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, 2018

or

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

For the transition period from to .

Commission file number 001-36183

Eiger BioPharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**33-0971591**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2155 Park Boulevard, Palo Alto, CA	**94306**
(Address of principal executive offices)	**(Zip Code)**

(650) 272 6138

(Registrant's telephone number, including area code)

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

Title of each class	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	**The NASDAQ Global Market**

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

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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:

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒
Emerging growth company	☒		

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, 2018 totaled approximately $122,624,067 based on the closing price of $12.20 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 11, 2019 was 19,260,443.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates certain information by reference from the registrant's proxy statement for the 2019 Annual Meeting of Shareholders. Such proxy statement will be filed no later than 120 days after the close of the registrant's fiscal year ended December 31, 2018.

Eiger BioPharmaceuticals, Inc.
Form 10-K
For the Fiscal Year Ended December 31, 2018

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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, lonafarnib boosted with ritonavir, peginterferon lambda (Lambda), and avexitide (formerly known as exendin 9-39), 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 file a new drug application or NDA, file a marketing authorization application or MAA, and complete all clinical trials that may potentially be required to file for regulatory approval, for any of our product candidates;
- the commercialization of our product candidates, if approved, including whether commercializing lonafarnib for use in the progeria and progeroid laminopathies indications would result in receipt of a priority review voucher or otherwise be cash flow positive as a program for us;
- 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;
- our ability to obtain favorable reimbursement and pricing and the rate and degree of market acceptance of our product candidates;
- our ability to manufacture product necessary to support regulatory approvals and timely meet commercial requirements;
- 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.

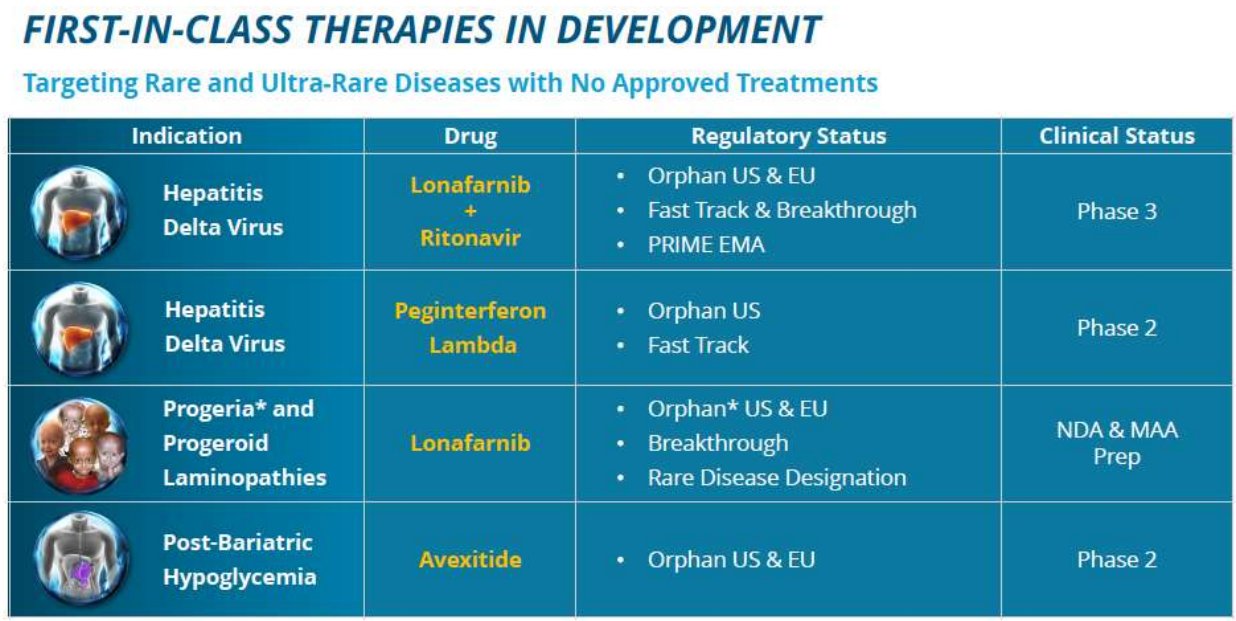
Overview

Eiger is a late-stage biopharmaceutical company focused on the development and commercialization of well-characterized drugs for life-threatening, rare and ultra-rare diseases with high unmet medical needs and no approved therapies. Eiger has reported positive proof-of-concept clinical results in four programs: lonafarnib boosted with ritonavir, peginterferon, lambda, avexitide, and lonafarnib monotherapy, all with first-in-class drugs, now advancing into submission for regulatory approvals or Phase 3 clinical development.

Eiger's lead program is in Phase 3, developing lonafarnib, a first-in-class prenylation inhibitor for the treatment of Hepatitis Delta Virus (HDV) infection. The company is also preparing an NDA and MAA with plans to submit in 2019 for lonafarnib in the treatment of Hutchinson-Gilford Progeria Syndrome (HGPS or Progeria) and Progeroid Laminopathies. In addition, we recently announced positive Phase 2 data with peginterferon lambda for HDV infection and avexitide for post-bariatric hypoglycemia (PBH).

Our programs have several aspects in common: the disease targets represent conditions of high unmet medical need with no approved therapies; 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.

Our pipeline overview is 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 and licensed peginterferon lambda from Bristol-Myers Squibb, or BMS, in April 2016. We have relied upon Merck's and BMS' prior Phase 1/2/3 clinical data, manufacturing and experience with these two molecules to proceed directly into Phase 2 clinical trials following authorization by the U.S. Food and Drug Administration, or FDA, and will rely on that data and information to support potentially pivotal clinical trials and any filings for regulatory approvals.



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

Our product candidate pipeline includes four programs, all advancing toward Phase 3 or regulatory submissions for approval:

1. Lonafarnib (LNF) in Hepatitis Delta Virus (HDV)

Lonafarnib, or LNF, is a well-characterized, orally bioavailable, first-in-class farnesylation inhibitor in Phase 3 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 is a small molecule that blocks the production of HDV virus particles by inhibiting a key step, called farnesylation, in the virus life cycle. We have completed Phase 2 studies in 129 HDV-infected patients dosed with LNF across five international clinical trials. LNF has demonstrated dose-related activity in reducing HDV viral load both as a monotherapy and in combination with other agents. Phase 2 studies have identified two lonafarnib-based regimens that can achieve clinically meaningful composite endpoints of HDV RNA decline $\geq$ 2 logs from baseline and normalized alanine aminotransferase, or ALT, a key liver enzyme, at Week 24: all-oral regimen of LNF 50 mg boosted with ritonavir (RTV) twice daily and combination regimen of LNF boosted with RTV combined with PEG IFN-alfa-2a. Predominantly grade 1 gastrointestinal (GI) adverse events (AE) were observed in Phase 2 amongst per-protocol treated patients. Forty-eight-week dosing will be explored in Phase 3 and is expected to improve outcomes.

Our Phase 3 study is a single, pivotal, international trial called D-LIVR that is designed to support U.S. regulatory approval. D-LIVR has the potential to generate data for two lonafarnib-based ritonavir-boosted regimens for approval. An all-oral arm of LNF boosted with RTV and a combination arm of LNF boosted with RTV combined with PEG IFN-alfa-2a will each be compared to placebo in the Phase 3 D-LIVR study. The first site was initiated in December 2018, and we plan to complete enrollment (n=400) in 2019.

LNF for the treatment of HDV infection has been granted Orphan Drug designation by the FDA, and European Medicines Agency, or EMA, Fast Track and Breakthrough Therapy designation by FDA and PRIME designation by 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. Peginterferon Lambda (Lambda) in HDV

Peginterferon lambda, or 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 /or in a combination therapy with LNF + RTV. We completed a Phase 2 Lambda monotherapy study in 33 HDV-infected patients at four international sites and reported end of treatment data in October 2018. End of study data will be reported in April 2019. In August 2018, we initiated enrollment of a Phase 2 Lambda combination study with LNF boosted with RTV at the National Institutes of Health's National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) (n=26). End of treatment data is expected in the fourth quarter of 2019.

In July 2017, the FDA granted Fast Track designation for Lambda as a potential treatment for HDV infection, and in September 2017, the FDA granted Orphan Drug designation for Lambda for the treatment of HDV infection.

3. Lonafarnib (LNF) in Progeria and Progeroid Laminopathies (PL)

We are also developing lonafarnib for treatment of progeria and progeroid laminopathies, with plans to submit an NDA and MAA in 2019. Progeria, also known as Hutchinson-Gilford Progeria Syndrome (HGPS), is an ultra-rare and rapidly fatal genetic condition of accelerated aging in children. Progeria is caused by a point mutation in the *LMNA* gene, encoding the lamin A protein, yielding the farnesylated aberrant protein, progerin. Lamin A protein is part of the structural scaffolding that holds the nucleus together. Researchers now believe that progerin may make the nucleus unstable, and that cellular instability may lead to the process of premature aging in Progeria. Children with Progeria die of the same heart disease that affects millions of normally aging adults (arteriosclerosis), but at an average age of 14.5 years. Disease manifestations include severe failure to thrive, scleroderma-like skin, global lipodystrophy, alopecia, joint contractures, skeletal dysplasia, global accelerated atherosclerosis with cardiovascular decline, and debilitating strokes. It is estimated that 400 children worldwide have Progeria.

Progeroid laminopathies are genetic conditions of accelerated aging caused by a constellation of mutations in the lamin A and/or Zmpste24 genes yielding farnesylated proteins that are distinct from progerin. While non-progerin producing, these genetic mutations result in disease manifestations with phenotypes that have overlap with, but are distinct from Progeria. Collectively, worldwide prevalence of progeroid laminopathies is likely greater than Progeria.

In May 2018, the Company entered into an amendment to the license agreement with Merck Sharp & Dohme Corp. which provides for expansion of the existing exclusively licensed field of use under the license agreement with Merck to include all uses of lonafarnib related to the treatment of Progeria and progeroid laminopathies.

In August 2018, Eiger and the FDA engaged in a collaborative discussion regarding the survival data that was published in April 2018 Journal of the American Medical Association (JAMA) as potential support for submission of an NDA submission. This clinical study, which compared children with Progeria who received lonafarnib monotherapy with matched untreated children with Progeria, reported a primary outcome of significantly improved mortality. The study found that children taking lonafarnib monotherapy (n=63) experienced a 77 percent reduction in the risk of mortality compared to a natural history, matched-control cohort of untreated children (n=63) after two years of study. Eiger plans to submit a 505(b)(2) NDA and MAA based on this published study in 2019.

Lonafarnib has been granted Orphan Drug designation for Progeria by the FDA and EMA. In October 2018, lonafarnib was granted Rare Pediatric Disease (RPD) and Breakthrough Therapy designation by the FDA for both Progeria and progeroid laminopathies.

4. Avexitide in Post-Bariatric Hypoglycemia (PBH)

Avexitide (formerly known as exendin 9-39) is a well-characterized peptide that we are developing 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 completed four clinical studies demonstrating clinical proof of concept in 54 patients suffering from severe, refractory PBH indicating that avexitide can prevent post-prandial hypoglycemia in affected patients. Avexitide is a glucagon-like peptide-1, or GLP-1, receptor antagonist that competes with endogenous GLP-1 and prevents the excessive post-prandial insulin release that characterizes this disorder. These Phase 2 data were generated using both intravenous and subcutaneous, or SC, formulation delivery. Pharmacokinetics from these Phase 2 SC studies 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. In October 2018, we reported positive topline data from PREVENT, a multi-center, placebo-controlled study investigating the safety and durability of effect of 28-day dosing of SC avexitide in post-bariatric surgical patients. The primary efficacy endpoint of improved postprandial glucose nadir during mixed meal tolerance testing (MMTT) was achieved with statistical significance with fewer participants requiring glycemic rescue during each of the active dosing regimens than during placebo dosing. The secondary endpoint of reduced postprandial insulin peak during MMTT was also statistically significant.

Avexitide for the treatment of hyperinsulinemic hypoglycemia has been granted Orphan Drug designation by the FDA and for the treatment of non-insulinoma pancreatogenous hypoglycemia syndrome (NIPHS) by the EMA. NIPHS describes a spectrum of acquired metabolic disorders characterized by inappropriately high insulin levels (hyperinsulinemia) and low blood glucose levels (hypoglycemia), which includes PBH.

5. Ubenimex

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.

In October 2018, topline results for the Phase 2 ULTRA study results in primary and secondary lymphedema were announced. No improvement of ubenimex over placebo in the primary endpoint of skin thickness and secondary endpoints of limb volume and bioimpedance was observed. No safety signals attributed to ubenimex were identified. Eiger has discontinued development of ubenimex in lymphedema based on these results.

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. Eiger has discontinued development of ubenimex in PAH based on these results.

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 and academic institutions. With our focus on rare and ultra-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, Halozyme, Clinical Data Inc., New River Pharmaceuticals, Achillion Pharmaceuticals, Schering-Plough, Globe-Immune, Amylin, Zeneca, Aimmune Therapeutics, Jazz Pharmaceuticals, Onyx and Amgen.

Our Strategy

Our mission is to identify, develop, and, directly or through collaborations, bring to market novel products for the treatment of rare and ultra-rare diseases or conditions. We currently have a diverse portfolio of well-characterized product candidates with the potential to address life-threatening diseases for which the unmet medical need is high and, for which there is no approved therapy. Our goal is to be a leader in the development and commercialization of novel therapeutics for serious unmet medical needs in rare and ultra-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 (LNF) in HDV

Lonafarnib, or LNF, is a well-characterized, late-stage, first in class, farnesylation inhibitor that we in-licensed from Merck in 2010 for the treatment of HDV infection. LNF is a well-characterized, orally active, small molecule inhibitor of farnesyl transferase, an enzyme involved in modification of proteins through a process called farnesylation. HDV uses this farnesylation process inside host liver cells to complete a key step in its life cycle. LNF inhibits the farnesylation step of HDV replication inside liver cells and blocks the virus life cycle at the stage of assembly. Since farnesylation carried out by a host enzyme, there is a higher barrier to develop viral resistance mutations to LNF therapy.

