pay, each month during the remainder of the term of this Lease or any extension thereof, on the date that on which the Base Rent is due, an amount equal to 1/144th of the portion of such costs reasonably attributable to the Premises. Lessee shall pay Interest on the balance but may prepay its obligation at any time. If, however, such Capital Expenditure is required during the last 2 years of this Lease or if Lessor reasonably determines that it is not economically feasible to pay its share thereof, Lessor shall have the option to terminate this Lease upon 90 days prior written notice to Lessee unless Lessee notifies Lessor, in writing, within 10 days after receipt of Lessor's termination notice that Lessee will pay for such Capital Expenditure. If Lessor does not elect to terminate, and fails to tender its share of any such Capital Expenditure, Lessee may advance such funds and deduct same, with Interest, from Rent until Lessor's share of such costs have been fully paid. If Lessee is unable to finance Lessor's share, or if the balance of the Rent due and payable for the remainder of this Lease is not sufficient to fully reimburse Lessee on an offset basis, Lessee shall have the right to terminate this Lease upon 30 days written notice to Lessor.

(c) Notwithstanding the above, the provisions concerning Capital Expenditures are intended to apply only to non-voluntary, unexpected, and new Applicable Requirements. If the Capital Expenditures are instead triggered by Lessee as a result of an actual or proposed change in use, change in intensity of use, or modification to the Premises then, and in that event, Lessee shall either: (i) immediately cease such changed use or intensity of use and/or take such other steps as may be necessary to eliminate the requirement for such Capital Expenditure, or (ii) complete such Capital Expenditure at its own expense. Lessee shall not have any right to terminate this Lease.

2.4 Acknowledgements. Lessee acknowledges that: (a) it has been given an opportunity to inspect and measure the Premises, (b) Lessee has been advised by Lessor and/or Brokers to satisfy itself with respect to the size and condition of the Premises (including but not limited to the electrical, HVAC and fire sprinkler systems, security, environmental aspects, and compliance with Applicable Requirements), and their suitability for Lessee's intended use, (c) Lessee has made such investigation as it deems necessary with reference to such matters and assumes all responsibility therefor as the same relate to its occupancy of the Premises, (d) it is not relying on any representation as to the size of the Premises made by Brokers or Lessor, (e) the square footage of the Premises was not material to Lessee's decision to lease the Premises and pay the Rent stated herein, and (f) neither Lessor, Lessor's agents, nor Brokers have made any oral or written representations or warranties with respect to said matters other than as set forth in this Lease. In addition, Lessor acknowledges that: (i) Brokers have made no representations, promises or warranties concerning Lessee's ability to honor the Lease or suitability to occupy the Premises, and (ii) it is Lessor's sole responsibility to investigate the financial capability and/or suitability of all proposed tenants.

2.5 Lessee as Prior Owner/Occupant. The warranties made by Lessor in Paragraph 2 shall be of no force or effect if immediately prior to the Start Date, Lessee was the owner or occupant of the Premises. In such event, Lessee shall be responsible for any necessary corrective work. 2.6 Vehicle Parking. So long as Lessee is not in default, and subject to the Rules and Regulations attached hereto, and as established by Lessor from time to time, Lessee shall be entitled to

rent and use the number of parking spaces specified in Paragraph 1.2(b) at the rental rate applicable from time to time for monthly parking as set by Lessor and/or its licensee.
(a) If Lessee commits, permits or allows any of the prohibited activities described in the Lease or the rules then in effect, then Lessor shall have the right, without notice, in addition to such

other rights and remedies that It may have, to remove or tow away the vehicle involved and charge the cost to Lessee, which cost shall be immediately payable upon demand by Lessor. (b) The monthly rent per parking space specified in Paragraph 1.2(b) is subject to change upon 30 days prior written notice to Lessee. The rent for the parking is payable one month in advance prior to the first day of each calendar month.

Common Areas - Definition. The term "Common Areas" is defined as all areas and facilities outside the Premises and within the exterior boundary line of the Project and interior utility raceways and installations within the Premises that are provided and designated by the Lessor from time to time for the general nonexclusive use of Lessor, Lessee and other tenants of the Project and their respective employees, suppliers, shippers, customers, contractors and invitees, including, but not limited to, common entrances, lobbies, corridors, stairwells, public restrooms, elevators, parking areas, loading and unloading areas, trash areas, roadways, walkways, driveways and landscaped areas.

 2.8 Common Areas - Lessee's Rights. Lessor grants to Lessee, for the benefit of Lessee and its employees, suppliers, shippers, contractors, customers and invitees, during the term of this Lesse, the non-exclusive right to use, in common with others entitled to such use, the Common Areas as they exist from time to time, subject to any rights, powers, and privileges reserved by Lessor under the terms hereof or under the terms of any rules and regulations or restrictions governing the use of the Project. Under no circumstances shall the right herein grant herein grant here to use the Common Areas be deemed to include the right to store any property, temporarily or permanently, in the Common Areas. Any such storage shall be permitted only by the prior written consent of Lessor or Lessor's designated agent, which consent may be revoked at any time. In the event that any unauthorized storage shall occur, then Lessor shall have the right, without notice, in addition to such other rights and remedies

that it may have, to remove the property and charge the cost to Lessee, which cost shall be immediately payable upon demand by Lessor. 2.9 Common Areas - Rules and Regulations. Lessor or such other person(s) as Lessor may appoint shall have the exclusive control and management of the Common Areas and shall have the right, from time to time, to adopt, modify, amend and enforce reasonable rules and regulations ("Rules and Regulations") for the management, safety, care, and cleanliness of the grounds, the parking and unloading of vehicles and the preservation of good order, as well as for the convenience of other occupants or tenants of the Building and the Project and their invitees. The Lessee agrees to abide by and conform to all such Rules and Regulations, and shall use its best efforts to cause its employees, suppliers, shippers, customers, contractors and invitees to so abide and conform. Lessor shall not be responsible to Lessee for the noncompliance with said Rules and Regulations by other tenants of the Project.

2.10 Common Areas - Changes, Lessor shall have the right, in Lessor's sole discretion, from time to time:

(a) To make changes to the Common Areas, including, without limitation, changes in the location, size, shape and number of the lobbies, windows, stairways, air shafts, elevators,

escalators, restrooms, driveways, entrances, parking spaces, parking areas, loading and unloading areas, ingress, egress, direction of traffic, landscaped areas, walkways and utility raceways; (b) To close temporarily any of the Common Areas for maintenance purposes so long as reasonable access to the Premises remains available;

To designate other land outside the boundaries of the Project to be a part of the Common Areas; (c)

To add additional buildings and improvements to the Common Areas; (d)

(e) To use the Common Areas while engaged in making additional improvements, repairs or alterations to the Project, or any portion thereof; and

(f) To do and perform such other acts and make such other changes in, to or with respect to the Common Areas and Project as Lessor may, in the exercise of sound business judgment, deem to be appropriate.

#### 3. Term.

Term. The Commencement Date, Expiration Date and Original Term of this Lease are as specified in Paragraph 1.3. 31

3.2 Early Possession. Any provision herein granting Lessee Early Possession of the Premises is subject to and conditioned upon the Premises being available for such possession prior to the Commencement Date. Any grant of Early Possession only conveys a non-exclusive right to occupy the Premises. If Lessee totally or partially occupies the Premises prior to the Commencement Date, the obligation to pay Base Rent shall be abated for the period of such Early Possession. All other terms of this Lease (including but not limited to the obligations to pay Lessee's Share of the Operating Expenses) shall be in effect during such period. Any such Early Possession shall not affect the Expiration Date.

3.3 Delay In Possession. See Addendum Lossor agro es to use its best or on of the Promises to Les oo by the Comm programont Data If or is unable to deliver possession by such date, Lessor shall not be subject to affect the validity of this Ler ed shall run from the date of delivery of possession and continue for a period equal **to what** Lesse the terms hereof, but minus any days of delay ed by the ns of Lessee. If possession is not delivered within 60 days after the Comr ed under the terms of any Work Letter executed by rged fro riting within 10 days after the end of such 60 day period, ol this I <del>on is not received by Lesser within said 10 day period. Lessee's right to ca</del> ncel shall ter ween Lessor and Less e. in writina.

3.4 Lessee Compliance. Lessor shall not be required to deliver possession of the Premises to Lessee until Lessee complies with its obligation to provide evidence of insurance (Paragraph 8.5). Pending delivery of such evidence, Lessee shall be required to perform all of its obligations under this Lease from and after the Start Date, including the payment of Rent, notwithstanding Lessor's election to withhold possession pending receipt of such evidence of insurance. Further, if Lessee is required to perform any other conditions prior to or concurrent with the Start Date, the Start Date shall occur but Lessor may elect to withhold possession until such conditions are satisfied.

4. Rent. Rent Defined. All monetary obligations of Lessee to Lessor under the terms of this Lease (except for the Security Deposit) are deemed to be rent ("Rent"). 4.1

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4.2 Operating Expenses. Lessee shall pay to Lessor during the term hereof, in addition to the Base Rent, Lessee's Share of all Operating Expenses, as hereinafter defined, during each calendar year of the term of this Lease, in accordance with the following provisions:

"Operating Expenses" include all costs relating to the ownership and operation of the Project, calculated as if the Project was at least 95% occupied, including, but not limited to, the (a) following

(i) The operation, repair, and maintenance in neat, clean, safe, good order and condition, of the following:

(aa) The Common Areas, including their surfaces, coverings, decorative items, carpets, drapes and window coverings, and including parking areas, loading and unloading areas, trash areas, roadways, sidewalks, walkways, stairways, parkways, driveways, landscaped areas, striping, bumpers, irrigation systems, Common Area lighting facilities, building exteriors and roofs, fences and gates;

(bb) All heating, air conditioning, plumbing, electrical systems, life safety equipment, communication systems and other equipment used in common by, or for the benefit of, lessees or occupants of the Project, including elevators and escalators, tenant directories, fire detection systems including sprinkler system maintenance and repair.

(cc) The Premises and/or any other space occupied by a tenant.

The cost of trash disposal, janitorial and security services, and pest control services, and the costs of any environmental inspections; The cost of any other service to be provided by Lessor that is elsewhere in this Lease stated to be an "Operating Expense"; (ii)

(iii) The cost of the premiums for the insurance policies maintained by Lessor pursuant to paragraph 8 and any deductible portion of an insured loss concerning the Building or the (iv)

Common Areas:

The amount of the Real Property Taxes payable by Lessor pursuant to paragraph 10; (v)

The cost of water, sewer, gas, electricity, and other publicly mandated services not separately metered; (vi) (vii) Labor, salaries, and applicable fringe benefits and costs, materials, supplies and tools, used in maintaining and/or cleaning the Project and accounting and management fees attributable to the operation of the Project;

(viii) The cost to replace equipment or capital components such as the roof, foundations, or exterior walls, the cost to replace a Common Area capital improvement, such as the parking lot paving, elevators or fences, and/or the cost of any capital improvement to the Building or the Project not covered under the provisions of Paragraph 2.3. Provided however, that if such equipment or capital component has a useful life for accounting purposes of 5 years or more that Lessor shall allocate the cost of any such capital improvement over a 12 year period and Lessee shall not be required to pay more than Lessee's Share of 1/144th of the cost of such capital improvement in any given month; (ix) The cost to replace equipment or improvements that have a useful life for accounting purposes of 5 years or less.

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(b) Any item of Operating Expense that is specifically attributable to the Premises, the Building or to any other building in the Project or to the operation, repair and maintenance thereof, shall be allocated entirely to such Premises, Building, or other building. However, any such item that is not specifically attributable to the Building or to any other building or to the operation, repair and maintenance thereof, shall be equitably allocated by Lessor to all buildings in the Project.

(c) The inclusion of the improvements, facilities and services set forth in Subparagraph 4.2(a) shall not be deemed to impose an obligation upon Lessor to either have said improvements or facilities or to provide those services unless the Project already has the same, Lessor already provides the services, or Lessor has agreed elsewhere in this Lease to provide the same or some of them. (d) See Addendum Lessee's Share of Operating Expenses is payable monthly on the same days as the Base Rent it due hereunder. The amount of such, payments shall be based on s estimate of the Operating Expenses Within 60 days after written request (but net more than once each year) Lesser shall deliver, to Lessee a reasenably detailed statement showing Lessee's Share of the actual Operating Expenses for the preceding year, If Lessee's payments during such year exceed Lessee's Share, Lesser shall credit the amount of such over payment against Lessee's future paymente. If Lesses's payments during such year were less than Lesses's Share, Lesses shall pay to Lesser the amount of the deficiency within 10 days after delivery by Lesser to Lesses of the

(e) Operating Expenses shall not include any expenses paid by any tenant directly to third parties, or as to which Lessor is otherwise reimbursed by any third party, other tenant, or by insurance proceeds

4.3 Payment. Lessee shall cause payment of Rent to be received by Lessor in lawful money of the United States, without offset or deduction (except as specifically permitted in this Lease), on or before the day on which it is due. All monetary amounts shall be rounded to the nearest whole dollar. In the event that any invoice prepared by Lessor is inaccurate such inaccuracy shall not constitute a waiver and Lessee shall be obligated to pay the amount set forth in this Lease. Rent for any period during the term hereof which is for less than one full calendar month shall be prorated based upon the actual number of days of said month. Payment of Rent shall be made to Lessor at its address stated herein or to such other persons or place as Lessor may from time to time designate in writing. Acceptance of a payment which is less than the amount then due shall not be a waiver of Lessor's rights to the balance of such Rent, regardless of Lessor's endorsement of any check so stating. In the event that any check, draft, or other instrument of payment given by Lessee to Lessor is dishonored for any reason, Lessee agrees to pay to Lessor the sum of \$25 in addition to any Late Charge and Lessor, at its option, may require all future Rent be paid by cashier's check. Payments will be applied first to accrued late charges and attorney's fees, second to accrued interest, then to Base Rent and Operating Expenses, and any remaining amount to any other outstanding charges or costs.

Security Deposit. Lessee shall deposit with Lessor upon execution hereof the Security Deposit as security for Lessee's faithful performance of its obligations under this Lease. If Lessee fails to pay Rent, or otherwise Defaults under this Lease, Lessor may use, apply or retain all or any portion of said Security Deposit for the payment of any amount already due Lessor, for Rents which will be due in the future, and/ or to reimburse or compensate Lessor for any liability, expense, loss or damage which Lessor may suffer or incur by reason thereof. If Lessor uses or applies all or any portion of the Security Deposit, Lessee shall within 10 days after written request therefor deposit monies with Lessor sufficient to restore said Security Deposit to the full amount required by this Lease. if the Bes ring the term of this Lease,Lessee shall, upon written request from Less or, deposit add me proportion to the increased Base Rent the initial Security Deposit bore to the initial Base Rent Should the Agreed Use be amended to accommodate a material change in the business of Lessee or to accommodate a sublessee or assignee, Lessor shall have the right to increase the Security Deposit to the extent necessary. In Lessor's reasonable judgment, to account for any increased wear and tear that the Premises may suffer as a result thereof. If a change in control of Lessee occurs during this Lease and following such change the financial condition of Lessee is, in Lessor's reasonable judgment, significantly reduced, Lessee shall deposit such additional monies with Lessor as shall be sufficient to cause the Security Deposit to be at a commercially reasonable level based on such change in financial condition. Lessor shall not be required to keep the Security Deposit separate from its general accounts. Within 90 days after the expiration or termination of this Lease, Lessor shall return that portion of the Security Deposit not used or applied by Lessor. Lessor shall upon written request provide Lessee with an accounting showing how that portion of the Security Deposit that was not returned was applied. No part of the Security Deposit shall be considered to be held in trust, to bear interest or to be prepayment for any monies to be paid by Lessee under this Lease. THE SECURITY DEPOSIT SHALL NOT BE USED BY LESSEE IN LIEU OF PAYMENT OF THE LAST MONTH'S RENT.

#### 6. Use.

6.1 Use. Lessee shall use and occupy the Premises only for the Agreed Use, or any other legal use which is reasonably comparable thereto, and for no other purpose. Lessee shall not use or permit the use of the Premises in a manner that is unlawful, creates damage, waste or a nuisance, or that disturbs occupants of or causes damage to neighboring premises or properties. Other than guide, signal and seeing eye dogs, Lessee shall not keep or allow in the Premises any pets, animals, birds, fish, or reptiles. Lessor shall not unreasonably withhold or delay its consent to any written request for a modification of the Agreed Use, so long as the same will not impair the structural integrity of the improvements of the Building, will not adversely affect the mechanical, electrical, HVAC, and other systems of the Building, and/or will not affect the exterior appearance of the Building. If Lessor elects to withhold consent, Lessor shall within 7 days after such request give written notification of same, which notice shall include an explanation of Lessor's objections to the change in the Agreed Use.

#### 6.2 Hazardous Substances.

(a) Reportable Uses Require Consent. The term "Hazardous Substance" as used in this Lease shall mean any product, substance, or waste whose presence, use, manufacture, disposal, transportation, or release, either by Itself or in combination with other materials expected to be on the Premises, is either: (i) potentially injurious to the public health, safety or welfare, the environment or the Premises, (ii) regulated or monitored by any governmental authority, or (iii) a basis for potential liability of Lessor to any governmental agency or third party under any applicable statute or common law theory. Hazardous Substances shall include, but not be limited to, hydrocarbons, petroleum, gasoline, and/or crude oil or any products, byproducts or fractions thereof. Lessee shall not engage in any activity in or on the Premises which constitutes a Reportable Use of Hazardous Substances without the express prior written consent of Lessor and timely compliance (at Lesse's expense) with all Applicable Requirements. "Reportable Use" shall mean (i) the installation or use of any above or below ground storage tank, (ii) the generation, possession, storage, use, transportation, or disposal of a Hazardous Substance that requires a permit from, or with respect to which a report, notice, registration or business plan is required to be filed with, any governmental authority, and/or (iii) the presence at the Premises of a Hazardous Substance with respect to which any Applicable Requirements requires that a notice be given to persons entering or occupying the Premises or neighboring properties. Notwithstanding the foregoing, Lessee may use any ordinary and customary materials reasonably required to be used in the normal course of the Agreed Use such as ordinary office supplies (copier toner, liquid paper, glue, etc.) and common household cleaning materials, so long as such use is in compliance with all Applicable Requirements, is not a Reportable Use, and does not expose the Premises or neighboring property to any meaningful risk of contamination or damage or expose Lessor to any liability therefor. In addition, Lessor may condition its consent to any

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Reportable Use upon receiving such additional assurances as Lessor reasonably deems necessary to protect itself, the public, the Premises and/or the environment against damage, contamination, injury and/or liability, including, but not limited to, the installation (and removal on or before Lease expiration or termination) of protective modifications (such as concrete encasements) and/or increasing the Security Deposit.

(b) Duty to Inform Lessor. If Lessee knows, or has reasonable cause to believe, that a Hazardous Substance has come to be located in, on, under or about the Premises, other than as previously consented to by Lessor, Lessee shall immediately give written notice of such fact to Lessor, and provide Lessor with a copy of any report, notice, claim or other documentation which it has concerning the presence of such Hazardous Substance.

(c) Lessee Remediation. Lessee shall not cause or permit any Hazardous Substance to be spilled or released in, on, under, or about the Premises (including through the plumbing or sanitary sewer system) and shall promptly, at Lessee's expense, comply with all Applicable Requirements and take all investigatory and/or remedial action reasonably recommended, whether or not formally ordered or required, for the cleanup of any contamination of, and for the maintenance, security and/or monitoring of the Premises or neighboring properties, that was caused or materially contributed to by Lessee, or pertaining to or involving any Hazardous Substance brought onto the Premises during the term of this Lease, by or for Lessee, or any third party.