We are in Phase 3 with a single, pivotal, international trial called D-LIVR. D-LIVR has the potential to generate data for two LNF-based RTV-boosted regimens for approval. An all-oral arm of LNF boosted with RTV and a combination arm of LNF boosted with RTV combined with PEG IFN-alfa-2a will each be compared to placebo in the D-LIVR study. First site was initiated in December 2018, and we plan to complete enrollment (n=400) in 2019.

Peginterferon Lambda (Lambda) in HDV

Peginterferon Lambda (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 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 in BMS's clinical trials reduced the off-target effects associated with other IFNs and improved 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 lonafarnib. We have completed dosing in the Phase 2 LIMT Lambda monotherapy study (n=33) and reported topline data in November 2018 demonstrating comparable antiviral activity to peginterferon alfa with better tolerability. End of follow-up data will be reported at EASL 2019 where a 36% durable virologic response was demonstrated. We have also initiated enrollment of the Phase 2 LIFT combo study of Lambda in combination with LNF boosted with RTV at the NIH (n=26). Topline data from this 24-week dosing trial is expected in the fourth quarter of 2019.

Hepatitis Delta Virus Overview

About Hepatitis Delta Virus

Hepatitis delta infection is caused by HDV, a small circular ribonucleic acid, or RNA, that expresses only one protein, the hepatitis delta antigen, or HDAg. There are two forms of HDAg; small and large. Together, these two forms of HDAg and the single-stranded RNA genome are surrounded by a lipid envelope, which is embedded with Hepatitis B Virus, or HBV surface antigen, or HBsAg, proteins. HDV does not encode its own envelope proteins and must acquire them from HBV during the final steps of replication. Hence, natural HDV infections always occur in the presence of a co-existing HBV infection. HBsAg is the only element of HBV relied upon by HDV. HDV replication can occur independently of HBV replication.

HDV is the most severe form of viral hepatitis. HDV can be acquired either by co-infection (a simultaneous co-infection with HDV and HBV) or by super-infection (HDV infection of someone already harboring a chronic HBV infection). Both co-infection and super-infection with HDV result in more severe complications compared to infection with HBV alone. These complications include a greater likelihood of experiencing liver failure in acute infections and a rapid progression to liver cirrhosis, with an increased chance of developing liver cancer in chronic infections. HDV has the highest fatality rate of all the hepatitis infections at up to 20%. Although HDV/HBV simultaneous co-infection in adults usually resolves completely, in some cases it can become fulminant hepatitis, which carries a very high mortality rate. In the case of super-infections, the predominant form of HDV, HDV super-infection leads to a more severe form of disease than chronic HBV mono-infection. In a study published in 1987 in

the Journal of Infectious Diseases (Fattovich, G. et al. "Influence of Hepatitis Delta Virus Infection on Progression to Cirrhosis in Chronic Hepatitis Type B," J Infect Dis, 1987; 155:931), histological liver deterioration was observed in 77% of HBV patients co-infected with HDV over a 15-year follow-up period, versus 30% of patients infected with HBV alone ($p<0.01$). In a 2013 study of chronic HBV patients published in the Journal of Gastroenterology and Hepatology (Gish, R. et al. "Coinfection with hepatitis B and D: epidemiology, prevalence and disease in patients in Northern California," J Gastroenterol Hepatol, 2013; 28(9):1521), cirrhosis was present in 73% of HBV patients co-infected with HDV, compared to only 22% of those infected with HBV alone. Patients co-infected with HDV are more than twice-as-likely to develop liver-related complications, cirrhosis, or require liver transplants than matched patients infected with HBV alone.

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

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

There are diagnostic tests in use today in clinical laboratories to detect anti-HDV antibodies in serum. These tests are currently able to detect acute HDV infections after four weeks, but they are poor tests for active HDV infections. Active HDV infections are best detected by reverse transcriptase-polymerase chain reaction, or RT-PCR, assays for genomic RNA. These assays yield a quantitative assessment of the number of viral particles, or viral load, in serum. A commercial assay for quantitative HDV RNA has been available in Europe (Robogene®) since 2015. Quest Diagnostics and ARUP Laboratories offer commercial assays for quantitative HDV RNA testing in the United States. 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 approved therapy for hepatitis delta virus 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 HDV RNA occurs in greater than 50% of patients. HBV nucleoside analogs that suppress HBV DNA are ineffective against HDV since they are ineffective in suppressing the expression HBsAg. Current development programs targeting HBV functional cures are not expected to eliminate extra-hepatic reservoirs of HBsAg. Given that HDV only requires small amounts of HBsAg for viron assembly, functional cures, if achieved, will not eradicate HDV.

HDV Replication and Farnesylation

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 farnesylated by a host enzyme which covalently attaches a 15-carbon prenyl lipid (farnesyl-moiety) to the

cysteine of the CXXX box. Farnesylation 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 farnesylation, or protein farnesylation, which has been shown to be essential for the last steps in HDV replication, the assembly and release of new virus progeny.

In the 1980s farnesyltransferase inhibitors were developed by multiple pharmaceutical companies for oncology indications. Addition of a farnesyl or prenyl lipid group to the Ras protein, or Ras, a well-known and important regulator of cellular proliferation, allows for membrane association. Once membrane bound, Ras may then be activated. The importance of activated Ras in tumor development was demonstrated by sequence analyses of tumors from patients where up to 30% have mutations involving Ras. Several farnesylation 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 farnesyltransferase inhibitors block HDV viral production both in cellular experiments and in HDV transgenic mice. Targeting farnesylation or farnesyl transferase, a host target, significantly reduces the likelihood of HDV developing resistance to escape effects of antiviral therapy. Viruses mutate quickly and there is a higher rate of mutations in viral replication compared to mammalian cell division. However, no matter how much HDV may mutate, these changes are unlikely to alter the host process of farnesylation which HDV requires to complete packaging. Thus, targeting a host farnesylation process provides what we believe to be a higher barrier to resistance. Identification of clinic-ready farnesylation inhibitors has allowed us to move rapidly into proof-of-concept studies in humans.

Our Lead HDV Opportunity: LNF

LNF is a well-characterized, orally active inhibitor of farnesyl transferase. LNF inhibits the farnesylation step of HDV replication inside liver cells and blocks the ability of the virus to multiply. Since farnesylation is a host process, not under control of HDV, and LNF inhibits farnesylation, 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 and Breakthrough Therapy designation from FDA for the treatment of chronic HDV infections. In the United States, we have an issued patent, U.S. Patent No. 10,076,512, entitled “Treatment of Hepatitis Delta Virus Infection.” The issued claims cover a broad range of RTV-boosted LNF doses and durations. The European Patent Office and the Japan Patent Office have also both issued decisions to grant patents with claims covering a broad range of lonafarnib boosted with RTV dosing regimens for the treatment of HDV infection. With the grant of these new European and Japanese patents, LNF boosted with RTV has now obtained patent protection with claims covering treatment with LNF boosted with RTV in key major pharmaceutical markets including the U.S., Europe, and Japan. We are in Phase 3 with a single, pivotal, international trial called D-LIVR, with first site initiated in December 2018. This is a 48-week study with planned enrollment of 400 patients across 20 countries and over 100 sites. LNF has never been approved or commercialized for any indication.

LNF Phase 2 Clinical Data

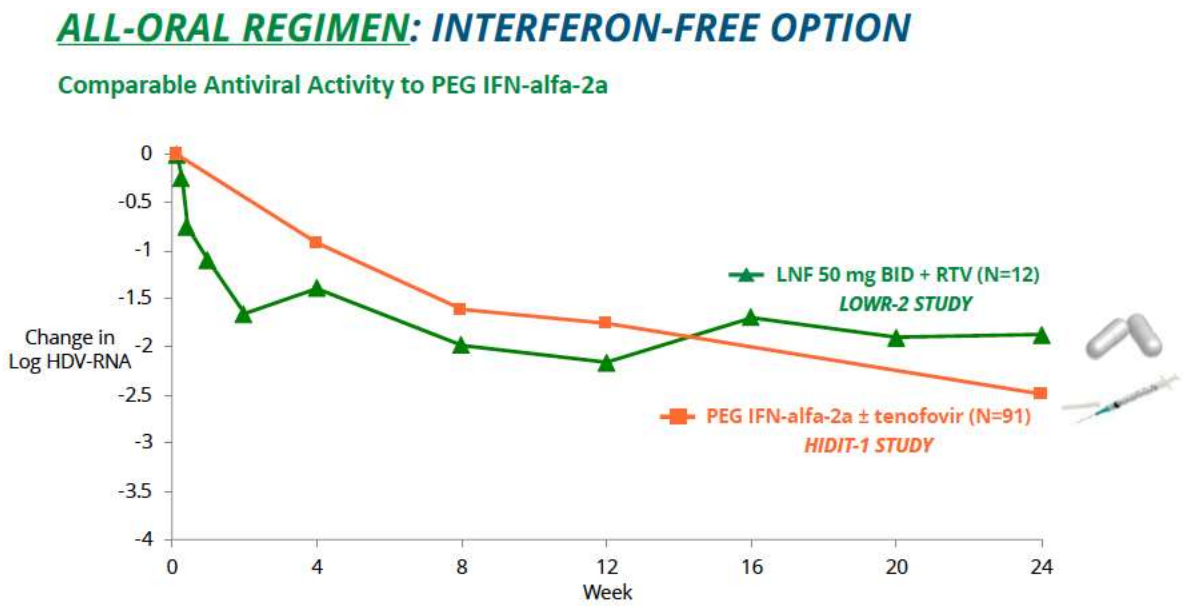
We in-licensed LNF from Merck in 2010, and have relied upon Merck’s prior Phase 1, 2 and 3 clinical experience with LNF in over 2000 patients to understand safety and pharmacokinetics.

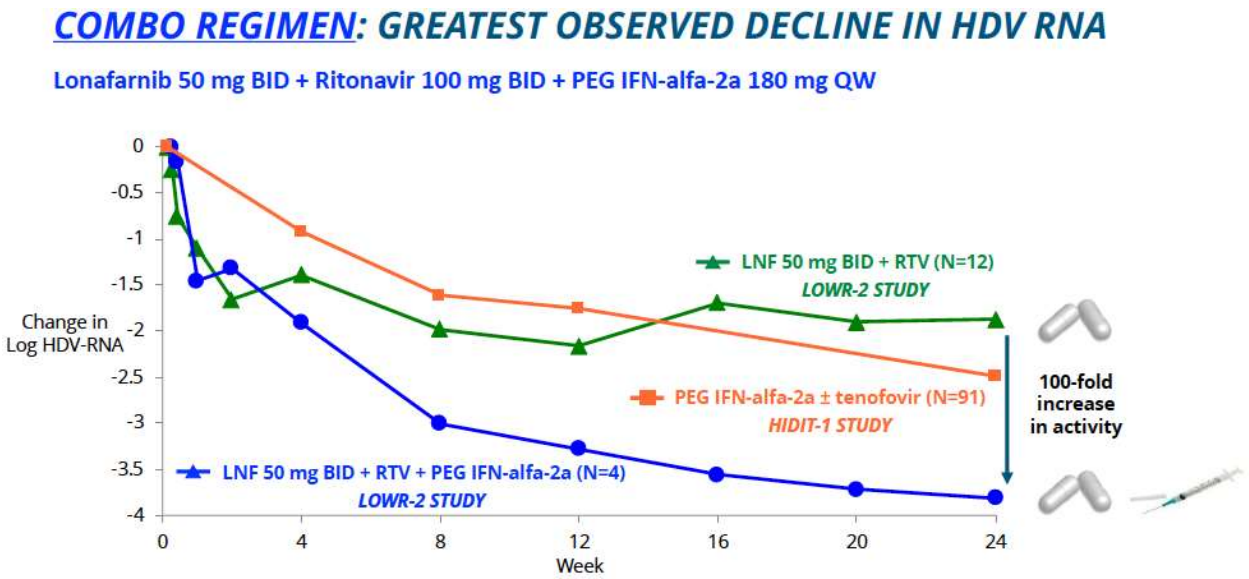
We have completed five Phase 2 trials (POC, LOWR-1, LOWR-2, LOWR-3, LOWR-4) with LNF in 129 HDV-infected patients. The Phase 2 LOWR HDV (Lonafarnib With Ritonavir in HDV) Program identified dose(s) and regimen(s) for registration.

- POC Study (Placebo-controlled LNF monotherapy) (n=14)
- LOWR-1 Study (Combination: LNF with RTV or PEG IFN-alfa-2a) (n=21)
- LOWR-2 Study (Dose Finding: LNF + RTV ± PEG IFN-alfa-2a) (n=58)
- LOWR-3 Study (QD Dosing: LNF + RTV) (n=21)
- LOWR-4 Study (Dose-Escalation: LNF + RTV) (n=15)

The Phase 2 NIH proof-of-concept study demonstrated statistically significant decreases in HDV RNA viral load with two LNF active groups versus placebo for 28-days. A statistically significant correlation between increasing LNF serum levels and decreasing HDV RNA viral loads was also observed, demonstrating that higher serum levels resulted in greater decline in HDV RNA.

The Phase 2 LOWR studies demonstrated benefits of twice daily RTV-boosting of LNF for up to 24 weeks of dosing. 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 Phase 2 LOWR HDV studies identified two LNF-based regimens that can achieve clinically meaningful composite endpoints of HDV RNA decline ≥ 2 logs from baseline and normalized ALT at Week 24: All-oral regimen of LNF 50 mg BID boosted with RTV twice daily and combination regimen of LNF 50 or 25 mg BID boosted with RTV combined with PEG IFN-alfa-2a (see figures below). These dosing regimens were associated with predominantly grade 1 GI AEs amongst per-protocol treated patient.