(d) Lessee Indemnification. Lessee shall indemnify, defend and hold Lessor, its agents, employees, lenders and ground lessor, if any, harmless from and against any and all loss of rents and/or damages, liabilities, judgments, claims, expenses, penalties, and attorneys' and consultants' fees arising out of or involving any Hazardous Substance brought onto the Premises by or for Lessee, or any third party (provided, however, that Lessee shall have no liability under this Lease with respect to underground migration of any Hazardous Substance brought onto the Premises from area soutside of the Project not caused or contributed to by Lessee's obligations shall include, but not be limited to, the effects of any contamination or liniury to person, property or the environment created or suffered by Lessee, and the cost of investigation, removal, remediation, restoration and/or abatement, and shall survive the expiration or termination of this Lease. No termination, cancellation or release agreement entered into by Lessee shall release Lessee from its obligations under this Lease with respect to Hazardous Substances, unless specifically so agreed by Lessor in writing at the time of such agreement.

(e) Lessor Indemnification. Except as otherwise provided in paragraph 8.7, Lessor and Its successors and assigns shall Indemnify, defend, reimburse and hold Lessee, its employees and lenders, harmless from and against any and all environmental damages, including the cost of remediation, which result from Hazardous Substances which existed on the Premises prior to Lessee's occupancy or which are caused by the gross negligence or willful misconduct of Lessor, its agents or employees. Lessor's obligations, as and when required by the Applicable Requirements, shall include, but not be limited to, the cost of investigation, removal, remediation, restoration and/or abatement, and shall survive the expiration or termination of this Lease,

(f) Investigations and Remediations. Lessor shall retain the responsibility and pay for any investigations or remediation measures required by governmental entities having jurisdiction with respect to the existence of Hazardous Substances on the Premises prior to Lesse's occupancy, unless such remediation measure is required as a result of Lesse's used (Including "Alterations", as defined in paragraph 7.3(a) below) of the Premises, In which event Lesse shall be responsible for such payment, Lessee shall cooperate fully in any such activities at the request of Lessor, including allowing Lessor and Lessor's agents to have reasonable access to the Premises at reasonable times in order to carry out Lessor's investigative and remedial responsibilities.

(g) Lessor Termination Option. If a Hazardous Substance Condition (see Paragraph 9.1(e)) occurs during the term of this Lease, unless Lessee is legally responsible therefor (in which case Lessee shall make the investigation and remediation thereof required by the Applicable Requirements and this Lease shall continue in full force and effect, but subject to Lessor's rights under Paragraph 6.2(d) and Paragraph 13). Lessor may, at Lessor's option, either (i) investigate and remediate such LHazardous Substance Condition, if required, as soon as reasonably possible at Lessor's expense, in which event this Lease shall continue in full force and effect, or (ii) If the estimated cost to remediate such condition exceeds 12 times the then monthly Base Rent or \$100,000, whichever is greater, give written notice to Lessee, within 30 days after receipt by Lessor of knowledge of the occurrence of such Hazardous Substance Condition, of Lessor's desire to terminate this Lease as of the date 60 days following the date of such notice. In the event Lessor elects to give a termination notice, Lessee may, within 10 days thereafter, give written notice to Lessee of the remediation of such Hazardous Substance Condition is used to a substance to stand function exceeds an amount by which the cost of the remediation of such Hazardous Substance Condition exceeds an amount equal to 12 times the then monthly Base Rent or \$100,000, whichever is greater. Lessee shall provide Lessor with said funds or satisfactory assurance thereof within 30 days following such commitment. In such event, this Lease shall continue in full force and effect, and Lessor shall proceed to make such remediation as soon as reasonably possible after the required funds are available. If Lessee does not give such notice and provide the required funds or assurance thereof within in the time provide, this Lease shall terminate as of the date specified in Lessor's notice of termination.

6.3 Lessee's Compliance with Applicable Requirements. Except as otherwise provided In this Lease, Lessee shall, at Lessee's sole expense, fully, diligently and in a timely manner, materially comply with all Applicable Requirements, the requirements of any applicable fire insurance underwriter or rating bureau, and the recommendations of Lessor's engineers and/or consultants which relate in any manner to the Premises, without regard to whether said Applicable Requirements are now in effect or become effective after the Start Date. Lessee shall, within 10 days after receipt of Lessor's written request, provide Lessor with copies of all permits and other documents, and other information evidencing Lessee's compliance with any Applicable Requirements specified by Lessor, and shall immediately upon receipt, notify Lessor in writing (with copies of any documents involved) of any threatened or actual claim, notice, citation, warning, complaint or report pertaining to or Involving the failure of Lessee or the Premises to comply with any Applicable Requirements, Likewise, Lessee shall immediately give written notice to Lessor of: (i) any water damage to the Premises.

suspected seepage, pooling, dampness or other condition conducive to the production of mold; or (ii) any mustiness or other odors that might indicate the presence of mold in the Premises. 6.4 Inspection; Compliance. See Addendum Lessor and Lessor's "Lender" (as defined in Paragraph 30) and consultants authorized by Lessor shall have the right to entre into Premises at any time, in the case of an emergency, and otherwise at reasonable times, after reasonable notice, for the purpose of inspecting and/or testing the condition of the Premises and/or for verifying compliance by Lessee with this Lease. The cost of any such inspections shall be paid by Lessor, unless a violation of Applicable Requirements, or a Hazardous Substance Condition (see Paragraph 9.1) is found to exist or be imminent, or the inspection is requested or ordered by a governmental authority. In such case, Lessee shall upon request reimburse Lessor for the cost of such inspection, so long as such inspection is reasonably related to the violation or contamination. In addition, Lessee shall provide copies of all relevant material safety data sheets (MSDS) to Lessor within 10 days of the receipt of written request therefor. Lessee acknowledges that any failure on its part to allow such inspections or testing will expose Lessor to incur costs not contemplated by this Lease, the extent of which will be extremely difficult to ascertain. Accordingly, should the Lessee fail to allow such inspections and/or testing in a timely fashion the Base Rent shall be automatically increased, without any requirement for notice to Lessee, by an amount equal to 10% of the then existing Base Rent or \$100, whichever is greater for the remainder to the Lease. The Parites agree that such increase in Base Rent represents fair and reasonable compensation for the additional risk/costs that Lessor will incur by reason of Lessee's failure to allow such inspection and/or testing. Such increase in Base Rent shall in no event constitute a waiver of Lessee's Default or Br

#### 7. Maintenance; Repairs; Utility Installations; Trade Fixtures and Alterations.

7.1 Lessee's Obligations. Notwithstanding Lessor's obligation to keep the Premises in good condition and repair, Lessee shall be responsible for the cost of painting, repairing or replacing wall coverings, and to repair or replace any improvements within the Premises.

7.2 Lessor's Obligations. Subject to the provisions of Paragraphs 2.2 (Condition), 2.3 (Compliance), 4.2 (Operating Expenses), 6 (Use), 7.1 (Lessee's Obligations), 9 (Damage or Destruction) and 14 (Condemnation), Lessor, subject to reimbursement pursuant to Paragraph 4.2, shall keep in good order, condition and repair the Premises, the foundations, exterior walls, structural condition of interior bearing walls, exterior roof, fire sprinkler system, fire alarm and/or smoke detection systems, fire hydrants, and the Common Areas.

## 7.3 Utility Installations; Trade Fixtures; Alterations.

(a) Definitions. The term "Utility Installations" refers to all floor and window coverings, air lines, vacuum lines, power panels, electrical distribution, security and fire protection systems, communication cabling, lighting fixtures, HVAC equipment, and plumbing in or on the Premises. The term "Trade Fixtures" shall mean Lessee's machinery and equipment that can be removed without doing material damage to the Premises. The term "Alterations" shall mean any modification of the improvements, other than Utility Installations or Trade Fixtures, whether by addition or deletion. "Lessee Owned Alterations and/or Utility Installations" are defined as Alterations and/or Utility Installations made by Lessee that are not yet owned by Lessor pursuant to Paragraph 7.4(a).

(b) **Consent.** Lessee shall not make any Alterations or Utility Installations to the Premises without Lessor's prior written consent. Lessee may, however, make non-structural Alterations or Utility Installations to the interior of the Premises (excluding the roof) without such consent but upon notice to Lessor, as long as they are not visible from the outside, do not involve puncturing, relocating improvements to the Premises resulting from Applicable Requirements, such as compliance with Title 24, and the cumulative cost thereof during this Lesse as extended does not exceed \$2000\$15,000. Notwithstanding the foregoing, Lessee shall not make or permit any roof penetrations and/or install anything on the roof without the prior written approval of Lessor. Lessor may, as a precondition to granting such approval, require Lessee to utilize a contractor chosen and/or approved by Lessor. Any Alterations or Utility Installations that Lessee shall desire to make and which require the consent of the Lessor shall be presented to Lessor in written form with detailed plans. Consent shall be deemed conditioned upon Lessee's: (i) acquiring all applicable governmental permits, (ii) furnishing Lessor with copies of both the permits and the plans and specifications prior to commencement of the work, and (iii) compliance with all conditions of said permits and other Applicable Requirements in a prompt and expeditious manner. Any Alterations or Utility Installations shall be performed in a workmanlike manner with good and sufficient materials. Lessee shall promptly upon completion furnish Lessor with aspecifications. For work which costs an amount in excess of one month's Base Rent, Lessor may condition its consent upon Lessee providing a lien and completion bond in an amount equal to 150% of the

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estimated cost of such Alteration or Utility Installation and/or upon Lessee's posting an additional Security Deposit with Lessor. (c) Liens; Bonds. Lessee shall pay, when due, all claims for labor or materials furnished or alleged to have been furnished to or for Lessee at or for use on the Premises, which claims are or may be secured by any mechanic's or materialmen's lien against the Premises or any interest therein. Lessee shall give Lessor not less than 10 days notice prior to the commencement of any work in, on or about the Premises, and Lessor shall have the right to post notices of non-responsibility. If Lessee shall contest the validity of any such lien, claim or demand, then Lessee shall, at its sole expense defend and protect itself. Lessor and the Premises against the same and shall pay and satisfy any such adverse judgment that may be rendered thereon before the enforcement thereof. If Lessor shall require, Lessee shall furnish a surety bond in an amount equal to 150% of the amount of such contested lien, claim or demand, indemnifying Lessor against liability for the same. If Lessor elects to participate in any such action, Lessee shall pay Lessor's attorneys' fees and costs.

#### 7.4 Ownership; Removal; Surrender; and Restoration. See Addendum

(a) Ownership. Subject to Lessor's right to require removal or elect ownership as hereinafter provided, all Alterations and Utility Installations made by Lessee shall be the property of Lessee, but considered a part of the Premises. Lessor may, at any time, elect in writing to be the owner of all or any specified part of the Lessee Owned Alterations and Utility Installations. Unless otherwise instructed per paragraph 7.4(b) hereof, all Lessee Owned Alterations and Utility Installations shall, at the expiration or termination of this Lease, become the property of Lessor and be surrendered by Lessee with the Premises.

(b) Removal. By delivery to Lessee of written notice from Lessor not earlier than 90 and not later than 30 days prior to the end of the term of this Lease, Lessor may require that any or all Lessee Owned Alterations or Utility Installations be removed by the expiration or termination of this Lease. Lessor may require the removal at any time of all or any part of any Lessee Owned Alterations or Utility Installations made without the required consent.

(c) Surrender; Restoration. Lessee shall surrender the Premises by the Expiration Date or any earlier termination date, with all of the improvements, parts and surfaces thereof clean and free of debris, and in good operating order, condition and state of repair, ordinary wear and tear excepted. "Ordinary wear and tear" shall not include any damage or deterioration that would have been prevented by good maintenance practice. Notwithstanding the foregoing, if the Lessee occupies the Premises for 12 months or less, then Lessee shall surrender the Premises in the same condition as delivered to Lessee on the Start Date with NO allowance for ordinary wear and tear. Lessee shall repair any damage occasioned by the installation, maintenance or removal of Trade Fixtures, Lessee owned Alterations and/or Utility Installations, furnishings, and equipment as well as the removal of any storage tank installed by or for Lessee. Lessee shall also remove from the Premises any and all Hazardous Substances brought onto the Premises by or for Lessee, or any third party (except Hazardous Substances which were deposited via underground migration from areas outside of the Project) to the level specified in Applicable Requirements. Trade Fixtures shall remain the property of Lessee and shall be removed by Lessee. Any personal property of Lessee not removed on or before the Expiration Date or any earlier termination date shall be deemed to have been abandoned by Lessee and may be disposed of or retained by Lessor as Lessor may desire. The failure by Lessee to timely vacate the Premises pursuant to this Paragraph 7.4(c) without the express written consent of Lessor shall constitute a holdover under the provisions of Paragraph 26 below,

#### 8. Insurance; Indemnity.

8.1 Insurance Premiums. The cost of the premiums for the insurance policies maintained by Lessor pursuant to paragraph 8 are included as Operating Expenses (see paragraph 4.2 (a)(iv)). Said costs shall include increases in the premiums resulting from additional coverage related to requirements of the holder of a mortgage or deed of trust covering the Premises, Building and/or Project, increased valuation of the Premises, Building and/or Project, and/or a general premium rate increase. Said costs shall not, however, include any premium increases resulting from the nature of the occupancy of any other tenant of the Building. In no event, however, shall Lessee be responsible for any portion of the premium cost attributable to liability insurance coverage in excess of \$2,000,000 procured under Paragraph 8.2(b).

## 8.2 Liability Insurance.

(a) Carried by Lessee. Lessee shall obtain and keep in force a Commercial General Liability policy of insurance protecting Lessee and Lessor as an additional insured against claims for bodily injury, personal injury and property damage based upon or arising out of the ownership, use, occupancy or maintenance of the Premises and all areas appurtenant thereto. Such insurance shall be on an occurrence basis providing single limit coverage in an amount not less than \$24,000,000 per occurrence with an annual aggregate of not less than \$32,000,000. Lessee shall add Lessor as an additional insured by means of an endorsement at least as broad as the Insurance Service Organization's "Additional Insured-Managers or Lessors of Premises" Endorsement. The policy shall not contain any intra-insured exclusions as between insured persons or organizations, but shall include coverage for liability assumed under this Lease as an "insured contract" for the performance of Lessee's indemnity obligations under this Lease. The limits of said insurance shall not, however, limit the liability of Lessee nor relieve Lessee of any obligation hereunder. Lessee shall provide an endorsement on its liability policy(ies) which provides that its insurance shall be primary to and not contributory with any similar insurance carried by Lessor, whose insurance shall be considered excess insurance only. (b) Carried by Lessor. Lessor shall maintain liability insurance as described in Paragraph 8.2(a), in addition to, and not in lieu of, the insurance required to be maintained by Lessee.

#### Lessee shall not be named as an additional insured therein. 8.3 Property Insurance - Building, Improvements and Rental Value.

(a) Building and Improvements. Lessor shall obtain and keep in force a policy or policies of insurance in the name of Lessor, with loss payable to Lessor, any ground-lessor, and to any Lender insuring loss or damage to the Building and/or Project. The amount of such insurance shall be equal to the full insurable replacement cost of the Building and/or Project, as the same shall exist from time to time, or the amount required by any Lender, but in no event more than the commercially reasonable and available insurable value thereof. Lessee Owned Alterations and Utility Installations, Trade Fixtures, and Lessee's personal property shall be insured by Lessee not by Lessor. If the coverage is available and commercially appropriate, such policy or policies shall insure against all risks of direct physical loss or damage (except the perils of flood and/or earthquake unless required by a Lender), including coverage for debris removal and the enforcement of any Applicable Requirements requiring the upgrading, demolition, reconstruction or replacement of any portion of the Premises as the result of a covered loss. Said policy or policies shall also contain an agreed valuation provision in lieu of any coinsurance clause, waiver of subrogation, and inflation guard protection causing an increase in the annual property insurance coverage amount by a factor of not less than the adjusted U.S. Department of Labor Consumer Price Index for All Urban Consumers for the city nearest to where the Premises are located. If such insurance coverage has a deductible clause, the deductible amount shall not exceed \$5,000 per occurrence.

(b) Rental Value. Lessor shall also obtain and keep in force a policy or policies in the name of Lessor with loss payable to Lessor and any Lender, insuring the loss of the full Rent for one year with an extended period of indemnity for an additional 180 days ("Rental Value insurance"). Said insurance shall contain an agreed valuation provision in lieu of any coinsurance clause, and the amount of coverage shall be adjusted annually to reflect the projected Rent otherwise payable by Lessee, for the next 12 month period.

Adjacent Premises. Lessee shall pay for any increase in the premiums for the property insurance of the Building and for the Common Areas or other buildings in the Project if said (c)

increase is caused by Lessee's acts, omissions, use or occupancy of the Premises. (d) Lessee's Improvements. Since Lessor is the Insuring Party, Lessor shall not be required to insure Lessee Owned Alterations and Utility Installations unless the item in question has become the property of Lessor under the terms of this Lease.

#### 8.4 Lessee's Property: Business Interruption Insurance: Worker's Compensation Insurance.

(a) Property Damage. Lessee shall obtain and maintain insurance coverage on all of Lessee's personal property, Trade Fixtures, and Lessee Owned Alterations and Utility installations. Such insurance shall be full replacement cost coverage with a deductible of not to exceed \$1,000 per occurrence. The proceeds from any such insurance shall be used by Lessee for the replacement of personal property, Trade Fixtures and Lessee Owned Alterations and Utility Installations.

(b) Business Interruption. Lessee shall obtain and maintain loss of income and extra expense insurance in amounts as will reimburse Lessee for direct or indirect loss of earnings attributable to all perils commonly insured against by prudent lessees in the business of Lessee or attributable to prevention of access to the Premises as a result of such perils. (c) Worker's Compensation Insurance. Lessee shall obtain and maintain Worker's Compensation Insurance in such amount as may be required by Applicable Requirements. Such policy

shall include a 'Waiver of Subrogation' endorsement. Lessee shall provide Lessor with a copy of such endorsement along with the certificate of insurance or copy of the policy required by paragraph 8.5. (d) No Representation of Adequate Coverage. Lessor makes no representation that the limits or forms of coverage of insurance specified herein are adequate to cover Lessee's property, business operations or obligations under this Lease.

8.5 Insurance Policies. See Addendum Insurance required herein shall be by companies maintaining during the policy term a " Ceneral Policyholders Rating" of at least A., VII, as set forth in-surrent issue of " Best's Insurance Guide", or such other rating as may be required by a Lender, Lessee shall not do or permit to be done anything which invalidates the required insurance polici ents evidencing the existence and amounts of the all, prior to the Start Date, deliver to Lessor certified copies of policies of such insurance or certificates with copies of the required endo ed insurance. No such policy shall be canceable or subject to modification except after 30 days prior written notice to Lessor. Lessee shall, at least 10 days prior to the expiration of such policies, Lessor with evidence of renewals or "insurance binders" evidencing renewal thereof, or Lessor may increase his liability insurance coverage and charge the cost thereof to Less shall be payable by Lessee to Lessor upon domand. Such policies shall be for a term of at least one year, or the length of the remaining term of this Lease, whichever is less If either Party shall fall to to be carried by it, the other Party hav, but s

8.6 Waiver of Subrogation. Without affecting any other rights or remedies, Lessee and Lessor each hereby release and relieve the other, and waive their entire right to recover damages against the other, for loss of or damage to its property arising out of or incident to the perils required to be insured against herein. The effect of such

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releases and waivers is not limited by the amount of insurance carried or required, or by any deductibles applicable hereto. The Parties agree to have their respective property damage insurance carriers waive any right to subrogation that such companies may have against Lessor or Lessee, as the case may be, so long as the insurance is not invalidated thereby.

8.7 Indemnity. Except for Lessor's gross negligence or willful misconduct, Lessee shall indemnify, protect, defend and hold harmless the Premises, Lessor and its agents, Lessor's master or ground lessor, partners and Lenders, from and against any and all claims, loss of rents and/or damages, liens, judgments, penalties, attorneys' and consultants' fees, expenses and/or liabilities arising out of, involving, or in connection with, the use and/or occupancy of the Premises by Lessee. If any action or proceeding is brought against Lessor by reason of any of the foregoing matters, Lessee shall upon notice defend the same at Lessee's expense by counsel reasonably satisfactory to Lessor and Lessor shall cooperate with Lessee in such defense. Lessor need not have first paid any such claim in order to be defended or indemnified.

8.8 See Addendum Exemption of Lessor and its Agents from Liability. Notwithstanding the negligence or breach of this Lease by Lessor or its agents, neither Lessor nor its agents shall be liable under any circumstances for: (i) injury or damage to the person or goods, wares, merchandise or other property of Lessee, Lessee's employees, contractors, invitees, customers, or any other person in or about the Premises, whether such damage or injury is caused by or results from fire, steam, electricity, gas, water or rain, indoor air quality, the presence of mold or from the breakage, leakage, obstruction or other defects of pipes, fire sprinklers, wires, appliances, plumbing, HVAC or lighting fixtures, or from any other cause, whether such advage or from other sources or places, (ii) any damages arising from any act or neglect of any other tenant of Lessor or from the failure of Lessor or its agents to enforce the provisions of any other lease in the Project, or (iii) injury to Lessee's business or fing on so fincting or profit therefrom. Instead, it is intended that Lessee's sole recourse in the event of 'such damages or injury is to file a claim on the insurance policy(les) that Lessee is required to maintain pursuant to the provisions of paragraph 8.

8.9 Failure to Provide insurance. Lessee acknowledges that any failure on its part to obtain or maintain the insurance required herein will expose Lessor to risks and potentially cause Lessor to incur costs not contemplated by this Lease, the extent of which will be extremely difficult to ascertain. Accordingly, for any month or portion thereof that Lessee does not maintain the required insurance and/or does not provide Lessor with the required binders or certificates evidencing the existence of the required insurance, the Base Rent shall be automatically increased, without any requirement for notice to Lessee, by an amount equal to 10% of the then existing Base Rent or \$100, whichever is greater. The parties agree that such increase in Base Rent represents fair and reasonable compensation for the additional risk/costs that Lessor will incur by reason of Lessee's failure to maintain the required insurance. Such increase in Base Rent shall in no event constitute a waiver of Lessee's Default or Breach with the table to maintain such insurance, prevent the exercise of any of the other rights and remedies granted hereunder, nor relieve Lessee of its obligation to maintain the insurance specified in this Lease.

#### 9. Damage or Destruction. 9.1 Definitions.

(a) "Premises Partial Damage" shall mean damage or destruction to the improvements on the Premises, other than Lessee Owned Alterations and Utility Installations, which can reasonably be repaired in 3 months or less from the date of the damage or destruction, and the cost thereof does not exceed a sum equal to 6 month's Base Rent. Lessor shall notify Lessee in writing within 30 days from the date of the damage or destruction as to whether or not the damage is Partial or Total.

(b) "Premises Total Destruction" shall mean damage or destruction to the improvements on the Premises, other than Lessee Owned Alterations and Utility Installations and Trade Fixtures, which cannot reasonably be repaired in 3 months or less from the date of the damage or destruction and/or the cost thereof exceeds a sum equal to 6 month's Base Rent. Lessor shall notify Lessee in writing within 30 days from the date of the damage or destruction as to whether or not the damage is Partial or Total.

(c) "Insured Loss" shall mean damage or destruction to improvements on the Premises, other than Lessee Owned Alterations and Utility Installations and Trade Fixtures, which was caused by an event required to be covered by the insurance described in Paragraph 8.3(a), irrespective of any deductible amounts or coverage limits involved.

(d) "Replacement Cost" shall mean the cost to repair or rebuild the improvements owned by Lessor at the time of the occurrence to their condition existing immediately prior thereto, including demolition, debris removal and upgrading required by the operation of Applicable Requirements, and without deduction for depreciation.

(e) "Hazardous Substance Condition" shall mean the occurrence or discovery of a condition involving the presence of, or a contamination by, a Hazardous Substance, in, on, or under the Premises which requires restoration.

9.2 Partial Damage - Insured Loss. If a Premises Partial Damage that is an Insured Loss occurs, then Lessor shall, at Lessor's expense, repair such damage (but not Lesses's Trade Fixtures or Lessee Owned Alterations and Utility Installations) as soon as reasonably possible and this Lease shall continue in full force and effect; provided, however, that Lessor's election, make the repair of any damage or destruction the total cost to repair of which is \$5,000 or less, and, in such event, Lessor shall make any applicable insurance proceeds available to Lessee on a reasonable basis for that purpose. Notwithstanding the foregoing, if the required insurance was not in force or the insurance proceeds are not sufficient to effect such repair, the Insuring Party shall promptly contribute the shortage in proceeds as and when required to complete said repairs. In the event, however, such shortage was due to the fact that, by reason of the unique nature of the improvements, full replacement cost Insurance coverage was not commercially reasonable and available, Lessor shall have no obligation to pay for the shortage in proceeds or allow reasonable and available, Lessor shall have no obligation to pay for the shortage in such event, however, if the Premises unless Lessee provides Lessor with the funds to cover same, or adequate assurance thereof, within 10 days following receipt of written notice of such shortage and request therefor. If Lessor receives said funds or adequate assurance thereof within said 10 day period, the party responsible for making the repairs shall complete them as soon as easonable basis is commercially reasonable period. Lessor may nevertheless elect by written notice to Lessee within 10 days thereafter to; (i) make such restoration and repair as is commercially reasonable with Lesse this Lease shall remain in full force and effect. If such funds or assurance are not received, Lessor may nevertheless elect by written notice to Lessee within 10 days thereafter to; (i) make such restoration and repair a

9.3 Partial Damage - Uninsured Loss. If a Premises Partial Damage that is not an Insured Loss occurs, unless caused by a negligent or willful act of Lessee (in which event Lessee shall make the repairs at Lesse's expense), Lessor may either: (i) repair such damage as soon as reasonably possible at Lessor's expense (subject to reimbursement pursuant to Paragraph 4.2), in which event this Lease shall continue in full force and effect, or (ii) terminate this Lease by giving written notice to Lessee within 30 days after receipt by Lessor of knowledge of the occurrence of such damage, Such termination shall be effective 60 days following the date of such notice. In the event Lessor elects to terminate this Lease, Lessee shall have the right within 10 days after receipt of the termination notice to give written notice to Lessor without of such damage without reimbursement from Lessor. Lessee shall provide Lessor with said funds or satisfactory assurance thereof within 30 days after making such commitment. In such event this Lease shall continue in full force and effect, and Lessor shall proceed to make such repairs as soon as reasonably possible after the required funds are available. If Lessee does not make the required commitment, this Lease shall terminate as of the date specified in the termination notice.

9.4 Total Destruction. Notwithstanding any other provision hereof, if a Premises Total Destruction occurs, this Lease shall terminate 60 days following such Destruction. If the damage or destruction was caused by the gross negligence or willful misconduct of Lessee, Lessor shall have the right to recover Lessor's damages from Lessee, except as provided in Paragraph 8.6.
9.5 Damage Near End of Term. See Addendum if at any time during the last 6 months of this Lease there is damage for which the cost to repair-exceeds one month's Base Rent, whether or not

9.5 Damage Near End of Term. See Addendum if at any time during the last 6 months of this Lease there is damage for which the cost to repair exceeds one month's Base Rent, whether or not an Insured Less Lessor may terminate this Lease offective 60 days following the date of occurrence of such damage by giving a written termination notice to Lessee within 30 days after the date of occurrence of such damage. Notwithstanding the foregoing, if Lessee at that time has an exercisable option to extend this Lease to ro purchase the Premises, then Lessee may preserve this Lease by, (a) exercising such option and (b) providing Lessor with any shortage in insurance proceeds (or adequate assurance thereof) needed to make the repairs on or before the earlier of (i) the date which is 10 days after Lessee's receipt of Lessor's written notice purporting to terminate this Lease, or (ii) the date upon which such option expires. If Lessee duly exercises such option during such period and provides Lessor's written notice purporting to cover any shortage in insurance proceeds, Lessor shall, at Lessor's commercially reasonable expense, repair such damage as soon as reasonably possible and this Lease shall continue in full force and effect. If Lessee fails to exercise such option and provides such funds or assurance during such period, then this Lease shall terminate on the date specified in the termination notice and Lessee's option shall be extinguished.

### 9.6 Abatement of Rent; Lessee's Remedies.

(a) Abatement. In the event of Premises Partial Damage or Premises Total Destruction or a Hazardous Substance Condition for which Lessee is not responsible under this Lease, the Rent payable by Lessee for the period required for the repair, remediation or restoration of such damage shall be abated in proportion to the degree to which Lessee's use of the Premises is impaired, but not to exceed the proceeder received from the Rontal Value insurance. All other obligations of Lessee hereunder shall be performed by Lessee, and Lessor shall have no liability for any such damage, destruction, remediation, repair or restoration except as provided herein.

(b) Remedies. If Lessor shall be obligated to repair or restore the Premises and does not commence, in a substantial and meaningful way, such repair or restoration within 90 days after such obligation shall accrue, Lessee may, at any time prior to the commencement of such repair or restoration, give written notice to Lessor and to any Lenders of which Lessee has actual notice, of Lesse's election to terminate this Lease on a date not less than 60 days following the giving of such notice. If Lessee gives such notice and such repair or restoration is not commenced within 30 days, this Lease shall terminate as of the date specified in said notice. If the repair or restoration is commenced within such 30 days, this Lease shall continue in full force and effect. "Commence" shall ment either the unconditional authorization of the preparation of the required plans, or the beginning of the actual work on the Premises, whichever first occurs.

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9.7 Termination; Advance Payments. Upon termination of this Lease pursuant to Paragraph 6.2(g) or Paragraph 9, an equitable adjustment shall be made concerning advance Base Rent and any other advance payments made by Lessee to Lessor, Lessor shall, in addition, return to Lessee so much of Lessee's Security Deposit as has not been, or is not then required to be, used by Lessor,

#### 10. Real Property Taxes

10.1 Definitions. See Addendum As used herein, the term "Real Property Taxes" shall include any form of assessment; real estate, general, special, ordinary or extraordinary, or rental levy or tax (other than inheritance, personal income or estate taxes); improvement bond; and/or license fee imposed upon or levied against any legal or equitable interest of Lessor in the Project, Lessor's right to other income therefrom, and/or Lessor's business of leasing, by any authority having the direct or indirect power to tax and where the funds are generated with reference to the Project address. "Real Property Taxes" shall also include any tax, fee, levy, assessment or charge, or any increase therein: (i) imposed by reason of events occurring during the term of this Lease, including but not limited to, a change in the ownership of the Project, (ii) a change in the improvements thereon, and/or (iii) levied or assessed on machinery or equipment provided by Lessor to Lessee pursuant to this Lease. 10.2 Payment of Taxes. Except as otherwise provided in Paragraph 10.3, Lessor shall pay the Real Property Taxes applicable to the Project, and said payments shall be included in the

calculation of Operating Expenses in accordance with the provisions of Paragraph 4.2. 10.3 Additional Improvements. Operating Expenses shall not include Real Property Taxes specified in the tax assessor's records and work sheets as being caused by additional improvements

placed upon the Project by other lessees or by Lessor for the exclusive enjoyment of such other lessees. Notwithstanding Paragraph 10.2 hereof, Lessee shall, however, pay to Lessor at the time Operating Expenses are payable under Paragraph 4.2, the entirety of any increase in Real Property Taxes if assessed solely by reason of Alterations, Trade Fixtures or Utility Installations placed upon the Premises by Lessee or at Lessee's request or by reason of any alterations or improvements to the Premises made by Lessor subsequent to the execution of this Lease by the Parties. 10.4 Joint Assessment. If the Building is not separately assessed, Real Property Taxes allocated to the Building shall be an equitable proportion of the Real Property Taxes for all of the land and

Improvements included within the tax parcel assessed, such proportion to be determined by Lessor from the respective valuations assigned in the assessor's work sheets or such other information as

may be reasonably available. Lessor's reasonable determination thereof, in good faith, shall be conclusive. 10.5 Personal Property Taxes. Lessee shall pay prior to delinquency all taxes assessed against and levied upon Lessee Owned Alterations and Utility Installations, Trade Fixtures, furnishings, equipment and all personal property of Lessee contained in the Premises. When possible, Lessee shall cause its Lessee Owned Alterations and Utility Installations, Trade Fixtures, furnishings, equipment and all other personal property to be assessed and billed separately from the real property of Lesser. If any of Lessee's said property shall be assessed with Lessor's real property, Lessee shall pay Lessor the taxes attributable to Lessee's property within 10 days after receipt of a written statement setting forth the taxes applicable to Lessee's property.

#### 11. Utilities and Services.

11.1 Services Provided by Lessor. Lessor shall provide heating, ventilation, air conditioning, reasonable amounts of electricity for normal lighting and office machines, water for reasonable and normal drinking and lavatory use in connection with an office, and replacement light bulbs and/or fluorescent tubes and ballasts for standard overhead fixtures. Lessor shall also provide janitorial services to the Premises and Common Areas 5 times per week, excluding Building Holidays, or pursuant to the attached janitorial schedule, if any. Lessor shall not, however, be required to provide janitorial services to kitchens or storage areas included within the Premises.

11.2 Services Exclusive to Lessee. Notwithstanding the provision of paragraph 11.1, Lessee shall pay for all water, gas, heat, light, power, telephone and other utilities and services specially or exclusively supplied and/or metered exclusively to the Premises or to Lessee, together with any taxes thereon. If a service is deleted by Paragraph 1.13 and such service is not separately metered to the Premises, Lessee shall pay at Lessor's option, either Lessee's Share or a reasonable proportion to be determined by Lessor of all charges for such jointly metered service.

11.3 Hours of Service. Said services and utilities shall be provided during tin set forth in Paragraph 1.12. Utilities and se at other times shall be subi s.reau see to Lessor of the cost thereof.

11.4 Excess Usage by Lessee. Lessee shall not make connection to the utilities except by or through existing outlets and shall not install or use machiner t uses excess water, lighting or power, or suffer or permit any act that causes extra burden upon the utilities or services including but not limited to occurity and trash services, over standard office uge for the Project, Lessor shall require Lessee to reimburse Losser for any excess expenses or costs that may arise out of a branch of this subparagraph by Lessee, Lessor may, in its solo discreti at Lossoo's expense supplemental equipment and/ or separate na applicable to Lessee s excess use or load

11.5 Interruptions. There shall be no abatement of rent and Lessor shall not be liable in any respect whatsoever for the inadequacy, stoppage, interruption or discontinuance of any utility or service due to riot, strike, labor dispute, breakdown, accident, repair or other cause beyond Lessor's reasonable control or in cooperation with governmental request or directions.

# 12 Assignment and Subletting. See Addendum

12.1 Lessor's Consent Required.

(a) Lessee shall not voluntarily or by operation of law assign, transfer, mortgage or encumber (collectively, "assign or assignment") or sublet all or any part of Lessee's interest in this Lease or in the Premises without Lessor's prior written consent.

(b) Unless Lessee is a corporation and its stock is publicly traded on a national stock exchange, a change in the control of Lessee shall constitute an assignment requiring consent. The transfer, on a cumulative basis, of 26% 51% or more of the voting control of Lessee shall constitute a change in control for this purpose.

(c) The involvement of Lessee or its assets in any transaction, or series of transactions (by way of merger, sale not a formal assignment or hypothecation of this lease or Lesseo's assets occurs, which results or will result in a reduction of the Not Worth of Lessee by an amount gracter than 25% of such Net Worth as it was represented at the time of the execution of this Lease or at the time of the most recent assignment to which Lesser has consented, or as it exists immediately prior to said transaction or is constituting such reduction, whichever was or is greater, shall be considered an assignment of this Lease to which Lesser may withhold its consent "Net Worth of Lessee" shall mean the net worth of Lessee (excluding any quarantors) established under generally accepted accounting principles.

An assignment or subletting without consent shall, at Lessor's option, be a Default curable after notice per Paragraph 13.1(d), or a noncurable Breach without the necessity of any notice (d) and grace period. If Lessor elects to treat such unapproved assignment or subletting as a noncurable Breach, Lessor may either: (i) terminate this Lease, or (ii) upon 30 days written notice, increase the monthly Base Rent to 110% of the Base Rent then in effect. Further, in the event of such Breach and rental adjustment, (i) the purchase price of any option to purchase the Premises held by Lessee shall be subject to similar adjustment to 110% of the price previously in effect, and (ii) all fixed and non-fixed rental adjustments scheduled during the remainder of the Lease term shall be increased to 110% of the scheduled adjusted rent.

(e) Lessee's remedy for any breach of Paragraph 12.1 by Lessor shall be limited to compensatory damages and/or injunctive relief.

(f) Lessor may reasonably withhold consent to a proposed assignment or subletting if Lessee is in Default at the time consent is requested.

(g) Notwithstanding the foregoing, allowing a de minimis portion of the Premises, ie. 20 square feet or less, to be used by a third party vendor in connection with the installation of a vending machine or payphone shall not constitute a subletting.

12.2 Terms and Conditions Applicable to Assignment and Subletting.
(a) Regardless of Lessor's consent, no assignment or subletting shall: (i) be effective without the express written assumption by such assignee or sublessee of the obligations of Lessee under this Lease, (ii) release Lessee of any obligations hereunder, or (iii) alter the primary liability of Lessee for the payment of Rent or for the performance of any other obligations to be performed by Lessee

(b) Lessor may accept Rent or performance of Lessee's obligations from any person other than Lessee pending approval or disapproval of an assignment. Neither a delay in the approval or disapproval of such assignment nor the acceptance of Rent or performance shall constitute a waiver or estoppel of Lessor's right to exercise its remedies for Lessee's Default or Breach

(c) Lessor's consent to any assignment or subletting shall not constitute a consent to any subsequent assignment or subletting.
 (d) In the event of any Default or Breach by Lessee, Lessor may proceed directly against Lessee, any Guarantors or anyone else responsible for the performance of Lessee's obligations

under this Lease, including any assignee or sublessee, without first exhausting Lessor's remedies against any other person or entity responsible therefor to Lessor, or any security held by Lessor. (e) Each request for consent to an assignment or subletting shall be in writing, accompanied by information relevant to Lessor's determination as to the financial and operational responsibility and appropriateness of the proposed assignee or sublessee, including but not limited to the intended use and/or required modification of the Premises, if any, together with a fee of \$1,000500

as consideration for Lessor's considering and processing said request. Lessee agrees to provide Lessor with such other or additional information and/or documentation as may be reasonably requested. (See also Paragraph 36)

(f) Any assignee of, or sublessee under, this Lease shall, by reason of accepting such assignment, entering into such sublease, or entering into possession of the Premises or any portion thereof, be deemed to have assumed and agreed to conform and comply with each and every term, covenant, condition and obligation herein to be observed or performed by Lessee during the term of said assignment or sublease, other than such obligations as are contrary to or inconsistent with provisions of an assignment or sublease to which Lessor has specifically consented to in writing.

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(g) Lessor's consent to any assignment or subletting shall not transfer to the assignee or sublessee any Option granted to the original Lessee by this Lease unless such transfer is specifically consented to by Lessor in writing. (See Paragraph 39.2)

12.3 Additional Terms and Conditions Applicable to Subletting. The following terms and conditions shall apply to any subletting by Lessee of all or any part of the Premises and shall be deemed included in all subleases under this Lease whether or not expressly incorporated therein: (a) Lessee hereby assigns and transfers to Lessor all of Lessee's interest in all Rent payable on any sublease, and Lessor may collect such Rent and apply same toward Lessee's

(a) Lessee hereby assigns and transfers to Lessor all of Lessee's interest in all Rent payable on any sublease, and Lessor may collect such Rent and apply same toward Lessee's obligations under this Lease; provided, however, that until a Breach shall occur in the performance of Lessee's obligations, Lessee may collect said Rent. In the event that the amount collected by Lessor exceeds Lessee's then outstanding obligations any such excees shall be refunded to Lessee. Lessor shall not, by reason of the foregoing or any assignment of such sublease, nor by reason of the collection of Rent, be deemed liable to the sublessee for any failure of Lessee to perform and comply with any of Lessee's obligations to such sublessee. Lessor and directs any such sublease, upon receipt of a written notice from Lessor stating that a Breach exists in the performance of Lessee's obligation or right to inquire as to whether such Breach exists, notwithstanding any claim from Lessee shall rely upon any such notice from Lessor and shall pay all Rents to Lessor without any obligation or right to inquire as to whether such Breach exists, notwithstanding any claim from Lessee to the contrary.