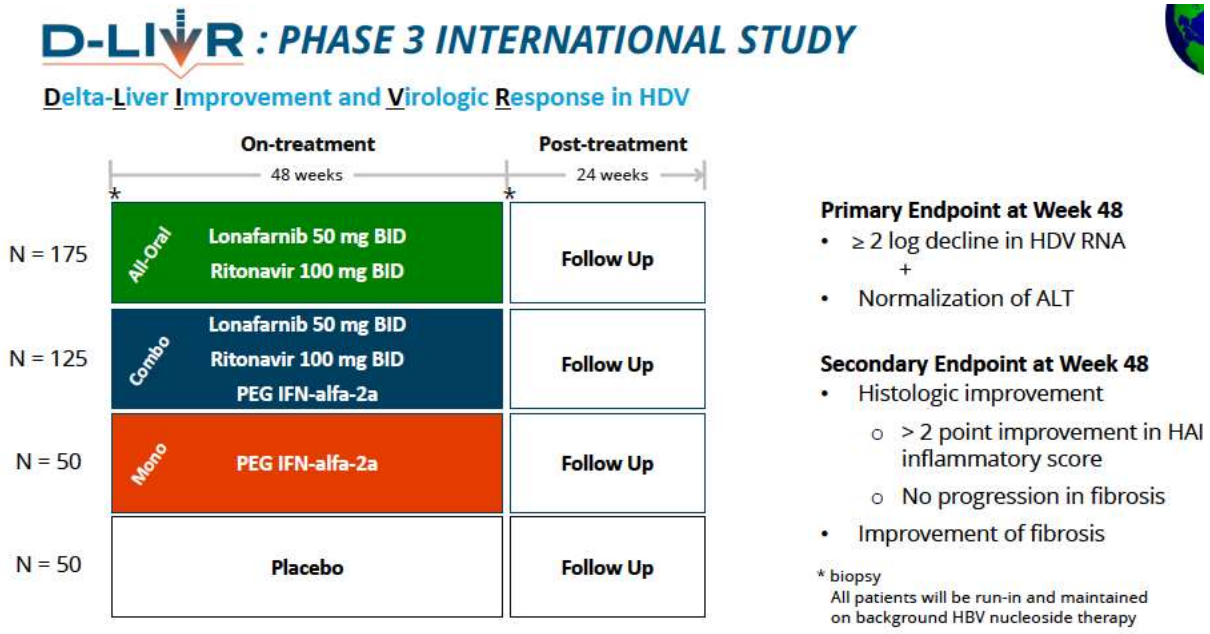




Phase 3 D-LIVR Study

D-LIVR (Delta Liver Improvement and Virologic Response in HDV) is an international, multi-center, Phase 3 study of approximately 300 LNF-treated patients (total N=400 patients including controls) to evaluate an all-oral arm of LNF boosted with RTV and a combination arm of LNF boosted with RTV combined with pegylated interferon-alfa-2a (PEG IFN-alfa-2a), with each arm to be compared to a placebo arm (background HBV nucleos(t)ide only), in HDV-infected patients. A PEG IFN-alfa-2a alone arm will be dosed to demonstrate contribution of effect only. The LNF containing arms will not be required to demonstrate superiority over PEG IFN-alfa-2a alone. A combined primary endpoint of ≥ 2 $\log_{10}$ decline in HDV RNA and ALT normalization at end of 48 weeks of treatment will be used to assess activity of LNF-based regimens versus placebo in the D-LIVR study.

First D-LIVR site initiated in December 2018. This is a 48-week study has planned enrollment of 400 patients across 20 countries and over 100 sites.



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-2a, 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-2a. We plan to develop Lambda as a monotherapy and in a combination therapy with LNF. We completed the Phase 2 LIMT monotherapy study using Lambda to treat HDV in 33 patients at four international sites and reported end of treatment data in October 2018. 24 week follow-up data will be reported in April 2019 at EASL where 36% durable virologic response was observed at 24 weeks post-treatment. In August 2018, we initiated enrollment of the Phase 2 LIFT combination study of Lambda combined with LNF

boosted with RTV at the NIH (n=26). End of treatment data is expected in the fourth quarter of 2019. Lambda has never been approved or commercialized for any indication.

Lambda Clinical Data

LIMT HDV Monotherapy Phase 2 Clinical Trial

The LIMT HDV was a 1:1 randomized, open-label Phase 2 study of Lambda 120 or 180 microgram subcutaneous injections administered weekly for 48 weeks in 33 patients with chronic HDV. End of treatment will be followed by a treatment-free 24-week observation period. The primary objective of the Phase 2 study was to evaluate the safety, tolerability, and efficacy of treatment with two dose levels of Lambda monotherapy in patients with chronic HDV infection. All patients were 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.

End of treatment Week 48 data was presented during AASLD 2018 in San Francisco. At Week 48, patients in the 180 µg Lambda treated group experienced a -2.4 $\log_{10}$ mean decline in HDV-RNA, with 6 of 10 (60%) experiencing ≥ 2 $\log_{10}$ decline, 4 of 10 (40%) patients were HDV-RNA negative at end of treatment. At Week 48, patients in the 120 µg Lambda treated group experienced a -1.5 $\log_{10}$ mean decline in HDV RNA, with 6 of 14 (42.9%) experiencing ≥ 2 $\log_{10}$ decline, 2 of 14 (14.3%) patients were HDV-RNA negative at end of treatment. The most commonly reported AEs were moderate headache, pyrexia, fatigue, and myalgia. ALT flares are due to vigorous antiviral immunological response to treatment, not due to direct hepatotoxicity. End of 24-week follow-up demonstrated a 36% durable virologic response which will be presented at EASL 2019. Lambda is a promising agent for mono or combination treatment (i.e. with lonafarnib) development in the treatment of HDV.

LIFT HDV Combotherapy Phase 2 Clinical Trial

LIFT (Lambda Interferon combo-Therapy) is an open-label, Phase 2 study evaluating Lambda + Lonafarnib + Ritonavir in 26 HDV-infected patients. Patients will be dosed for 24 weeks + undergo follow up for 24 weeks. Primary endpoint will be ≥ 2 log decline in HDV RNA at end of treatment. Secondary endpoints will include histology (> 2 point improvement in histological activity index and no progression in fibrosis) at end of treatment. LIFT is being conducted within the National Institutes of Health (NIH) at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). LIFT plans to complete enrollment with 26 patients in the first quarter of 2019, and end of treatment data is expected in the fourth quarter of 2019.

Potential for Registration in HDV for LNF and Lambda

Our current goal in developing LNF and Lambda is to suppress the virus and reduce liver inflammation. Therefore, we have defined a primary endpoint for D-LIVR as a 2 log reduction in HDV RNA and ALT normalization. Our long term 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 anti-HDV investigational 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-2a 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.

Avexitide for Post-Bariatric Hypoglycemia

Avexitide is the third product candidate in our pipeline. Avexitide 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. Avexitide blocks GLP-1 from binding to the GLP-1 receptor, inhibiting the GLP-1-mediated incretin effect. We are developing avexitide 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 54 patients suffering from PBH that avexitide 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 avexitide in healthy volunteers in mid-2017. We completed a Phase 2 multiple ascending dosing trial (up to 3 days) in affected patients with our avexitide SC novel liquid formulation in 2017, and have completed a Phase 2, 28 day study (PREVENT) in affected patients using of the new SC formulation in the third quarter 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. Surgically-altered nutrient transit, such as a Roux-en-Y procedure, causes early nutrient sensing by the intestinal "L" cells, resulting in enhanced secretion of GLP-1 leading to elevated insulin secretion. This effect may play a primary role in the early resolution of Type 2 diabetes after surgery. A number of synthetic analogs of GLP-1, or agonists, have been approved for the treatment of Type 2 diabetes including Byetta™ (exenatide), Victoza™ (liraglutide), and Trulicity™ (dulaglutide). These drugs, all agonists, bind to the GLP-1 receptor and enhance the release of insulin in a glucose-dependent manner. In patients with PBH, excessive secretion of GLP-1 and/or exaggerated sensitivity to GLP-1 results in dysfunctional insulin release, leading to severe, debilitating hypoglycemia. GLP-1 receptor antagonists compete with endogenous GLP-1 and has the potential to prevent dysfunctional insulin release and resultant symptomatic hypoglycemia.

Approximately 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: Avexitide to Treat Post-Bariatric Hypoglycemia

Avexitide (formerly exendin 9-39) has recently been adopted by the United States Adopted Name (USAN) Council and will be the International Nonproprietary Name (INN), which is used to identify pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognized. Eiger plans to seek approval for a proprietary name or brand name during Phase 3 development.

Avexitide is a well-characterized, competitive antagonist of GLP-1 at its receptor. Avexitide is a 31 amino acid fragment of exenatide, a commercially available GLP-1 agonist, brand named Byetta™ used in the treatment of type 2 diabetes. Avexitide 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, avexitide is a new molecular entity and has never been approved nor commercialized for any indication.

Clinical Data to Date

We have demonstrated in four clinical studies with avexitide that pharmacologic blockade of the GLP-1 receptor can prevent hypoglycemia in affected patients and mitigate symptoms of hypoglycemia. We believe that avexitide may represent the first targeted medical treatment for patients with PBH. In the four completed studies, there were no significant adverse drug reactions attributed to avexitide.

The first avexitide study was a Phase 1, double-blinded crossover study wherein eight patients with PBH were randomly assigned to receive IV infusion of avexitide 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.

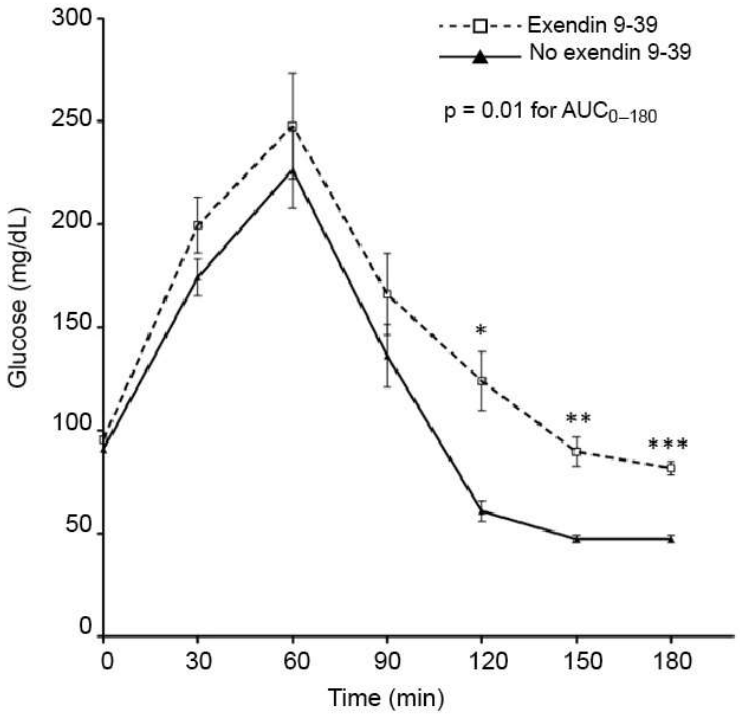
In this trial, IV infusion of avexitide raised the postprandial glucose nadir by over 70% and lowered the area under the curve insulin by 57%, normalizing both parameters relative to healthy nonsurgical controls, and preventing hypoglycemia in all eight participants. In contrast, during placebo infusion 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 avexitide 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 avexitide 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 avexitide 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 avexitide was administered subcutaneously in eight patients with PBH. This was the first investigation involving the SC administration of avexitide in human subjects and was designed to examine the PK, PD, and local tolerability of SC avexitide 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 avexitide dose, ranging from approximately 10–30 mg (0.13–0.38 mg/kg).

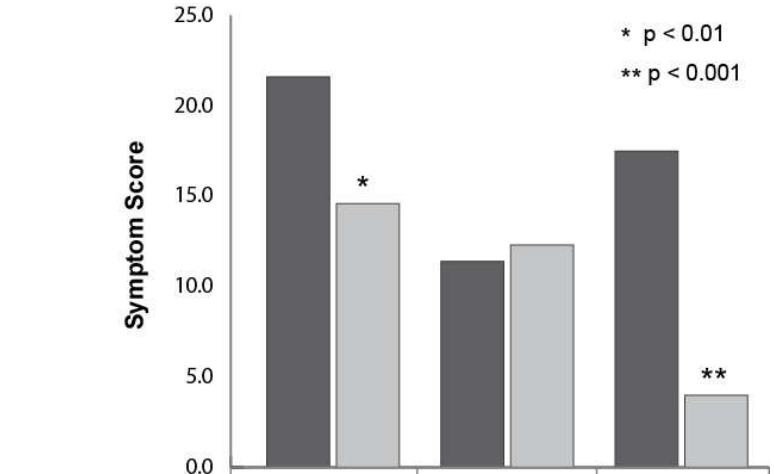
In all eight patients undergoing the OGTT, avexitide administration prevented hypoglycemia and reduced symptoms of hypoglycemia. The baseline OGTT resulted in a high peak in plasma glucose concentration for all eight patients, followed by a rapid, steep decline, with all patients requiring rescue with IV dextrose at a plasma glucose concentration of 50 mg/dL. In contrast, prevention of hypoglycemia occurred at all dose levels of SC avexitide 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 avexitide, 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.

Avexitide SC Injection SAD Study Results



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

Symptoms of PBH were assessed using the Edinburgh Hypoglycemia Symptom Scale, which was completed by patients every 30 minutes during each 180-minute OGTT. Patients used the scale to report the presence and severity of autonomic or neuroglycopenic symptoms or symptoms of malaise. SC avexitide 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 avexitide were identified, and no injection site reactions were reported in any patients in this study.