(b) In the event of a Breach by Lessee, Lessor may, at its option, require sublessee to attorn to Lessor, in which event Lessor shall undertake the obligations of the sublessor under such sublease from the time of the exercise of said option to the expiration of such sublease; provided, however, Lessor shall not be liable for any prepaid rents or security deposit paid by such sublessee to such sublessor or for any prior Defaults or Breaches of such sublessor.

(c) Any matter requiring the consent of the sublessor under a sublease shall also require the consent of Lessor,

(d) No sublessee shall further assign or sublet all or any part of the Premises without Lessor's prior written consent.

(e) Lessor shall deliver a copy of any notice of Default or Breach by Lessee to the sublessee, who shall have the right to cure the Default of Lessee within the grace period, if any, specified in such notice. The sublessee shall have a right of reimbursement and offset from and against Lessee for any such Defaults cured by the sublessee.

#### 13. Default; Breach; Remedies. See Addendum

13.1 Default; Breach. A "Default" is defined as a failure by the Lessee to comply with or perform any of the terms, covenants, conditions or Rules and Regulations under this Lease. A "Breach" is defined as the occurrence of one or more of the following Defaults, and the failure of Lessee to cure such Default within any applicable grace period:

(a) The abandonment of the Premises; or the vacating of the Premises without providing a commercially reasonable level of security, or where the coverage of the property insurance described in Paragraph 8.3 is jeopardized as a result thereof, or without providing reasonable assurances to minimize potential vandalism.

(b) The failure of Lessee to make any payment of Rent or any Security Deposit required to be made by Lessee hereunder, whether to Lessor or to a third party, when due, to provide reasonable evidence of insurance or surety bond, or to fulfill any obligation under this Lease which endangers or threatens life or property, where such failure continues for a period of 3 business days following written notice to Lessee. THE ACCEPTANCE BY LESSOR OF A PARTIAL PAYMENT OF RENT OR SECURITY DEPOSIT SHALL NOT CONSTITUTE A WAIVER OF ANY OF LESSOR'S RIGHT TO RECOVER POSSESSION OF THE PREMISES.

(c) The failure of Lessee to allow Lessor and/or its agents access to the Premises or the commission of waste, act or acts constituting public or private nuisance, and/or an illegal activity on the Premises by Lessee, where such actions continue for a period of 3 business days following written notice to Lessee. In the event that Lessee commits waste, a nuisance or an illegal activity a second time then, the Lessor may elect to treat such conduct as a non-curable Breach rather than a Default.
 (d) The failure by Lessee to provide (i) reasonable written evidence of compliance with Applicable Requirements, (ii) the service contracts, (iii) the rescission of an unauthorized assignment

(d) The failure by Lessee to provide (i) reasonable written evidence of compliance with Applicable Requirements, (ii) the service contracts, (iii) the rescission of an unauthorized assignment or subletting, (iv) an Estoppel Certificate or financial statements, (v) a requested subordination, (vi) evidence concerning any guaranty and/or Guarantor, (vii) any document requested under Paragraph 41, (viii) material safety data sheets (MSDS), or (ix) any other documentation or information which Lessor may reasonably require of Lessee under the terms of this Lease, where any such failure continues for a period of 10 days following written notice to Lessee.

(e) A Default by Lessee as to the terms, covenants, conditions or provisions of this Lease, or of the rules adopted under Paragraph 2.9 hereof, other than those described in subparagraphs 13.1(a), (b), (c) or (d), above, where such Default continues for a period of 30 days after written notice; provided, however, that if the nature of Lessee's Default is such that more than 30 days are reasonably required for its cure, then it shall not be deemed to be a Breach if Lessee commences such cure within said 30 day period and thereafter diligently prosecutes such cure to completion.

(f) The occurrence of any of the following events: (i) the making of any general arrangement or assignment for the benefit of creditors; (ii) becoming a "debtor" as defined in 11 U.S.C. § 101 or any successor statute thereto (unless, in the case of a petition filed against Lessee, the same is dismissed within 60 days); (iii) the appointment of a trustee or receiver to take possession of substantially all of Lessee's assets located at the Premises or of Lessee's interest in this Lease, where possession is not restored to Lessee within 30 days; or (iv) the attachment, execution or other judicial seizure of substantially all of Lessee's assets located at the Premises or of Lessee's interest in this Lease, where such seizure is not discharged within 30 days; provided, however, in the event that any provision of this subparagraph (e) is contrary to any applicable law, such provision shall be of no force or effect, and not affect the validity of the remaining provisions. (g) The discovery that any financial statement of Lessee or of any Guarantor given to Lessor was materially false.

(h) If the performance of Lessee's obligations under this Lease is guaranteed: (i) the death of a Guarantor, (ii) the termination of a Guarantor's liability with respect to this Lease other than in accordance with the terms of such guaranty, (iii) a Guarantor's becoming insolvent or the subject of a bankruptcy filing, (iv) a Guarantor's refusal to honor the guaranty, or (v) a Guarantor's breach of its guaranty obligation on an anticipatory basis, and Lessee's failure, within 60 days following written notice of any such event, to provide written alternative assurance or security, which, when coupled with the then existing resources of Lessee, equals or exceeds the combined financial resources of Lessee and the Guarantors that existed at the time of execution of this Lease.

13.2 Remedies. If Lessee fails to perform any of its affirmative duties or obligations, within 10 days after written notice (or in case of an emergency, without notice), Lessor may, at its option, perform such duty or obligation on Lessee's behalf, including but not limited to the obtaining of reasonably required bonds, insurance policies, or governmental licenses, permits or approvals. Lessee shall pay to Lessor an amount equal to 115% of the costs and expenses incurred by Lessor in such performance upon receipt of an invoice therefor. In the event of a Breach, Lessor may, with or without further notice or demand, and without limiting Lessor in the exercise of any right or remedy which Lessor may have by reason of such Breach:

(a) Terminate Lessee's right to possession of the Premises by any lawful means, in which case this Lease shall terminate and Lessee shall immediately surrender possession to Lessor. In such event Lessor shall be entitled to recover from Lessee: (i) the unpaid Rent which had been earned at the time of termination; (ii) the worth at the time of award of the amount by which the unpaid rent which would have been earned after termination until the time of award of the amount of such rental loss that the Lessee proves could have been reasonably avoided; (iii) the worth at the time of award of the amount py which the unpaid rent for the balance of the term after the time of award exceeds the amount of such rental loss that the Lessee proves could have been reasonably avoided; (iii) any other amount necessary to compensate Lessor for all the detiment proximately caused by the Lessee's failure to perform its obligations under this Lease or which in the ordinary course of things would be likely to result therefrom, including but not limited to the cost of recovering possession of the Premises, expenses of releting, including necessary renovation and alteration of the Premises, reasonable attorneys' fees, and that portion of any leasing commission paid by Lessor in connection with this Lease explicable to the unexpired term of this Lease. The worth at the time of award of the amount referred to in provision (iii) of the immediately preceding sentence shall be computed by discounting such amount at the discount rate of the Federal Reserve Bank of the District within which the Premises are located at the time of award pus one percent. Efforts by Lessor to mitigate damages caused by Lessee's Breach of this Lease shall have the right to recover in such proceeding any unpaid Rent and damages as are recoverable therein, or Lessor may reserve the right to recover all or any part thereof in a separate suit. If a notice and grace period required under Paragraph 13.1 was not previously given, a notice to pay rent or quit, or to per

(b) Continue the Lease and Lessee's right to possession and recover the Rent as it becomes due, in which event Lessee may sublet or assign, subject only to reasonable limitations. Acts of maintenance, efforts to relet, and/or the appointment of a receiver to protect the Lessor's interests, shall not constitute a termination of the Lessee's right to possession.

(c) Pursue any other remedy now or hereafter available under the laws or judicial decisions of the state wherein the Premises are located. The expiration or termination of this Lease and/or the termination of Lessee's right to possession shall not relieve Lessee from liability under any indemnity provisions of this Lease as to matters occurring or accruing during the term hereof or by reason of Lessee's occupancy of the Premises.

13.3 Inducement Recapture. Any agreement for free or abated rent or other charges, the cost of tenant improvements for Lessee paid for or performed by Lessor, or for the giving or paying by Lessor to or for Lessee of any cash or other bonus, inducement or consideration for Lessee's entering into this Lease, all of which concessions are hereinafter referred to as "Inducement Provisions," shall be deemed conditioned upon Lessee's full and faithful performance of all of the terms, covenants and conditions of this Lease. Upon Breach of this Lease, any such Inducement Provision shall be deemed deleted from this Lease and of no further force or effect, and any rent, other charge, bonus, inducement or consideration theretofore abated, given or paid by Lessor under such an Inducement Provision shall be immediately due and payable by Lesse to Lessor, notwithstanding any subsequent cure of said Breach by Lessee. The acceptance by Lessor of rent or the cure of the Breach which initiated the operation of this paragraph shall not be deemed a waiver by Lessor of the provisions of this paragraph unless specifically so stated in writing by Lessor at the time of such acceptance.

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13.4 Sec Addendum Late Charges. Lessee hereby acknowledges that late payment by Lessee of Rent will cause Lessor to incur costs not contemplated by this Lease, the exact amount of which will be extremely difficult to ascertain. Such costs include, but are not limited to, processing and accounting charges, and late charges which may be imposed upon Lessor by any Lender. Accordingly, if any Rent shall not be received by Lessor within 5 days after such amount shall be due, then, without any requirement for notice to Lessee, Lessee shall immediately pay to Lessor a one-time late charge equal to 10% of each such overdue amount or \$100, whichever is greater. The parties hereby agree that such late charge represents a fair and reasonable estimate of the costs Lessor will incur by reason of such late payment. Acceptance of such late charge by Lessor shall in no event constitute a waiver of Lessee's Default or Breach with respect to such overdue amount, nor prevent the exercise of any of the other rights and remedies granted hereunder. In the event that a late charge is payable hereunder, whether or not collected, for 3 consecutive installments of Base Rent, then notwithstanding any provision of this Lease to the contrary, Base Rent shall, at Lessor's option, become due and payable quarterly in advance.

provision of this Lease to the contrary, Base Rent shall, at Lessor's option, become due and payable quarterly in advance. 13.5 Interest. Any monetary payment due Lessor hereunder, other than late charges, not received by Lessor, when due shall bear interest from the 31st day after it was due. The interest ('Interest') charged shall be computed at the rate of 10% per annum but shall not exceed the maximum rate allowed by law. Interest is payable in addition to the potential late charge provided for In Paragraph 13.4.

### 13.6 Breach by Lessor.

(a) Notice of Breach. Lessor shall not be deemed in breach of this Lease unless Lessor fails within a reasonable time to perform an obligation required to be performed by Lessor. For purposes of this Paragraph, a reasonable time shall in no event be less than 30 days after receipt by Lessor, and any Lender whose name and address shall have been furnished to Lessee in writing for such purpose, of written notice specifying wherein such obligation of Lessor has not been performed; provided, however, that if the nature of Lessor's obligation is such that more than 30 days are reasonably required for its performance, then Lessor shall note in breach if performance is commenced within such 30 day period and thereafter diligently pursued to completion. (b) Performance by Lessoe on Behalf of Lessor. In the event that neither Lessor nor Lender cures said breach within 30 days after receipt of said notice,

(b) Performance by Lessee on Behalf of Lesses. In the event that neither Lessor nor Lender cures said breach within 30 days after receipt of said notice, or if having commenced said cure they do not diligently pursue it to completion, then Lessee may elect to cure said breach at Lesse's expense and offset from Rent the actual and reasonable cost to perform such cure, provided, however, that such offset shall not exceed an amount equal to the greater of one month's Base Rent or the Security Deposit, reserving Lessee's right to seek reimbursement from Lessor for any such expense in excess of such offset. Lessee shall document the cost of said cure and supply said documentation to Lessor.

14. Condemnation. If the Premises or any portion thereof are taken under the power of eminent domain or sold under the threat of the exercise of said power (collectively "Condemnation"), this Lease shall terminate as to the part taken as of the date the condemning authority takes title or possession, whichever first occurs. If more than 10% of the rentable floor area of the Premises, or more than 25% of Lessee's Reserved Parking Spaces, if any, are taken by Condemnation, Lessee may, at Lessee's option, to be exercised in writing within 10 days after Lessor shall have given Lessee written notice of such taking (or in the absence of such notice, within 10 days after the condemning authority takes such possession) terminate this Lease as of the date the condemning authority takes such possession. If Lessee does not terminate this Lease in accordance with the foregoing, this Lease shall remain in full force and effect as to the portion of the Premises remaining, except that the Base Rent shall be reduced in proportion to the reduction in utility of the Premises caused by such Condemnation. Condemnation awards and/or payments shall be the property of Lessor, whether such award shall be made as compensation for diminution in value of the leasehold, the value of the part taken, or for severance damages; provided, however, that Lessee shall be entitled to any compensation paid by the condemnor for Lessee's relocation expenses, loss of business goodwill and/or Trade Fixtures, without regard to whether or not this Lease is terminated pursuant to the provisions of this Paragraph. All Alterations and Utility Installations made to the Premises to use is not terminated by reason of the Condemnation, Lessor shall repair any damage to the Premises caused by such Condemnation.

#### 15. Brokerage Fees.

45.1 Additional Commission. In addition to the payments owed pursuant to Paragraph 1.10 above, Lessor agrees that: (a) if Lessee exercises any Option,(b) Lessee or anyone affiliated with Lessee acquires form Lesser any rights to the Premises or other premises owned by Lesser and leaded within the Project, (b) if Lessee remains in possession of the Premises, with the consent of Lesser, after the expiration of this Lease, or (d) if Base Rent is increased, whether by agreement or operation of an escalation clause herein, then, Lesser shall pay Brokers a fee in accordance with the fee schedule of the Brokers in offeet at the time the Lease was executed.

15.2 Assumption of Obligations. Any buyer or transferee of Lessor's interest in this Lease shall be deemed to have assumed Lessor's obligation hereunder. Brokers shall be third party beneficiaries of the provisions of Paragraphs 1.10, 15, 22 and 31. If Lessor fails to pay to Brokers any amounts due as and for brokerage fees pertaining to this Lease when due, then such amounts shall accrue Interest. In addition, if Lessor fails to pay any amounts to Lessee's Broker may send written notice to Lessor and Lessee of such failure and if Lessor fails to pay such amounts within 10 days after said notice, Lessee shall pay said monies to its Broker and offset such amounts against Rent. In addition, Lessee's Broker shall be deemed to be a third party beneficiary of any commission agreement entered into by and/or between Lessor and Lessor's Broker for the limited purpose of collecting any brokerage fee owed.
15.3 Representations and Indemnities of Broker Relationships. Lessee and Lessor each represent and warrant to the other that it has had no dealings with any person, firm, broker or finder

15.3 Representations and Indemnities of Broker Relationships. Lessee and Lessor each represent and warrant to the other that it has had no dealings with any person, firm, broker or finder (other than the Brokers, if any) in connection with this Lesse, and that no one other than said named Brokers is entitled to any commission or finder's fee in connection herewith. Lessee and Lessor do each hereby agree to indemnify, protect, defend and hold the other harmless from and against liability for compensation or charges which may be claimed by any such unnamed broker, finder or other similar party by reason of any dealings or actions of the indemnifying Party, including any costs, expenses, attorneys' fees reasonably incurred with respect thereto.

#### 16. Estoppel Certificates.

(a) Each Party (as "**Responding Party**") shall within 10 days after written notice from the other Party (the "**Requesting Party**") execute, acknowledge and deliver to the Requesting Party a statement in writing in form similar to the then most current "**Estoppel Certificate**" form published BY AIR CRE, plus such additional information, confirmation and/or statements as may be reasonably requested by the Requesting Party.

(b) If the Responding Party shall fail to execute or deliver the Estoppel Certificate within such 10 day period, the Requesting Party may execute an Estoppel Certificate stating that: (i) the Lease is in full force and effect without modification except as may be represented by the Requesting Party, (ii) there are no uncured defaults in the Requesting Party's performance, and (iii) if Lessor is the Requesting Party shall be estopped from denying the truth of the facts contained in said Certificate. In addition, Lessee acknowledges that any failure on its part to provide such an Estoppel Certificate will expose Lessor to risks and potentially cause Lessor to incur costs not contemplated by this Lease, the extent of which will be extremely difficult to ascertain. Accordingly, should the Lessee fail to execute and/or deliver a requested Estoppel Certificate is remeander of the Lease. The Parties agree that such increase in Base Rent that Lessor will now by reason of Lessee's failure to provide the Estoppel Certificate nor prevent the exercise of any of the other rights and remedies granted hereunder.

(c) If Lessor desires to finance, refinance, or sell the Premises, or any part thereof, Lessee and all Guarantors shall within 10 days after written notice from Lessor deliver to any potential lender or purchaser designated by Lessor such financial statements as may be reasonably required by such lender or purchaser, including but not limited to Lessee's financial statements for the past 3 years. All such financial statements shall be received by Lessor and such lender or purchaser in confidence and shall be used only for the purposes herein set forth.

17. Definition of Lessor. The term "Lessor" as used herein shall mean the owner or owners at the time in question of the fee title to the Premises, or, if this is a sublease, of the Lessee's interest in the prior lease. In the event of a transfer of Lessor's title or interest in the Premises or this Lease, Lessor shall deliver to the transferee or assignee (in cash or by credit) any unused Security Deposit held by Lessor. Upon such transfer or assignment and delivery of the Security Deposit, as aforesaid, the prior Lessor shall be relieved of all liability with respect to the obligations and/or covenants under this Lease thereafter to be performed by the Lessor. Subject to the foregoing, the obligations and/or covenants in this Lease to be performed by the Lessor shall be binding only upon the Lessor as hereinabove defined.

18. Severability. The invalidity of any provision of this Lease, as determined by a court of competent jurisdiction, shall in no way affect the validity of any other provision hereof.

19. Days. Unless otherwise specifically indicated to the contrary, the word "days" as used in this Lease shall mean and refer to calendar days.

20. Limitation on Liability. The obligations of Lessor under this Lease shall not constitute personal obligations of Lessor, or its partners, members, directors, officers or shareholders, and Lessee shall look to the Project, and to no other assets of Lessor, for the satisfaction of any liability of Lessor with respect to this Lease, and shall not seek recourse against Lessor's partners, members, directors, officers or shareholders, or any of their personal assets for such satisfaction.

21. Time of Essence. Time is of the essence with respect to the performance of all obligations to be performed or observed by the Parties under this Lease.

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22. No Prior or Other Agreements; Broker Disclaimer. This Lease contains all agreements between the Parties with respect to any matter mentioned herein, and no other prior or contemporaneous agreement or understanding shall be effective. Lessor and Lessee each represents and warrants to the Brokers that it has made, and is relying solely upon. Its own investigation as to the nature, quality, character and financial responsibility of the other Party to this Lease and as to the use, nature, quality and character of the Premises. Brokers have no responsibility with respect thereto or with respect to any default or breach hereof by either Party.

#### 23. Notices

23.1 Notice Requirements. All notices required or permitted by this Lease or applicable law shall be in writing and may be delivered in person (by hand or by courier) or may be sent by regular, certified or registered mail or U.S. Postal Service Express Mail, with postage prepaid, or by faceimile transmission, or by email, and shall be deemed sufficiently given if served in a manner specified in this Paragraph 23. The addresses noted adjacent to a Party's signature on this Lease shall be that Party's address for delivery or mailing of notices. Either Party may by written notice to the other specify a different address for notice, except that upon Lessee's taking possession of the Premises, the Premises shall constitute Lessee's address for notice. A copy of all notices to Lessor shall be concurrently transmitted to such party or parties at such addresses as Lessor may from time to time hereafter designate in writing.