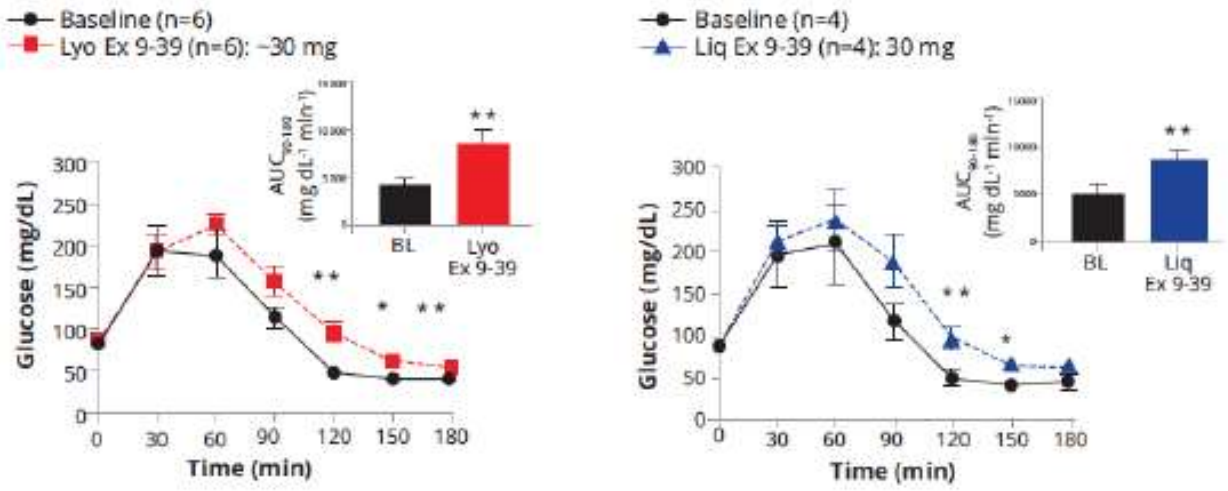
	Overall	Glucose Rise	Glucose Fall
Baseline	21.6	11.4	17.5
SC Exendin 9-39	14.6	12.3	4.0

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

A third study with avexitide completed in June 2017. This was a Phase 2 trial evaluating the safety, efficacy, and PK profile of multiple ascending doses of subcutaneously administered avexitide in patients with PBH. A liquid and a lyophilized formulation of SC avexitide were evaluated in the MAD study.

Key findings from this study demonstrated that both SC avexitide liquid and lyophilized formulations reduced postprandial hyperinsulinemic hypoglycemia, reduced hypoglycemic symptoms and were well tolerated with no related adverse events. In addition, SC avexitide 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.

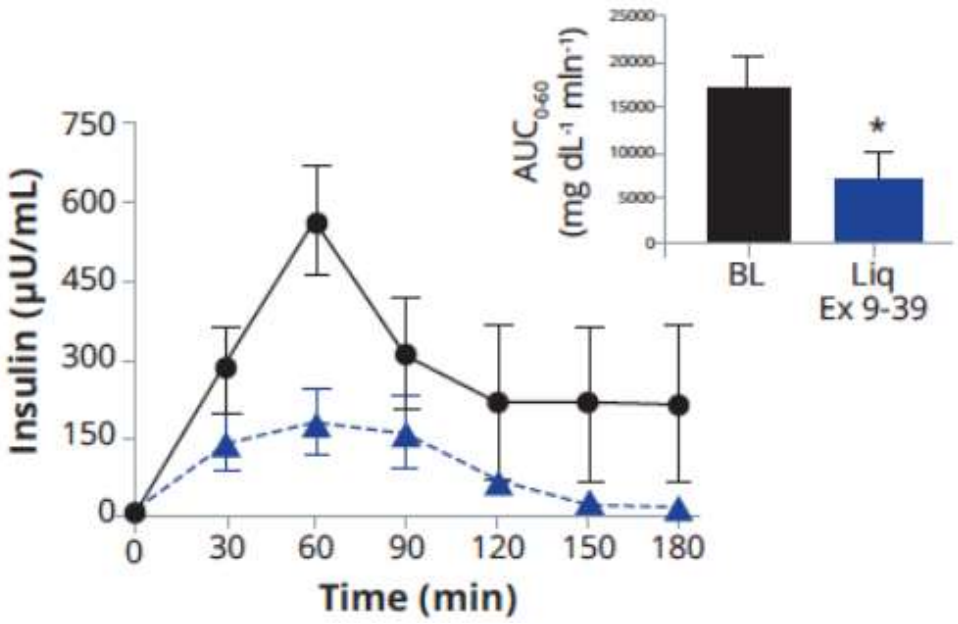
Avexitide SC Injection MAD Study Glycemic Results



Source: Craig et al ADA Poster, June 2017.

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

Avexitide SC Injection MAD Study Results



Source: Craig et al ADA Poster, June 2017.

The PREVENT study is the fourth Phase 2 study with avexitide completed in October 2018. The PREVENT study was a Phase 2, multicenter, randomized, single-blind, placebo-controlled cross-over study to assess the efficacy and safety of 28-day dosing of avexitide in patients with post-bariatric hypoglycemia (PBH). A total of 18 patients were enrolled and treated with two dosing regimens (once daily and twice daily) of avexitide for 28 days. All patients participated in three 14-day treatment periods, involving placebo subcutaneous (SC) injections, once-daily avexitide SC injections, and twice-daily avexitide SC injections. Patients self-administered injections in an outpatient setting. Participants underwent in-clinic mixed meal tolerance test (MMTT) provocations with concomitant blood draws and symptom assessments following each treatment period. Metabolic and clinical improvements were monitored during each patients' daily routines in the outpatient setting and assessed by electronic diary and continuous glucose monitoring (CGM). Outcomes include improvement in plasma glucose nadir levels, reduction in peak insulin concentrations, and the requirement for rescue during MMTT provocation.

The primary efficacy endpoint of improved postprandial glucose nadir during mixed meal tolerance testing (MMTT) was achieved with statistical significance with avexitide 30 mg BID (57.1 vs 47.1 mg/dL; $p = 0.001$) and 60 mg QD (59.2 vs 47.1 mg/dL; $p = 0.0002$), with fewer participants requiring glycemic rescue during each of the active dosing regimens than during placebo dosing. The secondary endpoint of reduced postprandial insulin peak during MMTT was also statistically significant with avexitide 30 mg BID (349.5 vs 454.5 μIU/mL; $p < 0.03$) and 60 mg QD (357.2 vs 454.5 μIU/mL; $p = 0.04$).

Metabolic and clinical improvements were also monitored during each patients' daily routine in the outpatient setting and assessed by electronic diary and continuous glucose monitoring (CGM). Patients experienced fewer episodes of hypoglycemia (hypoglycemia symptoms confirmed by self-blood glucose monitor (SBGM) concentrations of <70 mg/dL) and severe hypoglycemia (neuroglycopenic symptoms confirmed by SBGM concentrations <55 mg/dL) during both dosing regimens of avexitide as compared to placebo. These results were corroborated by CGM data.

Avexitide was well-tolerated. There were no treatment-related serious adverse events and no participant withdrawals. Adverse events were typically mild to moderate in severity. The most common adverse events were injection site bruising, nausea, and headache, all of which occurred with lower frequency during avexitide dosing periods than during the placebo dosing period.

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, 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.

Commercial contract manufacturers for Lonafarnib and Interferon Lambda have been identified and plan to proceed with qualifications.

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.

Peginterferon Lambda (Lambda)

We are completing the technology transfer from BMS for our Peginterferon Lambda program. 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 cGMP drug product manufacturing campaign in 2017 at a new Eiger designated manufacturing facility. The drug substance CMO remains the same CMO contracted by BMS and is currently under evaluation to update for the drug substance manufacturing process.

Both Lonafarnib and Lambda are GMP products from all CMOs.

Avexitide

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

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.

In the United States, we have obtained patent protection for the use of LNF in combination with RTV for the treatment of hepatitis delta virus (HDV) infection. On September 18, 2018, the United States Patent and Trademark Office (USPTO) issued U.S. Patent No. 10,076,512 to Eiger. This patent entitled, “Treatment of Hepatitis Delta Virus Infection,” includes claims covering broad range of RTV-boosted LNF doses and durations. The patent has a term that extends to 2035. Additional claims are being pursued in a continuation application. The European Patent Office and the Japan Patent Office have also both issued decisions to grant patents with claims covering a broad range of LNF boosted with RTV dosing regimens for the treatment of HDV infection. These patents will have a term that extends to 2035. In Europe, additional claims are being pursued in a divisional application. With the grant of these new European and Japanese patents, we have now obtained patent protection with claims covering treatment with LNF boosted with RTV in key major pharmaceutical markets including the U.S., Europe, and Japan.

Corresponding patent applications claiming the use of lonafarnib boosted with ritonavir are pending in China and Korea.

Additionally, a PCT application claiming particular dosage regimens for ritonavir-boosted lonafarnib for the treatment of HDV infections was filed and has now matured into national phase applications in Europe, China, Japan and Korea. Any patents that issue from these applications will expire in 2036. 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 also filed a PCT application for LNF/RTV combination drug products useful for treating HDV. This PCT application matured into currently pending patent applications in the United States, Europe, China, Japan and Korea. Any patents that issue from these applications will expire in 2036.

Peginterferon-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, which matured into patent applications in the United States, Europe, China, Japan and Korea. Any patents that issue from these applications will expire in 2036.

Avexitide. We have in-licensed from Stanford two PCT applications that claim the use of avexitide 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. Additionally, avexitide has been granted Orphan Drug designation in this indication by the FDA and the EMA, which provides seven years and ten years of regulatory exclusivity in the United States and Europe, respectively.

We also filed a PCT application for formulations of avexitide and the use of these formulations in the treatment of hypoglycemia associated with bariatric surgery. This application is still pending. Any patents that issue from this application will expire in 2037.

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 an 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 certain 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 (HDV): Myr (Phase 3), Replicor, Inc. (Phase 2)
- Progeria and Progeroid Laminopathies: none
- Post-Bariatric Hypoglycemia (PBH): Xeris Pharmaceuticals (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 lonafarnib. As consideration for such exclusive right, we issued Private Eiger convertible preferred stock with a fair value of $0.5 million when the agreement was executed in September 2010. This preferred stock was converted to 27,350 shares of common stock upon the Merger. In addition, we are obligated to pay Merck up to an aggregate of $27.0 million in development milestones and will be required to pay tiered royalties based on aggregate annual net sales of all licensed products ranging from mid-single to low double-digit royalties on net sales. Our obligation to pay royalties to Merck expires on a country-by-country and product-by-product basis on the later of the expiration of the last to expire patent assigned to us under the agreement, which is estimated to be in 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 year ended December 31, 2018.

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.

On May 15, 2018, we entered into an amendment to the exclusive license agreement with Merck, which provides for expansion of the existing exclusively licensed field of use under the license agreement with Merck to include all uses of lonafarnib related to the treatment of Hutchinson-Gilford Progeria Syndrome in humans at no cost to us. We have the sole responsibility and the continuing obligation for the manufacture and supply of lonafarnib to The Progeria Research Foundation. Merck will not receive milestone payments in relation to lonafarnib for the treatment of progeria and progeroid laminopathies or any royalty payments for sales of a specified quantity of lonafarnib to treat the currently estimated progeria and progeroid laminopathies patient population worldwide.

Asset Purchase Agreement with Eiger Group International, Inc.

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

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

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

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

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

License Agreement with Janssen Pharmaceutica NV

In December 2014, we, through our wholly-owned subsidiary EB Pharma, LLC, or EBP, entered a License Agreement 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, 2018, 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.

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 avexitide from the Sellers, including an assignment of a license agreement with Stanford which covered exclusive rights with respect to the compound avexitide. 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 avexitide.

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, single-digit royalty based on aggregate annual net sales of all products developed based on avexitide 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.

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, 2018, 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 program user fees. These fees are typically increased annually.

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

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

After the FDA evaluates the application and conducts its inspections, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies contained in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application, including potentially significant, expensive and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. Even if such data are submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive, and the FDA may interpret data differently than we do. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the application, the FDA will typically issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of additional information requested. FDA approval is never guaranteed. The FDA may refuse to approve an application if applicable regulatory criteria are not satisfied.

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

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

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

505(b)(2) NDA Pathway

As an alternative path to FDA approval, an applicant may submit an NDA under Section 505(b)(2) of the Food, Drug and Cosmetic Act. A Section 505(b)(2) NDA is an application that contains full reports of investigations of safety and effectiveness, but where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This type of application permits reliance for such approvals on literature or on an FDA finding of safety, effectiveness or both for an approved drug product.

Orphan Drugs

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

Rare Pediatric Disease, or RPD, designation by FDA enables priority review voucher, or PRV, eligibility upon U.S. market approval of a designated drug for rare pediatric diseases. The RPD-PRV program is intended to encourage development of therapies to prevent and treat rare pediatric diseases. The voucher, which is awarded upon NDA or BLA approval to the sponsor of a designated RPD can be sold or transferred to another entity and used by the holder to receive priority review for a future NDA or BLA submission, which reduces the FDA review time of such future submission from ten to six months.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. The Fast Track program is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track product has opportunities for frequent interactions with the review team during product development and, once an NDA or BLA is submitted, the product may be eligible for priority review. A fast track product may also be eligible for rolling review, where the FDA may consider for review sections of the NDA or BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

A product intended to treat a serious or life-threatening disease or condition may also be eligible for Breakthrough Therapy designation to expedite its development and review. A product can receive Breakthrough Therapy designation if preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product, including involvement of senior managers. PRIME designation by the EMA confers comparable benefits on qualifying drug product candidates.

Any marketing application for a biologic submitted to the FDA for approval, including a product with a Fast Track designation and/or Breakthrough Therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition compared to marketed products. For products containing new molecular entities, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (compared with ten months under standard review).

Fast Track designation, Breakthrough Therapy designation, priority review, accelerated approval and RMAT designation do not change the standards for approval but may expedite the development or approval process.

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 information security laws and regulations, including both foreign and domestic, in the locations in which we conduct our business. HIPAA and its respective implementing regulations imposes specific requirements relating to the privacy, security and transmission of individually identifiable health information and requires the adoption of administrative, physical and technical safeguards to protect such information. In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties.

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.