23.2 Date of Notice. Any notice sent by registered or certified mail, return receipt requested, shall be deemed given on the date of delivery shown on the receipt card, or if no delivery date is shown, the postmark thereon. If sent by regular mail the notice shall be deemed given 72 hours after the same is addressed as required herein and mailed with postage prepaid. Notices delivered by United States Express Mail or overnight courier that guarantees next day delivery shall be deemed given 24 hours after delivery of the same to the Postal Service or courier. Notices delivered by hand, er transmitted by faceimile transmission or by email shall be deemed delivered upon actual receipt. If notice is received on a Saturday, Sunday or legal holiday, it shall be deemed received on the next business day.

#### 24. Waivers

(a) No waiver by Lessor of the Default or Breach of any term, covenant or condition hereof by Lessee, shall be deemed a waiver of any other term, covenant or condition hereof, or of any subsequent Default or Breach by Lessee of the same or of any other term, covenant or condition hereof. Lessor's consent to, or approval of, any act shall not be deemed to render unnecessary the obtaining of Lessor's consent to, or approval of, any subsequent or similar act by Lessee, or be construed as the basis of an estoppel to enforce the provision or provisions of this Lease requiring such consent.

(b) The acceptance of Rent by Lessor shall not be a waiver of any Default or Breach by Lessee. Any payment by Lessee may be accepted by Lessor on account of monies or damages due Lessor, notwithstanding any qualifying statements or conditions made by Lessee in connection therewith, which such statements and/or conditions shall be of no force or effect whatsoever unless specifically agreed to in writing by Lessor at or before the time of deposit of such payment.

(c) THE PARTIES AGREE THAT THE TERMS OF THIS LEASE SHALL GOVERN WITH REGARD TO ALL MATTERS RELATED THERETO AND HEREBY WAIVE THE PROVISIONS OF ANY PRESENT OR FUTURE STATUTE TO THE EXTENT THAT SUCH STATUTE IS INCONSISTENT WITH THIS LEASE.

#### 25. Disclosures Regarding The Nature of a Real Estate Agency Relationship.

(a) When entering into a discussion with a real estate agent regarding a real estate transaction, a Lessor or Lessee should from the outset understand what type of agency relationship or representation it has with the agent or agents in the transaction. Lessor and Lessee acknowledge being advised by the Brokers in this transaction, as follows:

(i) <u>Lessor's Agent</u>. A Lessor's agent under a listing agreement with the Lessor acts as the agent for the Lessor only. A Lessor's agent or subagent has the following affirmative obligations: <u>To the Lessor</u>. A fiduciary duty of utmost care, integrity, honesty, and loyalty in dealings with the Lessor. <u>To the Lessee and the Lessor</u>. (a) Diligent exercise of reasonable skills and care in performance of the agent's duties. (b) A duty of honest and fair dealing and good faith. (c) A duty to disclose all facts known to the agent materially affecting the value or desirability of the property that are not known to, or within the diligent attention and observation of, the Parties. An agent is not obligated to reveal to either Party any confidential information obtained from the other Party which does not involve the affirmative duties set forth above.

(ii) <u>Lessee's Agent</u>. An agent can agree to act as agent for the Lessee only. In these situations, the agent is not the Lessor's agent, even if by agreement the agent may receive compensation for services rendered, either in full or in part from the Lessor. An agent acting only for a Lessee has the following affirmative obligations. <u>To the Lessee</u>: A fiduciary duty of honest and fair dealing and good faith. (c) A duty to disclose all facts known to the agent materially affecting the value or desirability of the property that are not known to, or within the diligent attention and observation of, the Parties. An agent is not obligated to reveal to either Party any confidential information obtained from the other Party which does not involve the affirmative duties set forth above.

(iii) <u>Agent Representing Both Lessor and Lessee</u>. A real estate agent, either acting directly or through one or more associate licenses, can legally be the agent of both the Lessor and the Lesser and the Lessee in a transaction, but only with the knowledge and consent of both the Lessor and the Lessee. In a dual agency situation, the agent has the following affirmative obligations to both the Lessor and the Lessee: (a) A fiduciary duty of utmost care, integrity, honesty and loyalty in the dealings with either Lessor or the Lessee. (b) Other duties to the Lessor and the Lesser and

(b) Brokers have no responsibility with respect to any default or breach hereof by either Party. The Parties agree that no lawsuit or other legal proceeding involving any breach of duty, error or omission relating to this Lease may be brought against Broker more than one year after the Start Date and that the liability (including court costs and attorneys' fees), of any Broker with respect to any such lawsuit and/or legal proceeding shall not exceed the fee received by such Broker pursuant to this Lease; provided, however, that the foregoing limitation on each Broker's liability shall not be applicable to any gross negligence or willful misconduct of such Broker.

(c) Lessor and Lessee agree to identify to Brokers as "Confidential" any communication or information given Brokers that is considered by such Party to be confidential.

26. No Right To Holdover. Lessee has no right to retain possession of the Premises or any part thereof beyond the expiration or termination of this Lease. In the event that Lessee holds over, then the Base Rent shall be increased to 150% of the Base Rent applicable immediately preceding the expiration or termination. Holdover Base Rent shall be calculated on a monthly basis. Nothing contained herein shall be construed as consent by Lessor to any holding over by Lessee.

27. Cumulative Remedies. No remedy or election hereunder shall be deemed exclusive but shall, wherever possible, be cumulative with all other remedies at law or in equity.

28. Covenants and Conditions; Construction of Agreement. All provisions of this Lease to be observed or performed by Lessee are both covenants and conditions. In construing this Lease, all headings and titles are for the convenience of the Parties only and shall not be considered a part of this Lease. Whenever required by the context, the singular shall include the plural and vice versa. This Lease shall not be construed as if prepared by one of the Parties, but rather according to its fair meaning as a whole, as if both Parties had prepared it.

29. Binding Effect; Choice of Law. This Lease shall be binding upon the parties, their personal representatives, successors and assigns and be governed by the laws of the State in which the Premises are located. Any litigation between the Parties hereto concerning this Lease shall be initiated in the county in which the Premises are located.

#### 30. Subordination; Attornment; Non-Disturbance.

30.1 Subordination. This Lease and any Option granted hereby shall be subject and subordinate to any ground lease, mortgage, deed of trust, or other hypothecation or security device (collectively, "Security Device"), now or hereafter placed upon the Premises, to any and all advances made on the security thereof, and to all renewals, modifications, and extensions thereof. Lessee agrees that the holders of any such Security Devices (in this Lease together referred to as "Lender") shall have no liability or obligation to perform any of the obligations of Lessor under this Lease. Any Lender may elect to have this Lease and/or any Option granted hereby superior to the lien of its Security Device by giving writing notice thereof to Lessee, whereupon this Lease and such Options shall be deemed prior to such Security Device, notwithstanding the relative dates of the documentation or recordation thereof. 30.2 Attornment. In the event that Lessor transfers title to the Premises, or the Premises are acquired by another upon the foreclosure or termination of a Security Device to which this Lease is

30.2 Attornment. In the event that Lessor transfers title to the Premises, or the Premises are acquired by another upon the foreclosure or termination of a Security Device to which this Lease is subordinated (i) Lesses shall, subject to the non-disturbance provisions of Paragraph 30.3, attorn to such new owner, and upon request, enter into a new lease, containing all of the terms and provisions of this Lease, with such new owner for the remainder of the term hereof, or, at the election of the new owner, this Lease will automatically become a new lease between Lessee and such new owner, and (ii) Lessor shall thereafter be relieved of any further obligations hereunder and

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such new owner shall assume all of Lessor's obligations, except that such new owner shall not: (a) be liable for any act or omission of any prior lessor or with respect to events occurring prior to acquisition of ownership; (b) be subject to any offsets or defenses which Lessee might have against any prior lessor, (c) be bound by prepayment of more than one month's rent, or (d) be liable for the return of any security deposit paid to any prior lessor.

30.3 Non-Disturbance. With respect to Security Devices entered into by Lessor after the execution of this Lease, Lesse's subordination of this Lease shall be subject to receiving a commercially reasonable non-disturbance agreement (a 'Non-Disturbance Agreement', from the Lender which Non-Disturbance Agreement provides that Lesse's possession of the Premises, and this Lease, including any options to extend the term hereof, will not be disturbed so long as Lessee is not in Breach hereof and attorns to the record owner of the Premises. Further, within 60 days after the execution of this Lease, Lessor shall, if requested by Lessee, use its commercially reasonable efforts to obtain a Non-Disturbance Agreement from the holder of any pre-existing Security Device which is secured by the Premises. In the event that Lessor is unable to provide the Non-Disturbance Agreement within said 60 days, then Lessee may, at Lesse's option, directly contact Lender and attempt to negotiate for the execution and delivery of a Non-Disturbance Agreement. 30.4 Self-Executing. The agreements contained in this Paragraph 30 shall be effective without the execution of any further documents; provided, however, that, upon written request from Lessor

30.4 Self-Executing. The agreements contained in this Paragraph 30 shall be effective without the execution of any further documents; provided, however, that, upon written request from Lessor or a Lender in connection with a sale, financing or refinancing of the Premises, Lesse and Lessor shall execute such further writings as may be reasonably required to separately document any subordination, attornment and/or Non-Disturbance Agreement provided for herein.

31. Attorneys' Fees. If any Party or Broker brings an action or proceeding involving the Premises whether founded in tort, contract or equity, or to declare rights hereunder, the Prevailing Party (as hereafter defined) in any such proceeding, action, or appeal thereon, shall be entitled to reasonable attorneys' fees. Such fees may be awarded in the same suit or recovered in a separate suit, whether or not such action or proceeding is pursued to decision or judgment. The term, "Prevailing Party" shall include, without limitation, a Party or Broker who substantially obtains or defeats the relief sought, as the case may be whether by compromise, settlement, judgment, or the abandonment by the other Party or Broker of its claim or defense. The attorneys' fees, costs and expenses incurred in the preparation and service of notices of Default and consultations in connection therewith, whether or not a legal action is subsequently commenced in connection with such Default or resulting Breach (\$200 is a senable minimum per occurrence for such services and consultation).

32. Lessor's Access; Showing Premises; Repairs. Lessor and Lessor's agents shall have the right to enter the Premises at any time, in the case of an emergency, and otherwise at reasonable times after reasonable prior notice for the purpose of showing the same to prospective purchasers, lenders, or tenants, and making such alterations, repairs, improvements or additions to the Premises as Lessor may deem necessary or desirable and the erecting, using and maintaining of utilities, services, pipes and conduits through the Premises and/or other premises as long as there is no material adverse effect to Lessee's use of the Premises. All such activities shall be without abatement of rent or liability to Lessee. In addition, Lessor shall have the right to retain keys to the Premises and to unlock all doors in or upon the Premises other than to files, vaults and safes, and in the case of emergency to enter the Premises by any reasonably appropriate means, and any such entry shall not be deemed a forcible or unlawful entry or detainer of the Premises or an eviction. Lessee waives any charges for damages or injuries or interference with Lessee's property or business in connection therewith.

33. Auctions. Lessee shall not conduct, nor permit to be conducted, any auction upon the Premises without Lessor's prior written consent. Lessor shall not be obligated to exercise any standard of reasonableness in determining whether to permit an auction.

34. Signs. Lessor may place on the Premises ordinary "For Sale" signs at any time and ordinary "For Lease" signs during the last 6 months of the term hereof. Lessor may not place any sign on the exterior of the Building that covers any of the windows of the Premises. Except for ordinary "For Sublease" signs which may be placed only on the Premises, Lessee shall not place any sign upon the Project without Lessor's prior written consent. All signs must comply with all Applicable Requirements.

35. Termination; Merger. Unless specifically stated otherwise in writing by Lessor, the voluntary or other surrender of this Lease by Lessee, the mutual termination or cancellation hereof, or a termination hereof by Lessor for Breach by Lesse, shall automatically terminate any sublease or lesser estate in the Premises; provided, however, that Lessor may elect to continue any one or all existing subtenancies. Lessor's failure within 10 days following any such event to elect to the contrary by written notice to the holder of any such lesser interest, shall constitute Lessor's election to have such event constitute the termination of such interest.

36. Consents. See Addendum All requests for consent shall be in writing. Except as otherwise provided herein, wherever in this Lease the consent of a Party is required to an act by or for the other Party, such consent shall not be unreasonably withheld or delayed. Lessor's actual reasonable costs and expenses (including but not limited to architects', attorneys', engineers' and other consultants' fees) incurred in the consideration of, or response to, a request by Lessee for any Lessor consent, including but not limited to consents to an assignment, a subletting or the presence or use of a Hazardous Substance, shall be paid by Lessee upon receipt of an invoice and supporting documentation therefor. Lessor's consent to any act, assignment or subletting shall not constitute an acknowledgment that no Default or Breach by Lessee of this Lease exists, nor shall such consent be deemed a waiver of any then existing Default or Breach, except as may be otherwise specifically stated in writing by Lessor at the time of such consent. The failure to specify herein any particular condition to Lessor's consent shall not preclude the imposition by Lessor at the time of consent of such further or other conditions as are then reasonable with reference to the particular matter for which consent is being given. In the event that either Party disagrees with any determination made by the other hereunder and reasonable requests the reasons for such determining party shall furnish its reasons in writing and in reasonable detail within 10 business days following such request.

#### 37. Guarantor.

37.1 Execution. The Guarantors, if any, shall each execute a guaranty in the form most recently published BY AIR CRE.

37.2 Default. It shall constitute a Default of the Lessee if any Guarantor fails or refuses, upon request to provide: (a) evidence of the execution of the guaranty, including the authority of the party signing on Guarantor's behalf to obligate Guarantor, and in the case of a corporate Guarantor, a certified copy of a resolution of its board of directors authorizing the making of such guaranty, (b) current financial statements, (c) an Estoppel Certificate, or (d) written confirmation that the guaranty is still in effect.

38. Quiet Possession. Subject to payment by Lessee of the Rent and performance of all of the covenants, conditions and provisions on Lessee's part to be observed and performed under this Lease, Lessee shall have quiet possession and quiet enjoyment of the Premises during the term hereof.

39. Options. If Lessee is granted any option, as defined below, then the following provisions shall apply.

39.1 Definition. "Option" shall mean: (a) the right to extend or reduce the term of or renew this Lease or to extend or reduce the term of or renew any lease that Lessee has on other property of Lessor; (b) the right of first refusal or first offer to lease either the Premises or other property of Lessor; (c) the right to purchase, the right of first offer to purchase or the right of first refusal to purchase the Premises or other property of Lessor.

39.2 Options Personal To Original Lessee. Any Option granted to Lessee in this Lease is personal to the original Lessee, and cannot be assigned or exercised by anyone other than said original Lessee and only while the original Lessee is in full possession of the Premises and, if requested by Lessor, with Lessee certifying that Lessee has no intention of thereafter assigning or subletting. 39.3 Multiple Options. In the event that Lessee has any multiple Options to extend or renew this Lease, a later Option cannot be exercised unless the prior Options have been validly exercised. 39.4 Effect of Default on Options.

(a) Lessee shall have no right to exercise an Option: (i) during the period commencing with the giving of any notice of Default and continuing until said Default is cured, (ii) during the period of time any Rent is unpaid (without regard to whether notice thereof is given Lessee), (iii) during the time Lessee is in Breach of this Lease, or (iv) in the event that Lessee has been given 3 or more notices of separate Default, whether or not the Defaults are cured, during the 12 month period immediately preceding the exercise of the Option.

(b) The period of time within which an Option may be exercised shall not be extended or enlarged by reason of Lessee's inability to exercise an Option because of the provisions of Paragraph 39.4(a).

(c) An Option shall terminate and be of no further force or effect, notwithstanding Lessee's due and timely exercise of the Option, if, after such exercise and prior to the commencement of the extended term or completion of the purchase, (i) Lessee fails to pay Rent for a period of 30 days after such Rent becomes due (without any necessity of Lessor to give notice thereof), or (ii) if Lessee commits a Breach of this Lease.

40. Security Measures. Lessee hereby acknowledges that the Rent payable to Lessor hereunder does not include the cost of guard service or other security measures, and that Lessor shall have no obligation whatsoever to provide same. Lessee assumes all responsibility for the protection of the Premises, Lessee, its agents and invitees and their property from the acts of third parties. In the event, however, that Lessor should elect to provide security services, then the cost thereof shall be an Operating Expense.

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## 41. Reservations.

(a) Lessor reserves the right: (i) to grant, without the consent or joinder of Lessee, such easements, rights and dedications that Lessor deems necessary, (ii) to cause the recordation of parcel maps and restrictions, (iii) to create and/or install new utility raceways, so long as such easements, rights, dedications, maps, restrictions, and utility raceways do not unreasonably interfere with the use of the Premises by Lessee. Lessor may also: change the name, address or title of the Building or Project upon at least 90 days prior written notice; provide and install, at Lessee's expense, Building standard graphics on the door of the Premises and such portions of the Common Areas as Lessor shall reasonably deem appropriate; grant to any lessee the exclusive right to conduct any business as long as such exclusive right does not conflict with any rights expressly given herein; and to place such signs, notices or displays as Lessor the Building or the Project or on pole signs in the Common Areas. Lessee agrees to sign any documents reasonably requested by Lessor to effectuate such rights. The obstruction of Lessee's view, air, or light by any structure erected in the vicinity of the Building, whether by Lessor or third parties, shall in no way affect this Lease or inforce any liability upon Lessor.

(b) Lessor also reserves the right to move Lessee to other space of comparable size in the Building or...Project. Lesser must provide least days prior written notice of such move, and the new space must contain improvements of comparable quality to those contained within the Promises Lesser shall pay the ceasenable out of pocket costs that Lessen incurs with regard to such relocation including the expenses of moving and necessary stationary revision costs in no event, however, shall Lesser be required to pay an amount in excess of two months Base Rent. Lessee may not be relocated more than once during the term of this

(c) Lessee shall not: (i) use a representation (photographic or otherwise) of the Building or Project or their name(s) in connection with Lessee's business; or (ii) suffer or permit anyone, except in emergency, to go upon the roof of the Building.

42. Performance Under Protest. If at any time a dispute shall arise as to any amount or sum of money to be paid by one Party to the other under the provisions hereof, the Party against whom the obligation to pay the money is asserted shall have the right to make payment "under protest" and such payment shall not be regarded as a voluntary payment and there shall survive the right on the part of said Party to institute suit for recovery of such sum. If it shall be adjudged that there was no legal obligation on the part of said Party to pay such sum or any part thereof, said Party shall be entitled to recover such sum or so much thereof as it was not legally required to pay. A Party who does not initiate suit for the recovery of such spament.

#### 43. Authority; Multiple Parties; Execution.

(a) If either Party hereto is a corporation, trust, limited liability company, partnership, or similar entity, each individual executing this Lease on behalf of such entity represents and warrants that he or she is duly authorized to execute and deliver this Lease on its behalf. Each Party shall, within 30 days after request, deliver to the other Party satisfactory evidence of such authority.

(b) If this Lease is executed by more than one person or entity as "Lessee", each such person or entity shall be jointly and severally liable hereunder. It is agreed that any one of the named Lessees shall be empowered to execute any amendment to this Lease, or other document ancillary thereto and bind all of the named Lessees, and Lessor may rely on the same as if all of the named Lessees had executed such document.

(c) This Lease may be executed by the Parties in counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same instrument.

44. Conflict. Any conflict between the printed provisions of this Lease and the typewritten or handwritten provisions shall be controlled by the typewritten or handwritten provisions.

45. Offer. Preparation of this Lease by either party or their agent and submission of same to the other Party shall not be deemed an offer to lease to the other Party. This Lease is not intended to be binding until executed and delivered by all Parties hereto.

46. Amendments. This Lease may be modified only in writing, signed by the Parties in interest at the time of the modification. As long as they do not materially change Lessee's obligations hereunder, Lessee agrees to make such reasonable non-monetary modifications to this Lease as may be reasonably required by a Lender in connection with the obtaining of normal financing or refinancing of the Premises.

# 47. Waiver of Jury Trial. THE PARTIES HEREBY WAIVE THEIR RESPECTIVE RIGHTS TO TRIAL BY JURY IN ANY ACTION OR PROCEEDING INVOLVING THE PROPERTY OR ARISING OUT OF THIS AGREEMENT.

48. Arbitration of Disputes. An Addendum requiring the Arbitration of all disputes between the Parties and/or Brokers arising out of this Lease 🗆 is 🗆 is not attached to this Lease.

#### 49. Accessibility; Americans with Disabilities Act. (a) The Premises:

Image of the subject premises and determine whether the subject premises and determine whether the subject premises comply with all of the applicable construction-related accessibility standards under state law. Although state law does not require a CASp inspection of the subject premises, the commercial property owner or lessor may not prohibit the lessee or tenant from obtaining a CASp inspection of the subject premises for the occupancy or potential occupancy of the lessee or tenant, if requested by the lessee or tenant. The parties shall mutually agree on the arrangements for the time and manner of the CASp inspection, the payment of the fee for the CASp inspection, and the cost of making any repairs necessary to correct violations of construction-related accessibility standards within the premises.

□ have undergone an inspection by a Certified Access Specialist (CASp) and it was determined that the Premises met all applicable construction-related accessibility standards pursuant to California Civil Code §55.51 et seq. Lessee acknowledges that it received a copy of the inspection report at least 48 hours prior to executing this Lease and agrees to keep such report confidential.

□ have undergone an inspection by a Certified Access Specialist (CASp) and it was determined that the Premises did not meet all applicable construction-related accessibility standards pursuant to California Civil Code §55.51 et seq. Lessee acknowledges that it received a copy of the inspection report at least 48 hours prior to executing this Lease and agrees to keep such report confidential except as necessary to complete repairs and corrections of violations of construction related accessibility standards.

In the event that the Premises have been issued an inspection report by a CASp the Lessor shall provide a copy of the disability access inspection certificate to Lessee within 7 days of the execution of this Lease.

(b) Since compliance with the Americans with Disabilities Act (ADA) and other state and local accessibility statutes are dependent upon Lessee's specific use of the Premises, Lessor makes no warranty or representation as to whether or not the Premises comply with ADA or any similar legislation. In the event that Lessee's use of the Premises requires modifications or additions to the Premises in order to be in compliance with ADA or other accessibility statutes, Lessee agrees to make any such necessary modifications and/or additions at Lessee's expense.

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LESSOR AND LESSEE HAVE CAREFULLY READ AND REVIEWED THIS LEASE AND EACH TERM AND PROVISION CONTAINED HEREIN, AND BY THE EXECUTION OF THIS LEASE SHOW THEIR INFORMED AND VOLUNTARY CONSENT THERETO. THE PARTIES HEREBY AGREE THAT, AT THE TIME THIS LEASE IS EXECUTED, THE TERMS OF THIS LEASE ARE COMMERCIALLY REASONABLE AND EFFECTUATE THE INTENT AND PURPOSE OF LESSOR AND LESSEE WITH RESPECT TO THE PREMISES.

ATTENTION: NO REPRESENTATION OR RECOMMENDATION IS MADE BY AIR CRE OR BY ANY BROKER AS TO THE LEGAL SUFFICIENCY, LEGAL EFFECT, OR TAX CONSEQUENCES OF THIS LEASE OR THE TRANSACTION TO WHICH IT RELATES. THE PARTIES ARE URGED TO: 1. SEEK ADVICE OF COUNSEL AS TO THE LEGAL AND TAX CONSEQUENCES OF THIS LEASE.

2. RETAIN APPROPRIATE CONSULTANTS TO REVIEW AND INVESTIGATE THE CONDITION OF THE PREMISES. SAID INVESTIGATION SHOULD INCLUDE BUT NOT BE LIMITED TO: THE POSSIBLE PRESENCE OF HAZARDOUS SUBSTANCES, THE ZONING AND SIZE OF THE PREMISES, THE STRUCTURAL INTEGRITY, THE CONDITION OF THE ROOF AND OPERATING SYSTEMS, COMPLIANCE WITH THE AMERICANS WITH DISABILITIES ACT AND THE SUITABILITY OF THE PREMISES FOR LESSEE'S INTENDED USE.

WARNING: IF THE PREMISES ARE LOCATED IN A STATE OTHER THAN CALIFORNIA, CERTAIN PROVISIONS OF THE LEASE MAY NEED TO BE REVISED TO COMPLY WITH THE LAWS OF THE STATE IN WHICH THE PREMISES ARE LOCATED.

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The parties hereto have executed this Lease at the place and on the dates specified above their respective signatures.

Executed at:	Executed at:		
On: <u>12-8-17</u>	On: <u>12-7-17</u>		
By LESSOR:	By LESSEE		
McDonald Family Co. LLC	Eiger BioPharmaceuticals Inc.		
By: <u>[Signature]</u>	By: <u>[Signature]</u>		
Name Printed:	Name Printed: <u>JIM</u> WELCH		
Title:	Title: <u>CFO</u>		
Phone:	Phone: <u>650 -</u> 279 - 9845		
Fax:	Fax: <u>650 - 619 - 1621</u>		
Email:	Email: <u>jweich@eigevbio.com</u>		
By:	By:		
Name Printed:	Name Printed:		
Title:	Title:		
Phone:	Phone:		
Fax:	Fax:		
Email:	Email:		
Address:	Address:		
Federal ID No.:	Federal ID No.:		
BROKER	BROKER		
Attn:	Attn:		
Title:	Title:		
Address:	Address:		
Phone:	Phone:		
Fax:	Fax:		
Email:	Email:		
Federal ID No.:	Federal ID No.:		
Broker/Agent BRE License #:	Broker/Agent BRE License #:		
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# AIRCRE

# RULES AND REGULATIONS FOR STANDARD OFFICE LEASE

Date:	October 11, 2017	
By and Between		
Lessor:	McDonald Family Co. LLC	
Lessee:	Eiger BioPharmaceuticals Inc.	
Property Address:	2171 Park Blvd, Palo Alto, CA	

(street address, city, state, zip)

#### GENERAL RULES

1. Lessee shall not suffer or permit the obstruction of any Common Areas, including driveways, walkways and stairways.

- 2. Lessor reserves the right to refuse access to any persons Lessor in good faith judges to be a threat to the safety and reputation of the Project and its occupants
- 3. Lessee shall not make or permit any noise or odors that annoy or interfere with other lessees or persons having business within the Project.
- 4. Lessee shall not keep animals or birds within the Project, and shall not bring bicycles, motorcycles or other vehicles into areas not designated as authorized for same.
- 5. Lessee shall not make, suffer or permit litter except in appropriate receptacles for that purpose.
- 6. Lessee shall not alter any lock or install new or additional locks or bolts.

7. Lessee shall be responsible for the inappropriate use of any toilet rooms, plumbing or other utilities. No foreign substances of any kind are to be inserted therein.

8. Lessee shall not deface the walls, partitions or other surfaces of the Premises or Project.

- 9. Lessee shall not suffer or permit anything in or around the Premises or Building that causes excessive vibration or floor loading in any part of the Project.
- 10. Furniture, significant freight and equipment shall be moved into or out of the building only with the Lessor's knowledge and consent, and subject to such reasonable limitations, techniques and timing, as may be designated by Lessor. Lessee shall be responsible for any damage to the Office Building Project arising from any such activity.
- 11. Lessee shall not employ any service or contractor for services or work to be performed in the Building, except as approved by Lessor.
- 12. Lessor reserves the right to close and lock the Building on Saturdays, Sundays and Building Holidays, and on other days between the hours of \_\_\_\_\_\_ P.M. and \_\_\_\_\_\_ A.M. of the following day. If Lessee uses the Premises during such periods, Lessee shall be responsible for securely locking any doors it may have opened for entry.
- 13. Lessee shall return all keys at the termination of its tenancy and shall be responsible for the cost of replacing any keys that are lost.
- 14. No window coverings, shades or awnings shall be installed or used by Lessee.

15. No Lessee, employee or invitee shall go upon the roof of the Building.

- 16. Lessee shall not suffer or permit smoking or carrying of lighted cigars or cigarettes in areas reasonably designated by Lessor or by applicable governmental agencies as non-smoking areas.
- 17. Lessee shall not use any method of heating or air conditioning other than as provided by Lessor.

18. Lessee shall not install, maintain or operate any vending machines upon the Premises without Lessor's written consent.

19. The Premises shall not be used for lodging or manufacturing, cooking or food preparation.

20. Lessee shall comply with all safety, fire protection and evacuation regulations established by Lessor or any applicable governmental agency.

21. Lessor reserves the right to waive any one of these rules or regulations, and/or as to any particular Lessee, and any such waiver shall not constitute a waiver of any other rule or regulation or any subsequent application thereof to such Lessee.

22. Lessee assumes all risks from theft or vandalism and agrees to keep its Premises locked as may be required.

23. Lessor reserves the right to make such other reasonable rules and regulations as it may from time to time deem necessary for the appropriate operation and safety of the Project and its occupants. Lessee agrees to abide by these and such rules and regulations.

#### PARKING RULES

1. Parking areas shall be used only for parking by vehicles no longer than full size, passenger automobiles herein called "Permitted Size Vehicles." Vehicles other than Permitted Size Vehicles are herein referred to as "Oversized Vehicles."

2. Lessee shall not permit or allow any vehicles that belong to or are controlled by Lessee or Lessee's employees, suppliers, shippers, customers, or invitees to be loaded, unloaded, or parked in areas other than those designated by Lessor for such activities.

3. Parking stickers or identification devices shall be the property of Lessor and be returned to Lessor by the holder thereof upon termination of the holder's parking privileges. Lessee will pay such replacement charge as is reasonably established by Lessor for the loss of such devices.

4. Lessor reserves the right to refuse the sale of monthly identification devices to any person or entity that willfully refuses to comply with the applicable rules, regulations, laws and/or agreements.

5. Lessor reserves the right to relocate all or a part of parking spaces from floor to floor, within one floor, and/or to reasonably adjacent offsite location(s), and to reasonably allocate them between compact and standard size spaces, as long as the same complies with applicable laws, ordinances and regulations.

6. Users of the parking area will obey all posted signs and park only in the areas designated for vehicle parking.

7. Unless otherwise instructed, every person using the parking area is required to park and lock his own vehicle. Lessor will not be responsible for any damage to vehicles, injury to persons or loss of property, all of which risks are assumed by the party using the parking area.

8. Validation, if established, will be permissible only by such method or methods as Lessor and/or its licensee may establish at rates generally applicable to visitor parking

9. The maintenance, washing, waxing or cleaning of vehicles in the parking structure or Common Areas is prohibited.

10. Lessee shall be responsible for seeing that all of its employees, agents and invitees comply with the applicable parking rules, regulations, laws and agreements.

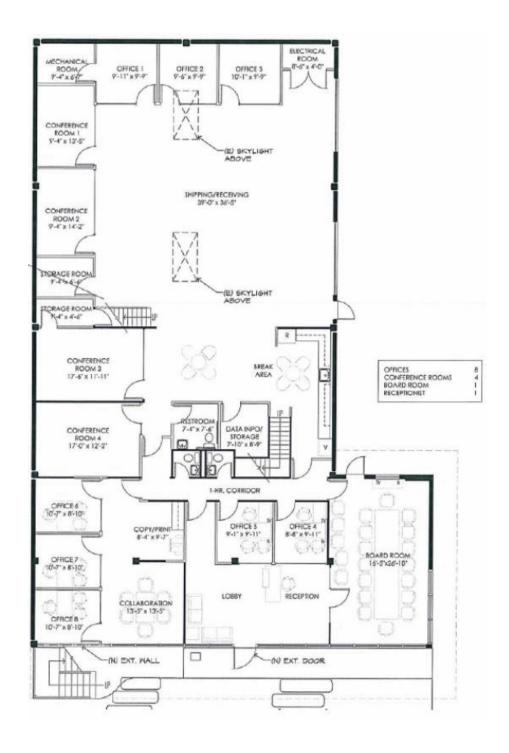
11. Lessor reserves the right to modify these rules and/or adopt such other reasonable and non-discriminatory rules and regulations as it may deem necessary for the proper operation of the parking area.

12. Such parking use as is herein provided is intended merely as a license only and no bailment is intended or shall be created hereby.

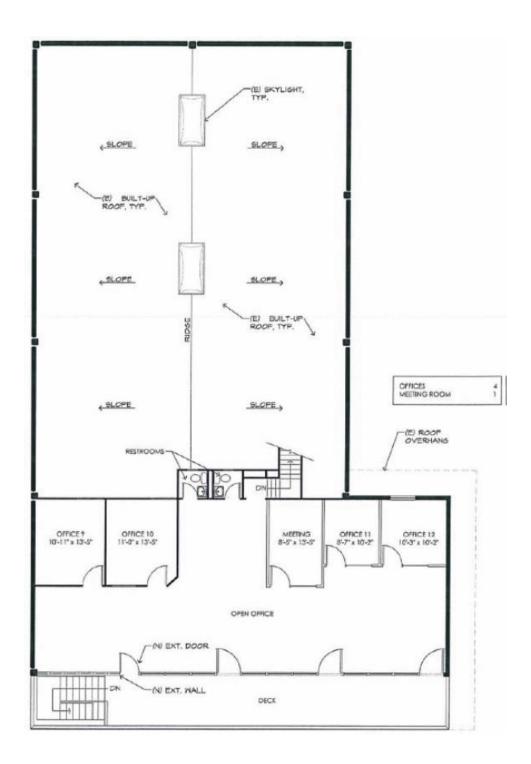
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# ADDENDUM TO LEASE

This ADDENDUM TO LEASE ("Addendum") is attached to and is an integral part of that certain Standard Multi - Tenant Office Lease-Net (the "Lease") dated October 11, 2017, by and between the McDonald Family Co. LLC, as Lessor, and Eiger BioPharmaceuticals, Inc., a Delaware corporation, as Lessee, for the Premises commonly known as 2171 Park Blvd, 1st & 2nd floor, Palo Alto, California consisting of approximately 8,029 rentable square feet.. Capitalized terms used herein without definition will have the same meanings as in the Lease. In the event of any conflict between this Addendum and the remainder of the Lease, this Addendum shall control.

# 50. Early Access:

Lessee, along with its contractors or agents, etc., shall be permitted to enter the Premises, without obligation to pay Base Rent or Operating Expenses, on February 1, 2018, provided that Lessee has delivered to Lessor proof of insurance required pursuant to Section 8.4 of the Lease (the "Early Access Period") for the purpose of installing Lessee's equipment, personal property, cabling and otherwise preparing the Premises for occupancy (the "Early Access Work"). Lessor and Lessee shall each take commercially reasonable efforts to ensure that Lessor's contractors and Lessee's contractors cooperate in commercially reasonable ways in order to avoid any delays in the substantial completion of the Lessor Work (as defined below). Notwithstanding Section 3.2 of the Lease, during the Early Access Period Lessee shall have no obligation to pay Base Rent or Operating Expenses, except that since the utilities serving the Premises are separately metered in the name of Lessor, Lessee shall be responsible for payment to Lessor of such separately metered utilities during the Early Access Period and for contracting and paying for janitorial services to the Premises during the Early Access Period.

51. Base Rent (NNN): The monthly Base Rent amount shall be as follows: Months 01-

12: \$6.00 per rentable square foot/mo./NNN(\$48,174.00) (March 1, 2018- February 28, 2019)

Months 13-24: \$6.18 per rentable square foot/mo./NNN(\$49,619.22)(March 1, 2019- February 29, 2020)

Months 25-36: \$6.37 per rentable square foot/mo./NNN(\$51,107.80) (March 1, 2020- February 28, 2021)

Months 37 - 48: \$6.56 per rentable square foot/mo./NNN(\$52,641.04) (March 1, 2021- February 28, 2022)

Months 49 - 60: \$6.75 per rentable square foot/mo./NNN(\$54,220.26) (March 1, 2022- February 28, 2023)

# 52. Vehicle Parking:

The words "beyond any applicable notice and cure periods" are hereby added after the words "not in default" in the first sentence of Paragraph 2.6 of the Lease. Additionally, there will be no charge for Lessee's parking during the Term and Paragraph 2.6(b) of the Lease is hereby deleted. Street parking from the City of Palo Alto will be available at City of Palo Alto rates.

# 53. Common Area Changes:

In the event that Lessor makes any of the Common Area changes set forth in Paragraph 2.10 of the Lease, Lessor and Lessee agree that there shall be no change to the square footage of the Premises as a result thereof, and Lessor shall use reasonable efforts to minimize any interference with Lessee's business caused by such changes and the construction thereof.

# 54. Delay in Possession:

Section 3.3 of the Lease is hereby deleted and replaced with the following:

"3.3 **Delay in Possession.** Lessor agrees to use its best commercially reasonable efforts to deliver possession of the Premises to Lessee by the Commencement Date. If, despite said efforts, Lessor is unable to deliver possession by such date, Lessor shall not be subject to any liability therefor, nor shall such failure affect the

validity of this Lease or change the Expiration Date. Lessee shall not, however, be obligated to pay Rent or perform its other obligations until Lessor delivers possession of the Premises and any period of rent abatement that Lessee would otherwise have enjoyed shall run from the date of delivery of possession and continue for a period equal to what Lessee would otherwise have enjoyed under the terms hereof, but minus any days of delay caused by the acts or omissions of Lessee. If Lessor is unable to deliver the Premises to Lessee with the Lessor's Work substantially complete on the Commencement Date, Lessee shall also be entitled to rent abatement for the period from the date which is forty (40) days following the Commencement Date through the date that is one hundred sixty (160) days after the Commencement Date, which abatement shall be applied beginning after the expiration of any rent abatement period set forth in the Lease. If possession is not delivered within 160 days after the Commencement Date, as the same may be extended under the terms of any Work Letter executed by Parties, Lessee may, at its option, by notice in writing after the end of such 160 day period, cancel this Lease, in which event the Parties shall be discharged from all obligations hereunder."

# 55. Operating Expenses:

**55.1** Lessor's estimate of Operating Expenses for the Premises for 2017 is \$.95/rsf/month, which amount Lessee shall use to calculate monthly Operating Expenses owed until receipt of Lessor's Statement for calendar year 2018.

**55.2** Notwithstanding anything to the contrary set forth in the Lease, Lessor will contract directly for utilities servicing the Premises and Lessee will be responsible for contracting directly for janitorial service to the Premises. The utilities are separately metered to the Premises and will be billed independently and not as an Operating Expense. Payments for utilities will be made promptly following the receipt of a written invoice therefor from Lessor, but in any event not later than twenty (20) days following receipt of such written invoice.

**55.3** Lessor's property management fee, not exceed three percent (3%) of the gross rents of the Building minus the amount of the management fee throughout the initial Term and any Extension Options, shall be included as an Operating Expense.

**55.4** Notwithstanding Lessee's Share stated in Paragraph 1.6 of the Lease, Lessee shall be responsible for 100 percent (100%) of all costs connected with maintenance, repair and replacement of the HVAC system that serves only the Premises.

55.5 The words "and the costs of any environmental inspections" are hereby deleted from Section 4.2(a)(ii).

55.6 Section 4.2(a)(x) is hereby deleted from the Lease and no reserves shall be part of Operating Expenses payable by Lessee.

**55.7** The capital improvement and replacement expenses set forth in Section 4.2(a)(viii) of the Lease shall be limited to those which are: (1) reasonably expected by Lessor to produce an actual reduction in operating charges or energy consumption or effect other economies in the operation or maintenance of the Building; or (2) required after the date of this Lease under any governmental law or regulation not in effect as of the Commencement Date (but not including any Capital Expenditure set forth in Section 2.3(b) of the Lease) (collectively, "*Permitted Capital Expenditures*").