International data protection laws, including, without limitation, the European Union's General Data Protection Regulation ("GDPR") and European Union ("EU") member state data protection legislation, also apply to health-related and other personal data that we process, including, without limitation, personal data relating to clinical trial participants in the EU. The GDPR imposes, significant obligations on controllers and processors of personal data, including, among other things, standards relating to the privacy and security of personal data, which require the adoption of administrative, physical, and technical safeguards to protect such information. These laws may also include, without limitation, requirements for establishing an appropriate legal basis for processing personal data, transparency requirements related to communications with data subjects regarding the processing of their personal data, notification requirements to individuals about the processing of their personal data, an individual data rights regime, mandatory data breach notifications, limitations on the retention of personal data, increased requirements pertaining to health data, requirements related to obtaining consent for processing personal information, and rules and restrictions on the transfer of personal data outside of the EU, including to the U.S. The GDPR also imposes obligations and required contractual provisions to be included in contracts between companies subject to the GDPR and that process personal data on behalf of such companies. The GDPR allows EU member states to make additional laws and regulations further limiting the processing of genetic, biometric or health data. Failure to comply with these laws, where applicable, can result in the imposition of significant regulatory fines and penalties.

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. 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 $37.1 million, $29.5 million and $33.0 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Employees

As of December 31, 2018, we had a total of 18 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 2155 Park Blvd in 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, 2018, 2017 and 2016, we reported a net loss of $52.4 million, $42.4 million and $47.1 million, respectively. As of December 31, 2018, we had an accumulated deficit of $171.2 million. Our prior losses, combined with expected future losses, have had and may continue to have an adverse effect on our stockholders' equity and working capital.

We believe that our currently available resources will be sufficient to fund our planned 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 and regulatory approval efforts and potential commercialization activities. Accordingly, we will need to raise substantial additional capital to continue to fund our operations. The amounts and timing of our future funding requirements will depend on many factors, including our ability to achieve regulatory approval and 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 submit an NDA for regulatory approval for lonafarnib in progeria and advance our clinical development programs in various clinical studies. In particular, at our meetings with the FDA throughout 2018, the FDA confirmed that we could submit an NDA for lonafarnib for the progeria indication and additionally conduct a single, 400 patient pivotal study to support the submission of an NDA for lonafarnib for use in a hepatitis D virus indication. We would need significant additional resources in order to aggressively move lonafarnib forward successfully based on the discussions with the FDA. 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 our 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, because the potential markets in which our product candidates may ultimately receive regulatory approval could be very small, we may never become profitable despite obtaining such market share and acceptance of our products. For example, if we receive approval for lonafarnib in the progeria indications, we have agreed with The Progeria Research Foundation to make available lonafarnib to Hutchinson-Gilford progeria syndrome patients.

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 and submit an NDA and MAA for lonafarnib in progeria and progeroid laminopathies in 2019;
- 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 boosted with ritonavir, lonafarnib for the treatment of progeria and progeroid laminopathies, Lambda for HDV, and avexitide for PBH;
- 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. The Oxford Loan is a $25.0 million debt financing arrangement with Oxford Finance wherein we borrowed the first tranche of $15.0 million upon closing of the debt financing in December 2016. In May 2018, we entered into an amendment to the Oxford Loan and borrowed $5.0 million, or, as amended the Oxford Loan. In August 2018, we drew the final $5.0 million upon achievement of certain clinical milestones. The Oxford Loan is secured by perfected first priority liens on the Company's assets, excluding intellectual property but including a commitment by the Company to not allow any liens to be placed upon such 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 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 the Oxford Loan restrict our business and operations in many ways and if we do not effectively comply with our covenants, our financial conditions and results of operations could be adversely affected.

The Oxford Loan provides for up to $25.0 million in term loans due on July 1, 2021, of which all $25.0 million in principal is outstanding. All of our current and future assets, except for intellectual property, secure our borrowings under the Oxford Loan. The Oxford Loan 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 Oxford Loan, which could permit the lenders to declare all or part of any outstanding borrowings to be immediately due and payable. If we are unable to repay those amounts, the lenders under the Oxford Loan could proceed against the collateral granted to them to secure that debt, and our inability to use or dispose of those assets 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 accelerate the maturity of the debt. Any default under the Oxford Loan would materially affect our liquidity and ability to fund our operations and complete our planned clinical trials and regulatory filings would be substantially impaired.

Risks Related to the Development of our Product Candidates

We are dependent on the success of our product candidates, which are in various 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 plan to submit an NDA for one of these programs in 2019. We currently generate no revenue from sales of any drugs, and we may never be able to develop or commercialize a product candidate. In addition, to the extent that we receive regulatory approval for lonafarnib in progeria and progeroid laminopathies, we expect our commitment to provide access for patients with progeria and progeroid laminopathies for no or minimal cost to those patients to result in a loss to us.

With respect to potential commercial products, we currently have one product candidate that is in Phase 3 clinical trials and two Phase 2 development programs focused on two separate indications. It may be years before our studies are initiated and completed, if at all. In October 2018, the FDA granted Rare Pediatric Disease, or RPD, designation to lonafarnib in the treatment of progeria and progeroid laminopathies. RPD designation enables priority review voucher, or PRV, eligibility upon U.S. market approval of lonafarnib for these ultra-rare and fatal genetic conditions characterized by accelerated aging in children. We are collaborating with The Progeria Research Foundation, or PRF, and we plan to submit a new drug application, or NDA, and marketing authorization approval, or MAA, in 2019. There can be no assurance that we will receive regulatory approval for lonafarnib in the treatment of progeria and progeroid laminopathies or that we will receive a PRV.

In January 2018, we announced that Phase 2 LIBERTY study results of ubenimex in pulmonary arterial hypertension (PAH) demonstrated no improvement overall or in key subgroups. In October 2018, we announced that our Phase 2 ULTRA study of ubenimex in primary and secondary lymphedema of the lower limb demonstrated no improvement of ubenimex over placebo. The Company discontinued development of ubenimex in both PAH and lymphedema 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.

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 would 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 currently have orphan drug designation for some of our product candidates in multiple 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;
- 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. For example, in 2018 we announced that two of our Phase 2 clinical trials of ubenimex in two different indications were negative results and as a result we have terminated further development of ubenimex.

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 contract research organizations, or 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;
- 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.

Our lonafarnib 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 lonafarnib for other indications or our own clinical trials. Additionally, while we have a license to another farnesyltransferase inhibitor compound, tipifarnib, from Janssen Pharmaceutica, N.V., or Janssen, Janssen has granted rights of tipifarnib to Kura Oncology, Inc., or Kura, in oncology and negative results or undesirable side effects from Kura's clinical trials for a compound with a similar mechanism of action may negatively impact the perception of lonafarnib for anti-viral indications. 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 may 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 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 4 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. We cannot assure you that our CROs and other vendors will meet these requirements, or that upon inspection by any regulatory authority, such regulatory authority will determine that efforts, including any of our clinical studies, comply with applicable requirements. Our failure to comply with these laws, regulations and guidelines may require us to repeat clinical studies or conduct larger additional studies, which would be costly and delay the regulatory approval process.

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

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

With respect to our lonafarnib 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 clinical studies.

The material used for Lonafarnib HDV pivotal trails and Progeria clinical studies are sourced from Eiger controlled CMOs. These same vendors are currently under development for commercial qualification.

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

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

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our marketing applications to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as cGMPs, for manufacture of our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

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

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

- We may be unable to identify manufacturers on acceptable terms or at all;
- Our third-party manufacturers might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- Contract manufacturers may not be able to execute our manufacturing procedures appropriately;
- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products;
- Manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards;
- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates; 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 due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our product candidates to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

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

We focus our product development principally on treatments for 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 lonafarnib 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 antiviral activity against HDV, there can be no assurance that our clinical trials will successfully address this condition. Likewise, the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business. Moreover, if lonafarnib receives regulatory approval for use in progeria, we expect that the supply of lonafarnib to patients with progeria and progeroid laminopathies will have limited profits.

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., Myr, Arrowhead Pharmaceuticals, Novartis International AG, Zealand Pharmaceuticals 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. In addition, if lonafarnib receives regulatory approval for use in progeria and progeroid laminopathies, we would be required to establish an expanded access program in order to make this product available for patients with progeria and progeroid laminopathies, which would require additional resources and costs in support of use in this indication.

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

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

- the efficacy of the product as demonstrated in clinical studies and potential advantages over competing treatments;
- the prevalence and severity of the disease and any side effects;
- the clinical indications for which approval is granted, including any limitations or warnings contained in a product's approved labeling;
- the convenience and ease of administration;
- the cost of treatment;
- the willingness of the patients and physicians to accept these therapies;
- the marketing, sales and distribution support for the product;
- the publicity concerning our products or competing products and treatments; and
- the pricing and availability of third-party insurance coverage and reimbursement.

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

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

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

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 lonafarnib 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, or the EU, 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 EU. 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 EU 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 EU, 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 lonafarnib 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-licensed 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 lonafarnib 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 lonafarnib, Lambda and avexitide, a substantial portion of the potential commercial opportunity will likely rely on patent term extensions, and we cannot provide any assurances that any such patent term extensions will be obtained and, if so, for how long. As a result, we may not be able to maintain exclusivity for our products for an extended period after regulatory approval, which would negatively impact our business and results of operations. If we do not have sufficient patent terms or regulatory exclusivity to protect our products, our business and results of operations will be adversely affected.

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

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

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

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

Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors, and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret.

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

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

Third parties may assert that we are 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 agreement for lonafarnib. We may not be able to achieve the required diligence milestones in a timely manner, which may result in Stanford's right to terminate the license agreement, and we may be unable to successfully negotiate an extension or waiver of those termination rights. Any termination of license agreements with third parties with respect to our product candidates would be expected to negatively impact our business prospects.

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

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

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

Our product candidates may be subject to generic competition.

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

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

We may not be successful in securing or maintaining proprietary patent protection 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, supply 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, 2018, we had 18 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 to comply with existing or future laws and regulations related to privacy or data security could lead to government enforcement actions (which could include civil or criminal fines or penalties), private litigation, other liabilities, and/or adverse publicity. Compliance or the failure to comply with such laws could increase the costs of our products and services, could limit their use or adoption, and could otherwise negatively affect our operating results and business.

Regulation of data processing is evolving, as federal, state, and foreign governments continue to adopt new, or modify existing, laws and regulations addressing data privacy and security, and the collection, processing, storage, transfer, and use of data. We and our partners may be subject to current, new, or modified federal, state, and foreign data protection laws and regulations (e.g., laws and regulations that address data privacy and data security including, without limitation, health data). These new or proposed laws and regulations are subject to differing interpretations and may be inconsistent among jurisdictions, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data. These and other requirements could require us or our partners to incur additional costs to achieve compliance, limit our competitiveness, necessitate the acceptance of more onerous obligations in our contracts, restrict our ability to use, store, transfer, and process data, impact our or our partners' ability to process or use data in order to support the provision of our products or services, affect our or our partners' ability to offer our products and services in certain locations, or cause regulators to reject, limit or disrupt our clinical trial activities.

In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. In addition, we may receive unintended health information in error from third parties (including research institutions from which we may obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to criminal penalties, including if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

International data protection laws, including, without limitation, the GDPR, that took effect in May 2018, and member state data protection legislation, may also apply to health-related and other personal information obtained outside of the United States. These laws impose strict obligations on the ability to process health-related and other personal information of data subjects in the EU, including in relation to use, collection, analysis, and transfer of such personal information. These laws include several requirements relating to obtaining the consent of the individuals to whom the personal data relates, limitations on data processing, establishing a legal basis for processing, notification of data processing obligations or security incidents to appropriate data protection authorities or data subjects, the security and confidentiality of the personal data and various rights that data subjects may exercise.

The GDPR prohibits the transfer, without an appropriate legal basis, of personal data to countries outside of the European Economic Area, or EEA, such as the United States, which are not considered by the European Commission to provide an adequate level of data protection. Switzerland has adopted similar restrictions. Although there are legal mechanisms to allow for the transfer of personal data from the EEA and Switzerland to the United States, uncertainty about compliance with EU data protection laws remains and such mechanisms may not be available or applicable with respect to the personal data processing activities necessary to research, develop and market our products and services. For example, ongoing legal challenges in Europe to the mechanisms allowing companies to transfer personal data from the EEA to the United States could result in further limitations on the ability to transfer personal data across borders, particularly if governments are unable or unwilling to reach new or maintain existing agreements that support cross-border data transfers, such as the European Union-U.S. and Swiss-U.S. Privacy Shield framework. Additionally, other countries have passed or are considering passing laws requiring local data residency and/or restricting the international transfer of data.

Under the GDPR, regulators may impose substantial fines and penalties for non-compliance. Companies that violate the GDPR can face fines of up to the greater of 20 million Euros or 4% of their worldwide annual turnover (revenue). The GDPR has increased our responsibility and liability in relation to personal data that we process, requiring us to put in place additional mechanisms to ensure compliance with the GDPR and other EU and international data protection rules.

Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties, fines or sanctions), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations related to security or privacy, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business. Compliance with data protection laws may be time-consuming, require additional resources and could result in increased expenses, reduce overall demand for our products and services and make it more difficult to meet expectations of or commitments to customers or partners.

Any of these matters could materially adversely affect our business, financial condition, or operational results.

Failure in our information technology and storage systems or our security measures, including without limitation, data breaches, or inadequacy of our business continuity and disaster recovery plans and procedures, 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, and the availability of data related to our products, services and operations. IT systems and data are vulnerable to risks and damages from a variety of sources, including catastrophe or natural disaster, telecommunications or network failures, malicious human acts, breaches of security, cyber-attacks, loss of power or other natural or man-made events. 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. If our business continuity and disaster recovery plans and procedures were disrupted, inadequate or unsuccessful in the event of a problem, we could experience a material adverse interruption of our operations.

Specifically, data security breaches, whether inadvertent or intentional, by employees or others, may expose proprietary information, trade secrets, personal information, clinical trial data or other sensitive data to unauthorized persons, impact the integrity, availability or confidentiality of our IT systems or data (including, but not limited to, data loss), or disrupt or interrupt our IT systems or operations. Our partners and vendors face similar risks and any security breach of their systems could adversely affect our security posture. Malicious attacks by third parties are of ever-increasing sophistication and can be made by groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, "hacktivists", nation states and others. The Foreign, federal, and state laws or regulations allows for the imposition of civil liability, fines and/or corrective action on entities that improperly use or disclose the personal information of individuals, including through a data security breach. Accordingly, data security breaches experienced by us, our collaborators or contractors could lead to significant fines, required corrective action, loss of trade secrets or other intellectual property, or could lead to the public exposure of personally identifiable information (including sensitive personal information) of our employees, collaborators, clinical trial patients, and others. A data security breach or privacy violation that leads to disclosure or modification of or prevents access to personal information, including personally identifiable information, patient information or protected health information, could result in civil liability, harm our reputation, compel us to comply with federal and/or state breach notification laws, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect personal data, resulting in increased costs or loss of revenue. If we are unable to prevent data security breaches or privacy violations, respond appropriately or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer civil liability to our customers or individuals, loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive patient data. In addition, these breaches and other inappropriate access events can be difficult to detect, and any delay in identifying and responding to them may lead to increased harm of the type described above. Moreover, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. While we have implemented security measures designed to protect our data security and information technology systems, no set of security measures is infallible, and these measures may not prevent such events.

Despite precautionary measures to prevent anticipated and unanticipated problems, including data breaches, there can be no assurance that our efforts to protect our data and information technology systems will prevent breakdowns or breaches in our systems (or that of our third-party providers). Such events could affect our IT systems, sustained or repeated system failures that interrupt our ability to generate, use and maintain data or our IT systems could adversely affect our ability to operate our business and result in increased costs or loss of revenue, other financial and reputational harm to us, theft of trade secrets and other proprietary information, legal claims or proceedings, liability under laws that protect the privacy of personal information and regulatory penalties.

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. Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain mandated fees under the ACA, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, among other things, amends the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". 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 may have the effect of limiting the amounts that government agencies will pay for healthcare products and services. Policy changes, including potential modification 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 EU 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 EU 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 foreign, 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 have not fully complied, with such laws, we could face substantial penalties, sanctions or other liability.

Our operations may be subject to various foreign, federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, physician sunshine laws, the GDPR and other 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 foreign, federal, and state governments 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 and its implementing regulations impose certain requirements relating to the privacy, security, and transmission of individually identifiable health information;
- The Physician Payments Sunshine Act, which 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.
- the GDPR and other EU member state data protection legislation, which require data controllers and processors, to adopt administrative, physical and technical safeguards to protect personal data, including health-related data, including mandatory contractual terms with third-party providers, requirements for establishing an appropriate legal basis for processing personal data, transparency requirements related to communications with data subjects regarding the processing their personal data, standards for obtaining consent from individuals to process their personal data, notification requirements to individuals about the processing of their personal data, an individual data rights regime, mandatory data breach notifications, limitations on the retention of personal data, increased requirements pertaining to health data, as well as strict rules and restrictions on the transfer of personal data outside of the EU, including to the U.S.

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, criminal and administrative penalties, damages, fines, sanctions, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

We are exposed to the risk of fraudulent conduct or other illegal activity by our employees, independent contractors, principal investigators, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: comply with the regulations of the FDA and non-U.S. regulators, provide accurate information to the FDA and non-U.S. regulators, comply with healthcare fraud and abuse laws in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, promotion, sales, marketing and certain business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of patient recruitment or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of business conduct and ethics applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

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

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

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

We believe our current product liability insurance coverage is appropriate in light of our clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for product candidates, we intend to increase our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability 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 outbreaks 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 have been the subject of securities class action lawsuits filed against Celladon and we cannot guarantee that additional securities litigation will not 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 district court dismissed the complaint on October 7, 2016 and closed the case on December 9, 2016. The lead plaintiff subsequently appealed the dismissal to the United States Court of Appeals for the Ninth Circuit, or the Ninth Circuit. On September 17, 2018, the Ninth Circuit affirmed the district court's order dismissing the complaint. The time to appeal the Ninth Circuit's decision has lapsed and the Ninth Circuit's opinion affirming the dismissal of the complaint is final, effectively terminating the shareholder lawsuit.

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, NDA, or MAA 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 2017 comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into U.S. law tax legislation, or the Tax Act, which significantly changed the Internal Revenue Code of 1986, as amended, or the Code. The Tax Act, among other things, contained significant changes to U.S. federal income corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%; for net operating losses generated after December 31, 2017, limitation of the deduction to 80% of current year taxable income; 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 Tax Act could be amended or subject to technical correction, possibly with a retroactive effect, which could change the financial impacts that were recorded at December 31, 2018 or are expected to be recorded in future periods.

Our net operating loss carryforwards and certain other tax attributes are now subject to limitations.

Our federal and state net operating loss, or NOL, carry-forwards will begin to expire, if not utilized, beginning in 2030 for federal income tax purposes and 2028 for California state income tax purposes. These NOL carry-forwards could expire unused and be unavailable to offset future income tax liabilities. While the Tax Act allows for federal net operating losses incurred in 2018 and in future years to be carried forward indefinitely, the deductibility of such federal net operating losses incurred in 2018 and in future years will be limited. Moreover, if a corporation undergoes an "ownership change" within the meaning of Section 382 of the Code, or Section 382, the corporation's NOL 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 such an ownership change and, accordingly, Celladon's NOL 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, as a result of the Merger that occurred from our formation through December 31, 2016. Based upon this assessment no reduction was made to Eiger's 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 NOL carryforwards. Consequently, even if we achieve profitability, we may not be able to utilize a material portion of our NOL carryforwards and other tax attributes, which could have a material adverse effect on cash flow and results of operations. A full valuation allowance has been provided for the entire amount of our remaining net operating losses.

ITEM 1B. Unresolved Staff Comments

Not applicable.

ITEM 2. Properties

Our corporate headquarters are located at 2155 Park Blvd in Palo Alto, California 94306 in a facility we lease encompassing 8,029 square feet of office space. The lease commenced 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

From time to time we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not presently a party to any legal proceedings that in the opinion of our management, if determined adversely to us, would have a material adverse effect on our business, financial condition, operating results or cash flows. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

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.

Holders of Record

As of March 11, 2019, there were approximately 30 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. The programs have several aspects in common: the disease targets represent conditions of high unmet medical need with no approved therapies; 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. Lonafarnib is our lead compound that we expect to advance into Phase 3 with a single pivotal trial to treat Hepatitis Delta Virus, or HDV, infection and for which we expect to file a new drug application, or NDA, and marketing authorization application, or MAA, for the treatment of Hutchinson-Gilford Progeria Syndrome, known as HGPS or progeria, and progeroid laminopathies in 2019. In addition, we recently announced positive Phase 2 data with peginterferon lambda (Lambda) for HDV infection and avexitide for post-bariatric hypoglycemia. All our programs address distinct rare diseases.

Recent Developments

Appointment of Stephana Patton as General Counsel, Corporate Secretary, and Chief Compliance Officer

On February 27, 2019, we announced the appointment of Dr. Stephana Patton as the Company's General Counsel, Corporate Secretary, and Chief Compliance Officer. Dr. Patton brings twenty years of legal experience to Eiger, and was most recently General Counsel, Corporate Secretary, and Chief Compliance Officer at BioTime, Inc., responsible for all legal and compliance matters at BioTime and its subsidiaries. Previously, Dr. Patton was Vice President, General Counsel, and Commercial Compliance Officer at BioDelivery Sciences International, Inc. Dr. Patton began her pharmaceutical industry career at Salix Pharmaceuticals, Inc., where she was Vice President of Intellectual Property and Licensing, until the company was acquired by Valeant, Inc. in 2015.

Patent Protection for Lonafarnib Boosted with Ritonavir for Treatment of Hepatitis Delta Virus Infection in Europe and Japan

On February 6, 2019, we announced that the European Patent Office and the Japan Patent Office had both issued decisions to grant patents with claims covering a broad range of lonafarnib boosted with ritonavir dosing regimens for the treatment of hepatitis delta virus (HDV) infection. A similar patent issued in the U.S. in 2018. With the grant of these new European and Japanese patents, lonafarnib boosted with ritonavir has now obtained patent protection with claims covering treatment with lonafarnib boosted with ritonavir in key major pharmaceutical markets including the U.S., Europe, and Japan. The patents, when granted, will expire in 2035. Similar patent applications are currently pending in China and Korea.

Oral Presentation of Phase 2 PREVENT Study of Avexitide in Post-Bariatric Hypoglycemia (PBH) at Upcoming Endocrine Society (ENDO) Meeting 2019 in New Orleans

On February 4, 2019, we announced an oral presentation had been granted for results of the Phase 2 PREVENT study at ENDO 2019 in New Orleans on March 25, 2019.

Appointment of Regulatory Expert and Industry Veteran Christine Murray, MS, RAC to Board of Directors

On January 7, 2019, we announced the appointment of Christine Murray, MS, RAC to our Board of Directors. Ms. Murray is a pharmaceutical industry veteran with broad regulatory experience spanning over two decades in large pharma and biotechnology companies across diverse therapeutic areas including liver disease, metabolic disease, antivirals, and rare and ultra-rare disease programs, with multiple successful international regulatory submissions and outcomes. Ms. Murray is currently Senior Vice President of Global Regulatory Affairs at Ultragenyx Pharmaceutical, Inc.

Breakthrough Therapy Designation Granted by FDA for Lonafarnib for Treatment of HDV Infection

On December 19, 2018, we announced that the Food and Drug Administration (FDA) has granted Breakthrough Therapy designation for lonafarnib for the treatment of HGPS or Progeria and progeroid laminopathies. FDA Breakthrough Therapy designation is designed to expedite the development and review of medicines intended to treat serious or life-threatening diseases.

PRIME Designation Granted by European Medicines Agency for Lonafarnib for Treatment of HDV

On December 18, 2018, we announced that the European Medicines Agency (EMA) has granted PRIME (PRIority MEdicines) designation for lonafarnib for the treatment of HDV infection. Eiger's application was supported by data from Phase 2 clinical studies of lonafarnib treatment in HDV-infected patients, achieving endpoints which reflect an improvement in liver condition and virologic response rarely observed in untreated HDV patients.

Breakthrough Therapy Designation Granted by FDA for Lonafarnib for Treatment of Progeria and Progeroid Laminopathies

On December 17, 2018, we announced that the FDA has granted Breakthrough Therapy designation for lonafarnib for the treatment of HDV infection. FDA Breakthrough Therapy designation involves a Fast Track development and FDA review process with guidance designed to expedite the development and review of medicines intended to treat serious or life-threatening diseases.

Rare Pediatric Disease Designation for Lonafarnib in the Treatment of Progeria and Progeroid Laminopathies

On October 22, 2018, we announced that the FDA granted Rare Pediatric Disease, or RPD, designation to lonafarnib in the treatment of progeria and progeroid laminopathies. RPD designation enables priority review voucher, or PRV, eligibility upon U.S. market approval of lonafarnib for these ultra-rare and fatal genetic conditions characterized by accelerated aging in children. We are collaborating with The Progeria Research Foundation, or PRF, and we plan to submit an NDA in 2019. There is currently no approved treatment for progeria or progeroid laminopathies.

The Priority Review Voucher Program is focused on encouraging development of therapies to prevent and treat rare pediatric diseases. If lonafarnib is approved by the FDA for progeria and progeroid laminopathies, the RPD designation qualifies Eiger, as the therapeutic sponsor, for the PRV upon marketing approval. The voucher, which can be sold or transferred to another entity, can be used by the holder to receive priority review for a future NDA or biologics license application submission, which reduces the FDA submission review time from ten to six months. Pursuant to our collaboration and Supply Agreement with PRF, we will equally share with PRF any proceeds from the monetization of any PRV that we may receive for lonafarnib for the treatment of progeria and progeroid laminopathies to support future progeria research.

Phase 2 LIMT Study

On October 17, 2018, we announced positive data with Peginterferon Lambda, or Lambda, in our Phase 2 LIMT HDV (Lambda Interferon MonoTherapy in Hepatitis Delta Virus) Study. LIMT HDV enrolled a total of 33 patients, randomized to Lambda 180 µg (N=16) or Lambda 120 µg (N=17), respectively, with weekly subcutaneous injections for 48 weeks in patients with chronic HDV. Lambda is a first in class, type III interferon, in development for the treatment of HDV.

At Week 48, patients in the 180 µg Lambda treated group experienced a -2.4 log_{10} mean decline in HDV-RNA, with 6 of 10 (60%) experiencing 2log10 decline, 4 of 10 (40%) patients were HDV-RNA negative at end of treatment. At Week 48, patients in the 120 µg Lambda treated group experienced a -1.5 log_{10} mean decline in HDV RNA, with 6 of 14 (42.9%) experiencing 2log10 decline, 2 of 14 (14.3%) patients were HDV-RNA negative at end of treatment. The most common adverse events included mild to moderate flu-like symptoms and elevated transaminase levels.

Phase 2 PREVENT Study

On October 16, 2018, we announced positive results from our Phase 2 PREVENT study, which is a multi-center, placebo-controlled study investigating the safety and durability of effect of 28-day dosing of subcutaneous, or SC, avexitide (formerly known as exendin 9-39) in post-bariatric surgical patients who experience dangerously low, postprandial blood glucose levels known as post-bariatric hypoglycemia, or PBH. Avexitide is a first in class glucagon-like peptide-1, or GLP-1, antagonist in development for PBH as a convenient, novel liquid formulation for SC administration. PBH is an orphan disease with a high unmet medical need and no approved pharmacologic therapy.

Eighteen patients with refractory, severe PBH were enrolled across five U.S. academic centers and dosed as outpatients in the PREVENT study. All patients received placebo subcutaneous injections for 14 days in a single-blinded manner followed by avexitide subcutaneous injections of 30 mg twice daily, or BID, injections for 14 days and 60 mg once daily, or QD, injections for 14 days, for a total of 28 days active dosing, in a double-blinded to dose, cross-over design.