**55.8** Section 4.2(d) is hereby deleted and replaced with the following:

"Lessee's Share of Operating Expenses is payable monthly on the same day as the Base Rent is due hereunder. The amount of such payments shall be based on Lessor's good faith estimate of Operating Expenses for the current calendar year. Within ninety (90) days following the end of any given calendar year, Lessor will use reasonable efforts to furnish to Lessee a statement in reasonable detail, setting forth the actual Operating Expenses for the applicable calendar year (**"Lessor's Statement"**). If the estimated monthly payments of Lessee's Share of Operating Expenses that Lessee has paid has paid are greater than Lessee's Share of Operating Expenses as set forth in Lessor's Statement, Lessor shall credit such overpayment against subsequent obligations of Lessee for payment of Operating Expenses, or refund such overpayment if the Term has ended and Lessee has no further obligations to Lessor hereunder. If the estimated monthly payments of Lessee's Share

of Operating Expenses are less than the amount due for such calendar year, Lessee shall pay the balance due within twenty (20) days from receiving Lessor's Statement.

**55.9** During the sixty (60)-day period after receipt of any Lessor's Statement (the "**Review Period**"), Lessee may, at its sole cost and expense, inspect and audit on a non-contingency basis Lessor's records relevant to the cost and expense items reflected in such Lessor's Statement at a reasonable time mutually agreeable to Lessor and Lessee during Lessor's usual business hours. Each Lessor's Statement shall be conclusive and binding upon Lessee unless within the Review Period Lessee notifies Lessor in writing that it disputes the correctness of Lessor's Statement and specifies how Lessor's Statement is claimed to be incorrect. All inspections and audits of Lessor's books and records and any arbitration shall be subject to a confidentiality agreement reasonably acceptable to Lessor. If Lessee's audit determines that actual Operating Expenses have been overstated by more than five percent (5%), then Lessor shall reimburse Lessee for the reasonable out-of-pocket costs of such audit and Lessee's rent shall be appropriately adjusted to reflect any overstatement in Operating Expenses.

55.10 Notwithstanding anything to the contrary in Section 4 of the Lease, the following items shall be excluded from Operating Expenses:

- i. Any fines, penalty charges, or interest incurred by Lessor due to violation of law or late payment.
- ii. Expenses incurred in connection with the services provided to others but not to Lessee.
- Expenses incurred in connection with leasing, drafting, or enforcing leases in the Building, such as, but not limited to,
   (l) real estate broker's commission, (2) accounting, legal, architectural, space planning, or engineering fees, or (3) advertising or promotions costs.
- iv. Repairs and maintenance necessary because of negligence or willful misconduct of other tenants, their officers, agents, employees, invitees, licensees, and those parties working through or under those tenants.
- v. Except for Permitted Capital Expenditures, any capital improvement or replacement costs.
- vi. Ground lease rental (except for any ground lease rental fee attributable to the area where Lessee's parking spaces described in Section 1.2(b) of the Lease are located, which rental fees may be included in Operating Expenses up to an amount not to exceed \$200 per month) and depreciation; principal and interest payments of mortgages (and any fees or points associated with any mortgages) and other non-operating debts of Lessor.
- vii. Sums paid to subsidiaries or other affiliates of Lessor for services on or to the Building and/or Premises, but only to the extent that the costs of such services exceed the competitive cost for such services rendered by unrelated persons or entities of similar skill, competence and experience.
- viii. All costs associated with the operation of the business of the entity which constitutes "Lessor" (as distinguished from the costs of operating, maintaining, repairing and managing the Building) including, but not limited to, Lessor's or Lessor's managing agent's general corporate overhead and general administrative expenses;
- ix. Costs for alterations of other tenants' premises prior to and during duration of leases.
- x. Costs incurred in connection with the original construction or any future expansion of the Building (including without limitation costs to correct defects in, or inadequacy of, the initial design or construction).
- xi. Costs incurred to obtain or upgrade a LEED certification or similar rating for the Building (provided that monitoring and maintenance costs required to maintain such a

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rating or certification once obtained may be included in Operating Expenses).

- Xii. Any fines, penalties or interest resulting from the active negligence or willful misconduct of Lessor.
- xiii. Any cost or expense related to removal, cleaning, abatement or remediation of Hazardous Substances existing as of the date of this Lease in, about or under the Building or migrating onto or under thereafter.
- xiv. To the extent any employee of Lessor spends only a portion of his or her time working with respect to the Building (as opposed to full time work with respect to the Building), a prorated amount of such employee's wages, salaries and compensation based upon the portion of time spent by such employee with respect to the projects other than the Building.
- xv. Costs of services for which Lessee or any tenant of the Building is obligated to separately reimburse Lessor pursuant to this Lease or its respective lease with its Lessor.
- xvi. Except with respect to insurance deductibles (but subject to any express limitations set forth in this Lease), the cost of repairs or replacements incurred by reason of fire or other casualty or condemnation;
- xvii. Any costs expressly excluded from Operating Expenses elsewhere in the Lease and/or this Addendum.

xviii. Costs related to travel expenses, charitable or political contributions or art work.

56. Real Property Taxes Exclusions: Paragraph 10.1 of the Lease is hereby amended by adding the following to the end thereof:

"Real Property Taxes shall not include:

(i) Inheritance or estate taxes imposed upon or assessed against the interest of any person in the Building;

- (ii) Taxes computed upon the basis of the net income of any owners of any interest in the Building; or
- (iii) Any penalties, interest or fees attributable to Lessor's negligent failure to pay any Real Property Taxes when due and payable."

# 57. Use:

Lessee may use the Premises for Professional, Office and R&D uses and other permitted legal uses.

# 58. Lessor Work-Delivery Condition:

**58.1** Upon the Commencement Date, Lessor, at its sole cost and expense, will deliver the Premises in compliance with applicable laws and codes, clean and free of all Hazardous Substances, free of all personal property, with the roof and building envelope in watertight condition, with all Building systems operational and in good condition and repair and all of Lessor Work substantially completed ("Delivery Condition"). Lessor warrants such Building systems, including, but not limited to, the roof, building envelope and HVAC equipment, for the first six (6) months of the Term. In the event that any such Building systems are not in good condition and repair during the initial 6 months of the Term, Lessor shall repair such Building system and shall not include the cost of such repairs as an Operating Expense. Following the initial 6 months, to the extent Lessor is required to make such repairs, then the cost of such repairs may be included as an Operating Expense as set forth in paragraph 4.2 of the Lease. For the avoidance of doubt, notwithstanding the foregoing or anything to the contrary contained in this Lease, Lessee shall not be responsible for (i) compliance with any Applicable Requirements where such compliance is not related specifically to Lessee's particular use and occupancy of the Premises or where a failure of the Premises to comply with any Applicable Requirements

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arose prior to the Start Date, and (ii) in no event shall Lessee be liable for, and Lessor shall indemnify Lessee for any damages caused by, the storage, release or disposal of any Hazardous Substances on the Building or Property (A) prior to the Commencement Date, or (ii) by anyone other than Lessee.

**58.2** Lessor shall use commercially reasonable efforts to deliver the Premises to Lessee with the Lessor Work (as defined below) on or before the Commencement Date. Upon execution of this Lease, Lessor, at Lessor's sole cost and expense, shall have an architect develop a test fit of the Premises for the Lessee in line with Lessor's budget for the Lessor Work of Two Hundred Thousand and 00/100 Dollars (\$200,000) (the **"Lessor Work Budget"**). Lessee and Lessor will work together to develop a mutually agreeable space plan with mutually agreeable finishes. Lessor, at Lessor's cost, not to be passed through as an Operating Expense, shall design a space plan with:

- a. 7-10 Private offices
- b. 1 small conference room (4-6 people)
- c. 1 medium conference room (8-12 people)
- d. 2 call rooms/phone booths (1-2 people)
- e. 1 large conference room (14-20 people)
- f. Upgraded kitchenettes to new building standards
- g. New finishes.

As the same are depicted on Exhibit A attached hereto (collectively "Lessor Work"). Should Lessee request any additions to the Lessor Work ("Additional Lessor Work") it shall provide written notice thereof to Lessor and Lessor shall promptly provide Lessee with an estimate for completing such Additional Lessor Work (the "Lessor Estimate"). Should the Lessor Estimate indicate that the Additional Lessor Work would cause Lessor to exceed the Lessor Work Budget, any such increase in price over the Lessor Work Budget that is a result of the Additional Lessors Work shall be amortized over the initial Term of this Lease at 6% interest and added to the Base Rent. If applicable, Lessor's Estimate shall contain a calculation of any such increase in Base Rent. Following reception of the Lessor Estimate, Lessee shall provide Lessor written confirmation of whether it chooses to proceed with the Additional Lessor Work, and if so this Lease shall be amended to set forth the revised Base Rent, if applicable. Any changes to the Lessor Work in excess of Fifty Thousand Dollars and 00/100 (\$50,000.00) shall require a written change order approved by both Lessee and Lessor. Notwithstanding the foregoing, any costs in excess of the Lessor Work Budget relating to compliance with applicable laws and base building systems, up to an amount not to exceed Twenty Five Thousand Dollars and 00/100 (\$25,000.00), shall be borne solely by Lessor, not be passed on through Operating Expenses.

Once commenced, Lessor shall diligently proceed to achieve Substantial Completion of Lessor's Work As used herein, the term **"Substantial Completion"** shall mean that Lessor shall have substantially completed Lessor's Work, with the exception of minor punch list items that do not materially impede Lessee's moving into the Premises for Lessee's use and occupancy of the Premises. Following Substantial Completion of Lessor Work and prior to Lessee occupancy, Lessor and Lessee shall conduct a walkthrough of the Premises and if applicable, provide a punch list of any items to be repaired by Lessor. Lessor shall complete any repairs within thirty (30) days of the delivery date, subject only to availability of materials.

If any portion of Lessor's Work that requires repair or replacement is covered by a guaranty or warranty by a contractor, a subcontractor and/or a material supplier, Lessor shall assign to Lessee such guaranty or warranty. In addition to (1) any warranties or guaranties issued by contractors, subcontractors, or material suppliers relating to Lessor's Work and (2) Lessor's warranty in Paragraph 2.2 of the Lease (which warranty for electrical, mechanical, and plumbing systems shall extend for three months following the Commencement Date), Lessor warrants that Lessor's Work shall be free from material defects for a period of one year following the date of Substantial Completion.

Lessee, at Lessee cost, is responsible for installation of any additional improvements which Lessee desires, including network wiring, subject to Lessor prior approval, which approval shall not be unreasonably withheld or delayed.

Except for the Lessor Work and as otherwise set forth in this Lease, Lessor shall deliver the Premises to Lessee in their "as is" condition.

# 59. Assignment and Subletting.

**59.1** Affiliates. Despite any other provision of the Lease, Lessor's consent is not required for any transfer by operation of law, sale, assignment, transfer of any interest in Lessee or this Lease or the Premises, sublet of all or any part of the Premises, grant of any right to use the Premises or any part thereof ("Transfer") to an Affiliate, as defined below, as long as the following conditions are met: (i) At least ten (10) business days before the Transfer, Lessor receives written notice of the Transfer (as well as any documents or information reasonably requested by Lessor regarding the Transfer or the assignee ("Transferee")); (ii) The Transfer is not a subterfuge by Lessee to avoid its obligations under the Lease; (iii) if the Transfer is an assignment, Transferee assumes in writing all of Lessee's obligations under this Lease which include the use of the Premises and (iv) Transferee's net worth is equal to or greater than that of Lessee as of the date hereof; Lessor per 56.1 (i) above. An "Affiliate" shall mean (i) any entity that controls, is controlled by, or is under common control with Lessee. For this purpose, "control" shall mean the direct or indirect ownership of more than fifty percent (50%) of the voting securities of an entity or possession of the right to vote more than fifty percent (50%) of the voting interest in the ordinary direction of the entity's affairs.

Regardless of any provision in this Lease which might provide or be construed otherwise, however, the prohibition against Transfers will not be construed to include a prohibition against any transfer resulting from, or as a part of, a bona fide merger or consolidation, sale of assets, sale of a controlling interest in stock or other ownership interest, or by like manner, or by operation of law, so long as the resultant Transferee is of such financial standing and operational responsibility so as to give reasonable assurance of the payment of all Rent reserved in, and compliance with all of the other terms, provisions, covenants and conditions of, this Lease (in any such case, a "Corporate Transfer"); however, Lessee in undertaking any such Corporate Transfer, may not manipulate the ownership interests of Lessee as a means to subvert the general prohibition against Transfers set forth herein. Affiliate Transfers and Corporate Transfers, any of which may be undertaken and accomplished without the need for obtaining Lessor's consent, are referred to herein as "Approved Affiliates".

**59.2:** Rent-Sharing. As a reasonable condition to Lessor's consent to any assignment or subletting, Lessee shall pay to Lessor the Transfer Premium. "Transfer Premium" shall mean fifty percent (50%) of the following: all base rent, additional rent, and other consideration, cash or non-cash, payable by a Transfere to Lessee (including key money and bonus money and any payment in excess of fair market value for services rendered by Lessee to Transferee or assets, fixtures, inventory, equipment, or furniture transferred by Lessee to Transferee in connection with the Transfer ("Transferee Rent")), after deducting the rent payable by Lessee under this Lease (excluding the Transfer Premium) for the portion of the Premises that is subject to the Transfer ("Lessee Rent"). Lessee shall pay the Transfer Premium on a monthly basis, together with its payment of Base Rent. In calculating the Transfer Premium, Lessee Rent, and Transferee Rent, the parties shall first adjust the rent to the actual effective rent to be paid, taking into consideration only any rent credit (free rent provided to Transferee), reasonable subtenant improvements, legal fees and broker commission paid. For purposes of calculating the effective rent, all those concessions shall be amortized on a straight-line basis over the relevant term. On Lessor's request, Lessee shall furnish a complete statement describing in detail the computation of any Transfer Premium that Lessee has derived or will derive from the Transfer If Lessor's independent certified public accountant finds that the Transfer Premium for any Transfer has been understated, Lessee shall, within thirty (30) days after demand, pay the deficiency and if such understatement is greater than 5%, also Lessor's costs of that audit.

**59.3 Recapture.** If Lessee proposes to sublease or assign all of the Premises for the remainder of the Term, once a letter of intent for such sublease or assignment has been executed, Lessee shall provide notice to Lessor (the **"Recapture Notice"**) of such intended sublease or assignment together with a copy of the executed letter of intent. Lessor shall have the option to recapture the entire Premises for the remainder of the Term by giving written notice thereof to Lessee within five (5) business days after receipt of the Recapture Notice. Such recapture notice shall cancel and terminate this Lease in its entirety as of the date stated in the Recapture Notice as the effective date of the proposed Transfer. If Lessor declines, or fails to elect in a timely manner to recapture the Premises under this Section 59.3, then it shall have waived its right to recapture such sublease or assignment and Lessee may proceed with the negotiation of such sublease or assignment and request consent thereto from Lessor pursuant to Section 12 of the Lease.

# 60. Option to Extend:

**60.1: Generally.** According to Article 39 of the Lease, if Lessee is not in Breach at the time of giving the Extension Option Notice (defined below), then Lessee shall have the option (**"Extension Option"**) to extend the Term for an additional thirty-six (36) months, starting immediately upon expiration of the Initial Term (**"Extension Term"**). Any Default by Lessee hereunder or termination of this Lease during the Original Term shall terminate this Extension Option. The Extension Term shall be under all of the covenants, terms and conditions of the Lease, except that the following provisions will not be part of this Lease for the Extension Term:(i) the amount of Base Rent to be paid by Lessee during the Extension Term, which shall be established as set forth below,(ii) the Extension Option to extend provided for in this Paragraph 56.1, and (iii) any Lessor obligations to construct or to fund initial improvements. The Extension Option is personal to Lessee or an Approved Affiliate and may not be assigned or transferred without Lessor's express prior written consent except to an Approved Affiliate. If Lessee elects to exercise the Extension Option, Lessee shall give Lessor written notice of such election (**"Extension Option Notice"**) not less than one hundred eighty (180) days and not more than two hundred seventy (270) days before the end of the Term.

**60.2: Rent During Option Term.** If Lessee exercises the Extension Option, Base Rent for the Extension Term shall be 95% of the Fair Market Rental Rate (as defined below) of the Premises in relation to market conditions for the Palo Alto California Avenue Office market at the time of the extension. The Fair Market Rental Rate hereunder shall be determined as follows:

(a) <u>Mutual Agreement</u>. After timely receipt by Lessor of the Extension Option Notice, Lessor and Lessee shall have a period of thirty (30) days in which to agree on the Fair Market Rental Rate of the Premises. If Lessor and Lessee agree on the Fair Market Rental Rate for the Premises, then they shall immediately execute an amendment to the Lease stating and incorporating such agreed-upon Fair Market Rental Rate as the Base Rent for the Extension Term.

# (b) Arbitration.

i. If Lessor and Lessee are unable to agree upon the Fair Market Rental Rate within thirty (30) days following Lessee's exercise of the Extension Option,

then the dispute shall proceed to arbitration. The arbitration procedure shall commence when either party submits the matter to arbitration. Not later than ten (10) days after the arbitration procedure has commenced, each party shall appoint an arbitrator and notify the other party of such appointment by identifying the appointee. Each party hereto agrees to select as its respective appointee a licensed real estate agent, who is an individual with at least 5 years' experience with respect to office building ownership, management and marketing in the downtown Palo Alto area. Neither party may consult directly or indirectly with any arbitrator regarding the Fair Market Rental Rate prior to appointment, or after appointment, outside the presence of the other party. The arbitration shall be conducted under the provisions of the commercial arbitration rules of the American Arbitration Association.

ii. Not later than (10) days after both arbitrators are appointed, each party shall separately, but simultaneously, submit in a sealed envelope to each arbitrator their separate suggested Fair Market Rental Rate and shall provide a copy of such submission to the other party. The two (2) selected arbitrators, after reviewing such submissions, shall determine whether Lessor's or Lessee's estimate of the Fair Market Rental Rate is closer to the actual Fair Market Rental Rate for the Premises. If both arbitrators agree that one of said declared estimates is closer to the actual Fair Market Rental Rate, and their decision shall be final and binding upon the parties.

iii. If the two (2) selected arbitrators are unable to agree that one of the declared estimates is closer to the actual Fair Market Rental Rate, within thirty (30) days after receipt of Lessor's and Lessee's submitted estimates, then the arbitrators shall inform the parties. Unless the parties shall both otherwise then direct, said arbitrators shall select a third arbitrator, not later than ten (10) days after the expiration of said thirty (30) day period. If no arbitrator is selected within such ten (10) day period, either party may immediately petition a court with appropriate jurisdiction to appoint such third arbitrator. The third arbitrator shall have the qualifications and restrictions set forth above, and shall conduct arbitration pursuant to the commercial arbitration rules of the American Arbitration Association. The third arbitrator's decision shall be final and binding as to which estimate (as between Lessor's and Lessee's) of the Fair Market Rental Rate is closer to the actual Fair Market Rental Rate. Such third arbitrator shall make a decision not later than thirty (30) days after appointment.

iv. Each party shall be responsible for the costs, charges and/or fees of its respective appointee and the parties shall share equally in the costs, charges and/or fees of the third arbitrator. The decision of the arbitrator(s) may be entered in any court having jurisdiction thereof.

(c) Fair Market Rental Rate. The term **"Fair Market Rental Rate"** shall mean the amount per rentable square foot that a willing, comparable, non-equity, non-renewal, non-expansion new tenant would pay and a willing, comparable landlord would accept at arm's length, giving appropriate consideration to rental rates per rentable square foot, the credit strength of Lessee, the type of escalation clauses (including, but without limitation, operating expense, real estate taxes, CPI), the extent of liability under the escalation clauses (e.g., whether determined on a "net lease" basis or by increases over a particular base year orbasedollaramount), abatementprovisions reflecting free rentand/omorent during the period of construction or any other period during the lease term, brokerage commissions, if any, length of lease term, size and location of premises being leased, and other generally applicable terms and conditions of tenancy for the space in question.