The primary efficacy endpoint of improved postprandial glucose nadir during mixed meal tolerance testing, or MMTT, was achieved with statistical significance with avexitide 30 mg BID (57.1 vs 47.1 mg/dL; $p = 0.001$) and 60 mg QD (59.2 vs 47.1 mg/dL; $p = 0.0002$), and with fewer participants requiring glycemic rescue during each of the active dosing regimens than during placebo dosing. The secondary endpoint of reduced postprandial insulin peak during MMTT was also statistically significant with avexitide 30 mg BID (349.5 vs 454.5 µIU/mL; $p < 0.03$) and 60 mg QD (357.2 vs 454.5 µIU/mL; $p = 0.04$).

Metabolic and clinical improvements were also monitored during each patients' daily routine in the outpatient setting and assessed by electronic diary and continuous glucose monitoring, or CGM. Patients experienced fewer episodes of hypoglycemia (hypoglycemia symptoms confirmed by self-blood glucose monitor, or SBGM, concentrations of <70 mg/dL) and severe hypoglycemia (neuroglycopenic symptoms confirmed by SBGM concentrations <55 mg/dL) during both dosing regimens of avexitide as compared to placebo. These results were corroborated by CGM data.

Avexitide was well-tolerated. There were no treatment-related serious adverse events and no participant withdrawals. Adverse events were typically mild to moderate in severity. The most common adverse events were injection site bruising, nausea, and headache, all of which occurred with lower frequency during avexitide dosing periods than during the placebo dosing period.

Phase 2 ULTRA Study

On October 16, 2018, we also announced results from our Phase 2 ULTRA study in primary and secondary lymphedema of the lower limb, which demonstrated no improvement of ubenimex over placebo in the primary endpoint of skin thickness and secondary endpoints of limb volume and bioimpedance. No safety signals attributed to ubenimex were identified.

Topline analysis suggests select, individual patient responses, which clinical investigators believe warrant further exploration. We currently plan no additional clinical work for ubenimex but will support any additional investigator analyses and will reevaluate if future findings suggest any potential pathway forward. We expect that we would only pursue such an option through a strategic partnership.

FDA Guidance on HDV Phase 3 Study Design: Primary Endpoint Established

On September 24, 2018, we announced the receipt of written guidance from the FDA, confirming concurrence on a pivotal trial design, including the primary endpoint for D-LIVR, the first-ever, registration study for HDV infection.

A combined primary endpoint of ≥ 2 $\log_{10}$ decline in HDV RNA and normalization of alanine aminotransferase (ALT) at the end of 48 weeks of treatment has been accepted by the FDA as the primary endpoint and would be supportive of an accelerated approval of two lonafarnib-based, ritonavir-boosted regimens. An all-oral arm of lonafarnib boosted with ritonavir and a combination arm of lonafarnib boosted with ritonavir combined with pegylated interferon-alfa will each be compared to placebo in the D-LIVR study. Accelerated approval could be based on successful achievement of this surrogate endpoint in this single pivotal study in addition to a post-marketing confirmatory trial to evaluate clinical benefit.

Notice of Allowance for Lonafarnib Patent Claims in HDV

On July 31, 2018, we announced the receipt of the Notice of Allowance from the United States Patent and Trademark Office for U.S. patent application number 15/335,327, entitled "Treatment of Hepatitis Delta Virus Infection." The allowed claims cover a broad range of doses and durations of lonafarnib boosted with ritonavir. Lonafarnib is an oral, small molecule farnesyl transferase inhibitor in development for the treatment of HDV infection. The resulting U.S. Patent 10,076,512 issued on September 18, 2018 and has a term extending to 2035. We are pursuing additional claims with continuation applications.

In January 2018, we announced that Phase 2 LIBERTY study results in pulmonary arterial hypertension or PAH demonstrated no improvement overall or in key subgroups. On October 16, 2018, we announced results from our Phase 2 ULTRA study in primary and secondary lymphedema of the lower limb, demonstrated no improvement of ubenimex over placebo in the primary endpoint of skin thickness and secondary endpoints of limb volume and bioimpedance. We discontinued development of ubenimex in both PAH and lymphedema based on these 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 $52.4 million, $42.4 million and $47.1 million for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, we had an accumulated deficit of $171.2 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 contract manufacturing arrangements, clinical trial material related costs 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, 2018, 2017 and 2016 (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Product candidates:			
Lonafarnib HDV	$ 18,816	$ 4,284	$ 5,237
Lambda HDV	1,945	3,892	7,244
Avexitide PBH	3,009	3,173	2,984
Ubenimex PAH (terminated in January 2018)	1,613	9,789	10,393
Ubenimex Lymphedema (terminated in October 2018)	2,503	2,132	2,271
Progeria	2,831	—	—
Internal research and development costs	6,374	6,249	4,885
Total research and development expense	$ 37,091	$ 29,519	$ 33,014

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. Our expenses include costs related to compliance with the rules and regulations of the SEC and NASDAQ, additional insurance, investor relations, banking fees and other administrative expenses and professional services.

Interest Expense

Interest expense for the years ended December 31, 2018 and 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 debt securities and cash equivalents.

Other Income (Expense), Net

Other income (expense), net in 2018 is not material.

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 the 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.

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

Critical Accounting Policies and Estimates

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

Accrued Research and Development Costs

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 research and 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, *Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting,* 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 adoption of ASU 2018-07, *Compensation—Stock Compensation (Topic 718)*, on January 1, 2018, stock options granted to non-employee consultants were recorded at fair value and remeasured at the end of each period as they vest using the Black-Scholes option-pricing model. After the adoption of ASU 2018-07, we elected to use the contractual term to determine the non-employee awards fair value at the grant date. The contractual term of options granted under the Plan is ten years.

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, 2018 and 2017

The following table summarizes results of operations for the years ended December 31, 2018 and 2017 (in thousands):

	Year Ended December 31,		Increase / (Decrease)	% Change
	2018	2017		
Operating expenses:				
Research and development	$ 37,091	29,519	$ 7,572	26%
General and administrative	13,956	12,001	1,955	16%
Total operating expenses	51,047	41,520	9,527	23%
Loss from operations	(51,047)	(41,520)	(9,527)	
Interest expense	(2,329)	(1,524)	(805)	53%
Interest income	997	410	587	143%
Other (expense) income, net	(12)	186	(198)	*
Net loss	$ (52,391)	$ (42,448)	$ (9,943)	23%

*Percentage not meaningful.

Research and development expenses

Research and development expenses increased by $7.6 million to $37.1 million for the year ended December 31, 2018, from $29.5 million for the same period in 2017. The increase was primarily due to a $7.4 million increase in consulting fees and clinical expenditures due to increased program activity, and a $0.3 million increase in stock-based compensation expense due to an increase in headcount and higher level of stock-based compensation expense in 2018, which was partially offset by a $0.2 million decrease in milestone payments to Stanford University investors as there were no such payments in 2018.

General and administrative expenses

General and administrative expenses increased by $2.0 million to $14.0 million for the year ended December 31, 2018, from $12.0 million for the same period in 2017. The increase was primarily due to a $0.8 million increase in compensation and personnel related expenses and a $0.5 million increase in stock-based compensation expense due to an increase in headcount and higher level of stock-based compensation expense in 2018, a $0.3 million increase in facility and insurance expenses related to the new office lease, and a $0.3 million increase in legal, consulting, advisory and accounting services.

Interest expense

Interest expense increased by $0.8 million to $2.3 million for the year ended December 31, 2018, from $1.5 million for the same period in 2017. Interest expense primarily increased due to the drawdown of an additional $10.0 million under the Oxford Loan in 2018.

Interest income

Interest income increased by $0.6 million to $1.0 million for the year ended December 31, 2018, from $0.4 million for the same period in 2017. The increase was primarily due to an increase in the interest earned on our investments in debt securities and cash equivalents in 2018 as compared to 2017.

Other (expense) income, net

Other (expense) income, net changed by $0.2 million to $12,000 of other expense for the year ended December 31, 2018, from $0.2 million of other income for the same period in 2017. Other income in 2017 consisted of the $0.2 million payment received from Theragene for MYDICAR sale, and there was no such income earned in 2018.

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):

	Year Ended December 31,		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)	(10)%
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	*
Net loss	$ (42,448)	$ (47,087)	$ 4,639	(10)%

*Percentage not meaningful.

Research and development expense

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 debt 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.

Sources of Liquidity

To date, our operations have been financed primarily through the public issuance of common stock and borrowings under the term loan agreement. As of December 31, 2018, we had $61.3 million of cash and cash equivalents, $39.1 million of short-term debt securities and an accumulated deficit of $171.2 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 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.

In December 2017, we filed the 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 May 2018, we completed an underwritten public offering of 3,680,000 shares of common stock, including 480,000 shares of common stock purchased to the underwriter's option to purchase additional shares, at an offering price of $12.50 for gross cash proceeds of $46.0 million under our shelf registration statement (File No. 333-221972).

In October 2018, we completed an underwritten public offering of 4,830,918 shares of common stock, including 630,120 shares of common stock purchased to the underwriter's option to purchase additional shares, at an offering price of $10.35 per share for gross cash proceeds of $50.0 million under our shelf registration statement (File No. 333-221972). As of December 31, 2018, an aggregate of approximately $112.5 million of securities remain available for issuance by us under both shelf registration statements, including up to approximately $24.9 million of our common stock that we may offer and sell, from time to time, at our discretion, through Cantor Fitzgerald & Co. as our sales agent under the ATM financing facility sales agreement.

In May and August 2018, we borrowed the final $10.0 million under the secured loan agreement with Oxford Finance LLC.

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):

	Year Ended December 31,		
	2018	2017	2016
Net cash provided by (used in):			
Operating activities	$ (42,671)	$ (38,372)	$ (37,970)
Investing activities	(29,085)	22,657	(4,194)
Financing activities	100,983	19,994	65,142
Net increase in cash and cash equivalents	$ 29,227	$ 4,279	$ 22,978

Cash flows from operating activities

Cash used in operating activities for the year ended December 31, 2018 was $42.7 million and primarily consisted of a net loss of $52.4 million and amortization of the debt securities of $0.4 million, which was partially offset by $5.0 million of stock-based compensation expense, $0.6 million of non-cash interest related to amortization of debt discount, and $0.4 million expense related to the vesting of common stock issued under the Product Development Agreement. Additionally, cash used in operating activities reflected changes in net operating assets due to an increase of $5.0 million in accounts payable, accrued liabilities, and other long term liabilities primarily associated with increase in business activity, which was partially offset by an increase of $0.8 million in prepaid expenses and other current assets primarily due to the timing of payments, and an increase of $0.1 million in other non-current assets.

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 flows from investing activities

Net cash used in investing activities for the year ended December 31, 2018 was $29.1 million. The net cash decrease was primarily due to $57.2 million purchases of debt securities and $0.1 million purchases of property and equipment, which was partially offset by $28.2 million proceeds from maturities of debt securities.

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 debt 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 debt 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 debt 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 debt securities.

Cash flows from financing activities

Cash provided by financing activities for the year ended December 31, 2018 was $101.0 million and consisted of $90.7 million of proceeds from the issuance of common stock upon public offering, $9.9 million of net proceeds from borrowings in connection with the Oxford Loan, $0.3 million of proceeds from the issuance of common stock upon stock option exercises, and $0.1 million of proceeds from the purchases of common stock under our ESPP.

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.

Contractual Obligations and Commitments

Leases and Term Loan

Refer to Notes 8 and 15 to our consolidated financial statements included within Item 8 of this Annual Report on Form 10-K for a description of our contractual obligations at December 31, 2018.

Asset and License Agreements

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.

Oxford Finance Term Loan

On December 30, 2016, we entered into the Oxford Loan for $25.0 million. We borrowed $15.0 million in December 2016 (“Tranche A”), $5.0 million in May 2018 (“Amended Tranche B”), and $5.0 million in August 2018 (“Amended Tranche C”). 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. Upon the receipt of Amended Tranche B in May 2018, the interest only period for borrowed funds was extended by six months until February 1, 2019, followed by 30 equal monthly payments of principal plus accrued interest. At the time of final payment, we are required to pay an exit fee of 7.5% of the original principal balance of each tranche, which is $1.1 million for Tranche A, $0.4 million for Amended Tranche B and $0.4 million for Amended Tranche

C. In addition, at the time of final payment of Amended Tranche B, we are required to pay an additional exit fee of $0.1 million. The loan is secured by 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, 2018, we were in compliance with all loan terms.

In March 2019, we entered into an amendment to the Oxford Loan (the "New Oxford Loan") to refinance our term loan due in July 2021. As amended, the New Oxford Loan has been increased to $35.0 million in aggregate commitments, maturing in March 2024.

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

Refer to Note 2 to our consolidated financial statements included within Item 8 of this Annual Report on Form 10-K for a description of recent accounting pronouncements adopted and not yet adopted for the year ended December 31, 2018.

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, 2018 and 2017, 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, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2018, 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 14, 2019

Eiger BioPharmaceuticals, Inc.
Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	December 31,	
	2018	2017
Assets		
Current assets:		
Cash and cash equivalents	$ 61,262	$ 32,035
Debt securities, available-for-sale	39,091	9,744
Prepaid expenses and other current assets	1,492	712
Total current assets	101,845	42,491
Property and equipment, net	167	79
Other assets	436	312
Total assets	$ 102,448	$ 42,882
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,830	$ 3,183
Accrued liabilities	4,194	2,084
Current portion of long term debt	—	2,002
Total current liabilities	10,024	7,269
Long term debt, net	25,620	13,091
Other long term liabilities	212	—
Total liabilities	$ 35,856	$ 20,360
Commitments and contingencies (Note 15)		
Stockholders' equity:		
Common stock, $0.001 par value, 200,000,000 shares authorized as of December 31, 2018 and 2017; 19,211,759 and 10,526,599 shares issued and outstanding as of December 31, 2018 and 2017, respectively	19	11
Additional paid-in capital	237,795	141,320
Accumulated other comprehensive loss	(25)	(3)
Accumulated deficit	(171,197)	(118,806)
Total stockholders' equity	66,592	22,522
Total liabilities and stockholders' equity	$ 102,448	$ 42,882

See accompanying notes to the consolidated financial statements.