# 61. Security Deposit/Prepaid Rent:

**61.1** Tenant shall pre-pay the first months' Base Rent, Estimated Operating Expenses and Security Deposit upon the execution of the Lease. The Security Deposit due upon execution of the Lease shall be equal to six (6) months' Base Rent calculated using the Base Rent rate payable upon execution of the Lease. Assuming Lessee is not in default (beyond notice and cure periods), Lessor will reduce the Security Deposit per the following schedule:

- Initial Security Deposit: \$289,044.00, equivalent to the first six (6) months of base rent.
- Lessor to give back two (2) months after the 24th month of the Term (\$96,348.00)
- Lessor to give back one (1) month after the 30<sup>th</sup> month of the Term (\$48,174.00)
- Lessor to give back one (1) month after the 48<sup>th</sup> month of the Term (\$48,174.00)
- Lessor will hold the remaining amount of \$96,348.00 through the remainder of the Term.

Lessor will return the above stated amounts to Lessee, by check at the address set forth in the Lease, within fifteen (15) days of the dates listed above.

**61.2** <u>Security Deposit</u>: Notwithstanding anything to the contrary contained in Section 5 of the Lease, Lessee shall have no obligation to increase the amount of the Security Deposit upon a transfer of the Lease.

# 62. Inspection; Compliance Notice:

The following is hereby added to the end of Paragraph 6.4 of the Lease: "Notwithstanding the provisions of this Paragraph 6.4, Lessor shall provide Lessee with at least 24 hours' prior actual notice before entering the Premises. In the event of an emergency, the determination of which shall require Lessor to be reasonable, Lessor shall use its best efforts to provide Lessee with notice reasonable in such situation. In the event of any entry by Lessor onto the Premises, Lessor shall use its best efforts not to interfere with the conduct of Lessee's business."

# 63. Alterations:

The dollar amount set forth in the fifth line of Section 7.3(b) of the Lease shall be \$15,000 (and not \$2,000). Lessee shall not be required to provide a bond or surety for any Alterations unless the cost of the work exceeds two (2) months' Base Rent. Notwithstanding Section 7.4(b) of the AIR Lease, Lessee shall not be required to remove any Alteration or Utility Installation unless Lessor notifies Lessee of the requirement to do so either (a) upon Lessor granting its consent to such Alteration or Utility Installation, or (b) within ten (10) days of Lessee's request for a determination from Lessor.

# 64. Insurance; Indemnity:

(a) Section 8.5 is hereby deleted in its entirety and replaced with the following:

8.5 **Insurance Policies.** Insurance required herein shall be by companies maintaining during the policy term a "General Policyholders Rating" of at least  $A \square$ , VII, as set forth in the most current issue of "Best's Insurance Guide", or such other rating as may be required by a Lender. Lessee shall not do or permit to be done anything which invalidates the required insurance policies. Lessee shall, prior to the Start Date, deliver to Lessor certified copies of certificates with copies of the required endorsements evidencing the existence and amounts of the required insurance. Lessee shall furnish Lessor with evidence of renewals or "insurance binders" evidencing renewal thereof in a reasonable amount of time after the renewal. Such policies shall be for a term of at least one year, or the length of the remaining term of this Lease, whichever is less. If either Party shall fail to procure and maintain the insurance required to be carried by it, the other Party may, but shall not be required to, procure and maintain the same."

(b) Lessee's waiver of Lessor liability under Section 8.8 of the Lease shall not apply to the extent any losses or injuries as set forth therein are caused by the gross negligence or willful misconduct of Lessor or its agents, or a breach by Lessor under this Lease.

# 65. Damage or Destruction:

Notwithstanding anything to the contrary in Section 9 of the AIR Lease:

- a. Notwithstanding Section 9.2 of the AIR Lease, Lessee shall not be required to make the repair of any damage or destruction.
- b. Lessor shall have thirty (30) days from the date of the damage or destruction to inform Lessee as to whether or not the damage is Partial or Total.
- c. Lessee's right to rent abatement set forth in Section 9.6(a) shall not be limited to the proceeds received from the Rental Value Insurance.
- d. The first sentence of Section 9.5 of the AIR Lease is hereby deleted and replaced with the following: "If at any time during the last twelve (12) months of this Lease there is damage for which the cost to repair exceeds one months' Base Rent, whether or not an Insured Loss, either party may terminate this Lease effective sixty (60) days following the date of occurrence of such damage by giving a written termination notice to the other party within thirty (30) days after the date of occurrence of such damage."
- e. If Lessor is obligated to repair or restore the Premises following Premises Partial Damage or Premises Total Destruction and does not commence, in a substantial and meaningful way, such repair or restoration within thirty (30) days after such obligation shall accrue, Lessee may exercise its right to terminate the Lease as set forth in Section 9.6(b).

# 66. Excess Utility Consumption:

Section 11.3 and 11.4 of the Lease are hereby deleted. Lessee may use utility services in amounts reasonably necessary for the conduct of its business operations on a 24 hours a day, seven days a week basis, and utilities will be provided on such basis and no advance request needs to be made for use thereof.

# 67. Utility Interruption:

Provided no Default shall then exist under this Lease (beyond any applicable notice and cure periods), if electrical power or HVAC is interrupted due to the negligence or willful misconduct of Lessor or its employees or agents (a **"Utility Interruption")**, and Lessee is unable to carry on its business in a reasonably normal manner due to the failure of any of such utilities and services, and therefore vacates all or the affected portion of the Premises and/or ceases business operations in the Premises for a period in excess of five (5) business days, the Base Rent and additional rental payable under this Lease shall be abated retroactively from the first day of the Utility Interruption (in proportion to the area of the Premises vacated by Lessee by reason of such failure, if less than all of the Premises is affected) and for as long as such inability to carry on Lessee's business continues, until such time as the service is restored or Lessee reoccupies the Premises or affected portion thereof, whichever is earlier. In the event of any curtailment, diminution, or failure with respect to utilities and services in the Building or the Premises, Lessor agrees to use due diligence to restore full service.

# 68. Lessor's Consent:

The word "cumulative" in Paragraph 12.1(b) of the Lease shall be amended to read "noncumulative" and the percentage provided in said Paragraph 12.1(b) shall be 51% (and not 25%). Further, Paragraph 12.1(c) of the Lease shall be deleted and of no force and effect.

# 69. Default:

Notwithstanding anything to the contrary in Section 13.1(d) of the Lease, Lessee shall have fifteen (15) days following written notice from Lessor to deliver the documents required under Section 13.1(d) before any failure to deliver shall constitute a Default under the Lease.

# 70. Remedies:

Notwithstanding anything to the contrary in the first paragraph of Section 13.2 of the Lease, (a) Lessor may not perform the duties or obligations of Lessee under the Lease unless Lessee fails to perform any of its affirmative

duties or obligations within thirty (30) days after written notice to Lessee, unless a longer period of time is required to cure the same, in which case Lessee shall have such longer period of time to perform the same so long as Lessee has commenced to perform within such thirty (30) day period and diligently performs the same to completion, and (b) Lessor shall not charge more than a 10% markup for work performed as a result of Lessee failures set forth in (a) above on the costs and expenses incurred by Lessor in performing such obligations or duties.

# 71. Late Charges:

Notwithstanding anything in Section 13.4 of the Lease to the contrary, Lessor will not assess a late charge until Lessor has given written notice of such late payment for the first later payment in any twelve (12) month period and after Lessee has not cured such late payment within three (3) days from receipt of such notice.

## 72. Lessor Access:

Notwithstanding anything to the contrary in the Lease: (a) Lessor shall give not less than 24 hours' notice to Lessee prior to entering the Premises (except in case of emergency), and (b) Lessee shall have the right to require that an employee, officer or agent of Lessee is present at all times during any such entry (except in case of emergency).

# 73. Consents:

Lessor's charges in connection with any request for consent by Lessee pursuant to Section 36 of the Lease shall not exceed \$1,500 per request.

## 74. ADA:

Lessor represents that the Premises complies with ADA provisions per negotiations with the City of Palo Alto during the permitting process for the Lessor Work, of the ADA in effect on the Effective Date of the Lease.

## 75. No Relocation:

Paragraph 41(b) of the Lease shall be deleted and of no force and effect.

# 76. Notice of Rule Changes:

Notwithstanding any provision of the Lease or the Rules and Regulations, Lessee shall not abide by any modifications, updates or changes to the Rules and Regulations unless Lessee has received such modifications, updates or changes in writing from Lessor.

#### 77. Parking Rules

Notwithstanding anything set forth in the parking rules and regulations, in no event shall Lessor move Lessee's parking spaces to adjacent or offsite locations.

# 78. Notices:

Lessor: McDonald Family Co. LLC 2183 Park Blvd Palo Alto, CA 94306 Attention: Brion McDonald

#### Lessee:

**Eiger BioPharmaceuticals, Inc.** 2171 Park Blvd. Palo Alto, CA 94306 Attention: Matthew Bys

with a copy to:

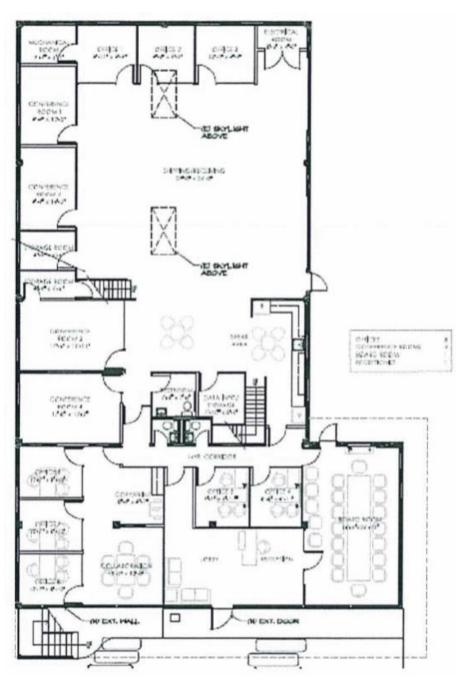
Cooley LLP 101 California St, 5<sup>th</sup> Floor San Francisco, CA 94111 Attention: Marlena C. Schultz

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IN WITNESS WHEREOF, Lessor and Lessee have executed this Addendum concurrently with the Lease of even date herewith.

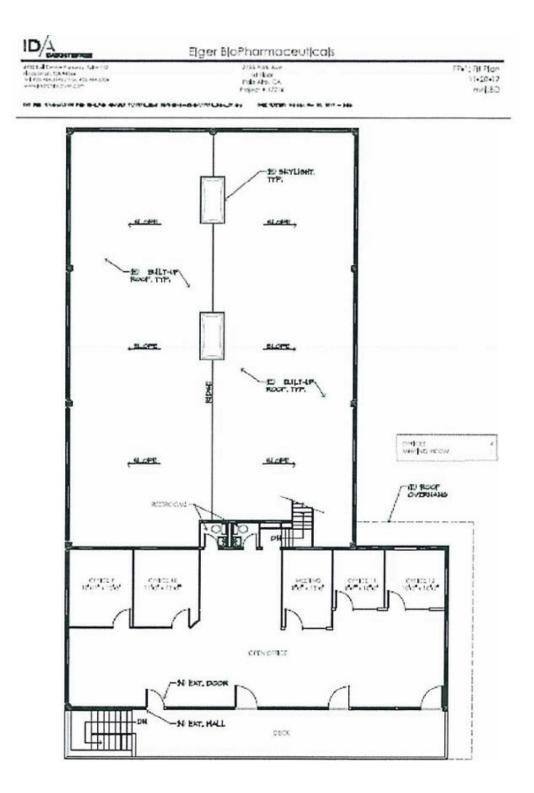
Lessor: McDonald Family Co., LLC a California limited Liability Co.			Lessee: Eiger BioPharmaceuticals, Inc., a Delaware corporation
Executed at:			Executed at:
On:	12/8/17	,2017	On: <u>12/7/17</u> ,2017
By:	/signature/		By: /signature/
Printed Name: Brian McDonald		Brian McDonald	Printed Name: Jim Welch
Title:	CEO		Title: CFO
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EXHIBIT A



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12



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# Offer Letter, dated as of December 12, 2017, by and between Eiger BioPharmaceuticals, Inc. and David Apelian, M.D., Ph.D.

December 8, 2017

Eiger BioPharmaceuticals, Inc. 350 Cambridge Avenue, Suite 350 Palo Alto, CA 94306

David Apelian, MD, PhD 3 Old Beach Glen Rd Boonton, NJ 07005

# Re: Employment Terms

Dear David:

Eiger BioPharmaceuticals, Inc. ("Eiger" or the "Company") is pleased to offer you the position of Chief Operating Officer and Executive Medical Officer, on the following terms.

You will be responsible for duties customarily associated with this position and will report to the President and CEO. You will work at our facility located at 350 Cambridge Avenue in Palo Alto, California. Of course, Eiger may change your position, duties, and work location from time to time in its discretion.

Your salary will be \$518,000 per year, less payroll deductions and withholdings. You will be paid semi-monthly. In addition you will be eligible for a targeted bonus of 40% of your base salary based upon your performance and attainment of Company objectives. As an exempt salaried employee, you will be expected to be available and working during the Company's regular business hours, and without additional compensation, for such extended hours or additional time as appropriate to manage your responsibilities. In addition, you will receive a \$180,000 one-time cash sign on bonus, less payroll deductions and standard withholdings.

You will be eligible for the following standard Company benefits: medical insurance, paid time off (PTO), 401(K), Employee Stock Purchase Plan (ESPP) and holidays. Details about these benefits are provided in the Employee Handbook and Summary Plan Descriptions, available for your review. Eiger may change compensation and benefits from time to time in its discretion.

Subject to approval by the Company's Board of Directors (the "Board"), under the Eiger Equity Incentive Plan (the "Plan"), the Company shall grant you an option to purchase 150,000 shares (the "Option") of the Company's Common Stock at fair market value as determined by the Board as of the date of grant. The Option will be subject to the terms and conditions of the Plan and your grant agreement. Your grant agreement will include a four-year vesting schedule, under which 25 percent of your shares will vest after twelve months of employment, with the remaining shares vesting monthly thereafter, until either your Option is fully vested or your employment ends, whichever occurs first.

As an Eiger employee, you will be expected to abide by Company rules and policies, and acknowledge in writing that you have read the Company's Employee Handbook. As a condition of employment, you must sign and comply with the attached Employee Confidential Information and Inventions Assignment Agreement which prohibits unauthorized use or disclosure of Eiger proprietary information, among other obligations.

## Offer Letter, dated as of December 12, 2017, by and between Eiger BioPharmaceuticals, Inc. and David Apelian, M.D., Ph.D.

In your work for the Company, you will be expected not to use or disclose any confidential information, including trade secrets, of any former employer or other person to whom you have an obligation of confidentiality. Rather, you will be expected to use only that information which is generally known and used by persons with training and experience comparable to your own, which is common knowledge in the industry or otherwise legally in the public domain, or which is otherwise provided or developed by the Company. You agree that you will not bring onto Company premises any unpublished documents or property belonging to any former employer or other person to whom you have an obligation of confidentiality. You hereby represent that you have disclosed to the Company any contract you have signed that may restrict your activities on behalf of the Company.

You may terminate your employment with Eiger at any time and for any reason whatsoever simply by notifying Eiger. Likewise, Eiger may terminate your employment at any time, with or without cause or advance notice. Your employment at-will status can only be modified in a written agreement signed by you and by an officer of Eiger.

In the event of a Change of Control of the Company after your first 6 months of employment that (i) requires a move of the Company over 50 miles or (ii) results in a substantial reduction in your responsibilities or compensation (that is not otherwise applicable to the other members of the management team):

- a. You will receive 12 months of your base salary, paid in the form of continuing base salary payments, less payroll deductions and standard withholdings
- b. Providing you elect COBRA in a timely manner, the Company will pay for your COBRA benefits for up to a maximum of 6 months or until you are enrolled in a separate benefits plan
- c. You will receive accelerated vesting of 100% of your unvested shares under the Option

In the event of your termination without Cause after your first 6 months of employment:

- a. You will receive 6 months of your base salary, paid in the form of continuing base salary payments, less payroll deductions and standard withholdings
- b. Providing you elect COBRA in a timely manner, the Company will pay for your COBRA benefits for up to a maximum of 6 months or until you are enrolled in a separate benefits plan
- c. You will receive accelerated vesting of 50% of your unvested shares under the Option

A "Change in Control" shall mean any consolidation or merger of the Company with or into any other corporation or other entity or person, or any other corporate reorganization, in which the capital stock of the Company immediately prior to such consolidation, merger or reorganization, represents less than 50% of the voting power of the surviving entity (or, if the surviving entity is a wholly owned subsidiary, its parent) immediately after such consolidation, merger or reorganization; or (B) any transaction or series of related transactions to which the Company is a party in which in excess of fifty percent (50%) of the Company's voting power is transferred; *provided* that a Change in Control shall not include (x) any consolidation or merger effected exclusively to change the domicile of the Company, or (y) any transaction or series of transactions principally for bona fide equity financing purposes in which cash is received by the Company or indebtedness of the Company is cancelled or converted or a combination thereof approved by two-thirds of the outstanding shares of preferred stock of the Company.

"Cause" shall mean that in the reasonable determination of the Board, you commit any felony or crime involving moral turpitude, participate in any fraud against the Company, willfully breach your duties to

# Offer Letter, dated as of December 12, 2017, by and between Eiger BioPharmaceuticals, Inc. and David Apelian, M.D., Ph.D.

the Company, wrongfully disclose any trade secrets or other confidential information of the Company, or materially breach any material provision of the Agreement, the Proprietary Information and Inventions Agreement or any other agreement entered into with the Company.

This offer is contingent upon a background check clearance, reference check, and satisfactory proof of your right to work in the United States. You agree to assist as needed and to complete any documentation at the Company's request to meet these conditions.

This letter, together with your Employee Confidential Information and Inventions Assignment Agreement, forms the complete and exclusive statement of your employment agreement with Eiger. It supersedes any other agreements or promises made to you by anyone, whether oral or written. Changes in your employment terms, other than those changes expressly reserved to the Company's discretion in this letter, require a written modification signed by an officer of Eiger.

Please sign and date this letter, and the enclosed Employee Confidential Information and Inventions Assignment Agreement and return them to me by December 15, 2017 if you wish to accept employment at Eiger under the terms described above. If you accept our offer, we would like you to start on January 3, 2018.

We look forward to your favorable reply and to a productive and enjoyable work relationship.

Sincerely,

/s/ David Cory David Cory, RPh, MBA

President and CEO

Accepted:

/s/ David Apelian David Apelian, MD, PhD

December 13, 2017 Date

Attachment: Employee Confidential Information and Inventions Assignment Agreement

# Subsidiaries of Registrant

Name of Subsidiary

EBPI Merger, Inc.

Jurisdiction of Incorporation

Delaware

## **Consent of Independent Registered Public Accounting Firm**

The Board of Directors Eiger BioPharmaceuticals, Inc.:

We consent to the incorporation by reference in the registration statements (Nos. 333-2221972, 333-212114, and 333-203153) on Form S-3 and the registration statements (Nos. 333-219936, 333-211009, 333-203154, and 333-193662) on Form S-8 of Eiger BioPharmaceuticals, Inc. and subsidiaries of our report dated March 9, 2018, with respect to the consolidated balance sheets of Eiger BioPharmaceuticals, Inc. as of December 31, 2017 and 2016, 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, 2017, and the related notes (collectively, the "consolidated financial statements"), which report appears in the December 31, 2017 annual report on Form 10-K of Eiger BioPharmaceuticals, Inc. and subsidiaries.

/s/ KPMG LLP

San Francisco, California March 9, 2018

# 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.;
- 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 9, 2018

/s/ David Cory

David Cory President and Chief Executive Officer (Principal Executive Officer)

#### 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.;
- 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 9, 2018

/s/ James Welch

James Welch Chief Financial Officer (Principal Financial and Accounting Officer)

### 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, 2017 (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 9, 2018

/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.