Eiger BioPharmaceuticals, Inc.
Consolidated Statements of Operations
(In thousands, except share and per share amounts)

	Year Ended December 31,		
	2018	2017	2016
Operating expenses:			
Research and development	$ 37,091	$ 29,519	$ 33,014
General and administrative	13,956	12,001	13,106
Total operating expenses	51,047	41,520	46,120
Loss from operations	(51,047)	(41,520)	(46,120)
Interest expense	(2,329)	(1,524)	(690)
Interest income	997	410	97
Other (expense) income, net	(12)	186	(374)
Net loss	$ (52,391)	$ (42,448)	$ (47,087)
Net loss per common share, basic and diluted	$ (3.82)	$ (4.86)	$ (7.84)
Weighted-average common shares outstanding, basic and diluted	13,711,034	8,727,935	6,007,027

See accompanying notes to the consolidated financial statements.

Eiger BioPharmaceuticals, Inc.
Consolidated Statements of Comprehensive Loss
(In thousands)

	Year Ended December 31,		
	2018	2017	2016
Net loss	$ (52,391)	$ (42,448)	$ (47,087)
Other comprehensive loss:			
Unrealized (loss) gain on available-for-sale debt securities, net	(22)	12	(15)
Comprehensive loss	$ (52,413)	$ (42,436)	$ (47,102)

See accompanying notes to the consolidated financial statements.

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

	Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Loss	Deficit	Equity (Deficit)
Balance at December 31, 2015	2,609,102	$ 22,567	273,993	$ —	$ 1,552	$ —	$ (29,271)	$ (5,152)
Issuance of common stock upon private placement, net of $1,300 of issuance cost	—	—	1,954,390	2	32,106	—	—	32,108
Issuance of common stock upon conversion of convertible promissory note	—	—	350,040	—	6,129	—	—	6,129
Issuance of common stock upon exercise of warrants	—	—	61,254	—	1,057	—	—	1,057
Issuance of common stock to Eiccose upon private placement	—	—	96,300	—	1,661	—	—	1,661
Conversion of preferred stock into common stock	(2,609,102)	(22,567)	2,609,102	3	22,564	—	—	—
Issuance of common stock upon reverse merger	—	—	1,596,959	2	27,388	—	—	27,390
Issuance of common stock upon execution of license agreement	—	—	157,587	—	3,172	—	—	3,172
Issuance of common stock upon public offering, net of $1,800 of issuance costs	—	—	1,250,000	1	18,228	—	—	18,229
Issuance of common stock upon exercise of stock option	—	—	7,034	—	39	—	—	39
Stock-based compensation expense	—	—	—	—	3,190	—	—	3,190
Unrealized loss on debt securities, net	—	—	—	—	—	(15)	—	(15)
Net loss	—	—	—	—		—	(47,087)	(47,087)
Balance at December 31, 2016	—	—	8,356,659	8	117,086	(15)	(76,358)	40,721
Issuance of common stock upon public offering, net of $376 of issuance costs	—	—	2,143,525	3	19,797	—	—	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 debt 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
Issuance of common stock upon public offering, net of $5,357 of issuance costs	—	—	8,510,918	8	90,634	—	—	90,642
Issuance of common stock upon ESPP purchase	—	—	17,508	—	96	—	—	96
Issuance of common stock upon stock option exercise	—	—	41,208	—	310	—	—	310
Issuance of common stock under Product Development Agreement	—	—	115,526	—	428	—	—	428
Stock-based compensation expense	—	—	—	—	5,007	—	—	5,007
Unrealized gain on debt securities, net	—	—	—	—	—	(22)	—	(22)
Net loss	—	—	—	—	—	—	(52,391)	(52,391)
Balance at December 31, 2018	—	$ —	19,211,759	$ 19	$ 237,795	$ (25)	$ (171,197)	$ 66,592

See accompanying notes to the consolidated financial statements.

Eiger BioPharmaceuticals, Inc.
Consolidated Statements of Cash Flow
(In thousands)

	Year Ended December 31,		
	2018	2017	2016
Operating Activities			
Net loss	$ (52,391)	$ (42,448)	$ (47,087)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	54	41	23
Amortization of debt securities discounts	(426)	(53)	(41)
Stock-based compensation	5,007	4,243	3,190
Non-cash interest expense	592	366	685
Gain on intellectual property sale	—	(200)	—
Issuance of common stock in connection with license, asset purchase, and product development agreements	428	—	3,172
Change in fair value of obligation to issue shares to Eiccose	—	—	204
Change in fair value of warrants liability	—	—	165
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(780)	(131)	326
Other non-current assets	(124)	(169)	(89)
Accounts payable	2,647	544	699
Accrued liabilities	2,110	(565)	783
Other long term liabilities	212	—	—
Net cash used in operating activities	(42,671)	(38,372)	(37,970)
Investing Activities			
Purchase of debt securities available-for-sale	(57,193)	(24,524)	(34,154)
Proceeds from maturities of debt securities available-for-sale	28,250	47,025	2,000
Proceeds from intellectual property sale	—	200	—
Cash received from merger transaction	—	—	28,018
Purchase of property and equipment	(142)	(44)	(58)
Net cash (used in) provided by investing activities	(29,085)	22,657	(4,194)
Financing Activities			
Proceeds from issuance of common stock upon public offering, net of issuance costs	90,642	19,800	18,229
Proceeds from borrowings in connection with term loan, net of issuance costs	9,935	—	14,759
Proceeds from issuance of common stock upon private placement, net of issuance costs	—	—	32,108
Proceeds from issuance of common stock upon ESPP purchase	96	142	—
Proceeds from issuance of common stock upon stock option exercises	310	52	39
Proceeds from issuance of common stock upon warrants exercises	—	—	7
Net cash provided by financing activities	100,983	19,994	65,142
Net increase in cash and cash equivalents	29,227	4,279	22,978
Cash and cash equivalents at beginning of period	32,035	27,756	4,778
Cash and cash equivalents at end of period	$ 61,262	$ 32,035	$ 27,756
Supplemental disclosure of cash flow information:			
Interest paid	$ 1,652	$ 1,038	$ —
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
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 private placement	—	—	6,129
Conversion of preferred stock to common stock upon reverse merger	—	—	22,567

See accompanying notes to the consolidated financial statements.

Eiger Biopharmaceuticals, Inc.
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's mission is to systematically reduce the time and cost of the drug development process to more rapidly deliver important medicines to patients with rare diseases. Lonafarnib is the Company's lead compound advancing into 1) Phase 3 in a single, pivotal trial to treat Hepatitis Delta Virus ("HDV") infection by the end of the year, 2) a new drug application ("NDA") and 3) a marketing authorization application ("MAA") for the treatment of Hutchinson-Gilford Progeria Syndrome ("HGPS" or "Progeria") in 2019. The Company's principal operations are based in Palo Alto, California and it operates in one segment.

Liquidity

As of December 31, 2018, the Company had $61.3 million of cash and cash equivalents and $39.1 million of short-term debt securities. In addition, the Company had an accumulated deficit of $171.2 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 the Company's planned operations for at least the next 12 months following the issuance date of these financial statements and through the anticipated readout of the Phase 3 D-LIVR study.

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 clinical trial accrued liabilities, stock-based compensation and income taxes. The Company bases its estimates on historical experience and on various other market-specific and relevant assumptions that the Company believes to be reasonable under the circumstances. Actual results could differ from those estimates.

Concentrations of Risk

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

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

Cash and Cash Equivalents

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

Short-Term Debt 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 debt 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 debt 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	5 years
Furniture	5 years
Computer equipment and software	3 years

Impairment of Long-Lived Assets

The Company evaluates its long-lived assets, including property and equipment, for impairment whenever events or changes in circumstances indicate that the carrying value of these assets may not be recoverable. The Company assesses the recoverability of long-lived assets by determining whether or not the carrying value of such assets will be recovered through undiscounted expected future cash flows. If the asset is considered to be impaired, the amount of any impairment is measured as the difference between the carrying value and the fair value of the impaired asset. Through December 31, 2018, the Company has not impaired any long-lived assets.

Accrued Research and Development Costs

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

Deferred Financing Costs

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

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). Share-based awards to non-employees are recorded at their fair value as of the grant date, using the Black-Scholes option pricing model and recognized as expense over the period in which the related services are received. 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.

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 except those resulting from and distributions to stockholders. The Company's unrealized gains and losses on debt 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,		
	2018	2017	2016
Options to purchase common stock	1,996,211	1,467,051	1,212,044
Warrants to purchase common stock	—	10,180	10,180
Total	1,996,211	1,477,231	1,222,224

Recently Adopted 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 has adopted this guidance during the quarter ended March 31, 2018. The adoption of this guidance did not have a significant impact on the operating results when adopted.

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 has adopted this guidance during the quarter ended March 31, 2018. The adoption of this guidance did not have a significant impact on the statement of cash flows when adopted.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718)*, which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. An entity should apply the requirements of Topic 718 to nonemployee awards except for certain exemptions specified in the amendment. The standard is effective for fiscal years beginning after December 15, 2018, including interim reporting periods within that fiscal year. Early adoption is permitted, but no earlier than the Company's adoption date of ASU No. 2014-09, *Revenue from Contracts with Customers* (Topic 606). The Company elected to early adopt this standard on January 1, 2018. The adoption did not have a material impact on the Company's consolidated financial statements.

Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842),* which requires lessees to recognize most leases on their balance sheet. The new standard will be effective for fiscal years beginning after December 15, 2018. Early adoption is permitted. Originally, entities were required to adopt ASU 2016-02 using a modified retrospective transition method. However, in July 2018, the FASB issued ASU No. 2018-11, *Targeted Improvements to Leases (Topic 842)*, which provides entities with an additional transition method. Under ASU No. 2018-11, entities have the option of recognizing the cumulative effect of applying the new standard as an adjustment to beginning retained earnings in the year of adoption while continuing to present all prior periods under previous lease accounting

guidance. Additionally, in July 2018, the FASB issued ASU No. 2018-10, *Codification Improvements to Leases (Topic 842)*, which clarifies how to apply certain aspects of ASU 2016-02. The Company will adopt this standard on January 1, 2019 using the transition method allowed per ASU 2018-11, and accordingly, comparative period financial information will not be adjusted for the effects of the new guidance. Management has substantially completed the process of identifying existing lease contracts and is currently performing detailed evaluations of its leases under the new standard. The Company believes the most significant changes to the consolidated financial statements relate to the recognition of right–of–use assets and offsetting lease liabilities in the consolidated balance sheet for operating leases. The Company anticipates the economic impact of the change to be approximately $2.0 million.

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 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820)*. The standard eliminates, modifies and adds disclosure requirements for fair value measurements. The pronouncement is effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. The Company is currently in the process of evaluating the impact the standard will have on its consolidated financial statements.

3. Fair Value Measurements

Fair value accounting is applied for all financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). At December 31, 2018 and 2017, 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 debt 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 assets or liabilities classified as Level 3 as of December 31, 2018 and 2017.

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, 2018			
	Level 1	Level 2	Level 3	Total
Financial Assets:				
Money market funds	$ 45,441	$ —	$ —	$ 45,441
Corporate debt securities	—	23,474	—	23,474
Commercial paper	—	15,617	—	15,617
Total	$ 45,441	$ 39,091	$ —	$ 84,532

	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

There were no financial liabilities as of December 31, 2018 and 2017.

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

	December 31, 2018			
	Amortized cost	Unrealized gain	Unrealized loss	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 45,441	$ —	$ —	$ 45,441
Total cash equivalents	$ 45,441	$ —	$ —	$ 45,441
Debt securities:				
Corporate debt securities	$ 23,489	$ 1	$ (16)	$ 23,474
Commercial paper	15,627	—	(10)	15,617
Total debt securities	$ 39,116	$ 1	$ (26)	$ 39,091

	December 31, 2017			
	Amortized cost	Unrealized gain	Unrealized loss	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 19,612	$ —	$ —	$ 19,612
Total cash equivalents	$ 19,612	$ —	$ —	$ 19,612
Debt securities:				
Corporate debt securities	$ 6,503	$ —	$ (2)	$ 6,501
Commercial paper	3,244	—	(1)	3,243
Total debt securities	$ 9,747	$ —	$ (3)	$ 9,744

As of December 31, 2018, the contractual maturity of the available-for-sale debt 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, 2018, the Company did not recognize any other-than-temporary impairment losses. All debt 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,	
	2018	2017
Lab equipment	$ 36	$ 36
Computer equipment and software	138	116
Furniture	98	34
Leasehold improvements	56	—
Total property and equipment	328	186
Less: accumulated depreciation	(161)	(107)
Property and equipment, net	$ 167	$ 79

Depreciation expense for the years ended December 31, 2018, 2017 and 2016 was $54,000, $41,000 and $23,000, respectively.

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2018	2017
Compensation and related benefits	$ 1,705	$ 1,262
Contract research costs	2,191	634
Consulting costs	258	87
Franchise tax	40	56
Contract manufacturing costs	—	4
Other	—	41
Total accrued liabilities	$ 4,194	$ 2,084

5. Reverse Merger

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

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

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

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

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

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

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

6. License, Collaboration, and Product Development Agreements

IQVIA General Services Agreement

On November 7, 2018, the Company entered into a General Services Agreement (the "GSA") with IQVIA RDS, Inc. ("IQVIA"), pursuant to which the Company will receive professional services for the project management of the phase III EIG-LNG-011 clinical trial (the "Study"). The services are to be provided through November 2021. As consideration, the Company agreed to pay $14.2 million for the professional services to be performed and $12.2 million for pass-through and miscellaneous expense over the term of the GSA. The GSA can be terminated by either party due to material health risk to the Study, a material breach, or by the Company without cause with 45 days prior written notice.

Product Development Agreement

On August 11, 2018, the Company entered into a Product Development Agreement and a First Project Agreement (the "Product Agreements"), pursuant to which the Company will receive development program support services for its hepatitis Delta virus ("HDV") program. The services are to be provided from July 1, 2018 through the completion of the Phase 3 Clinical Study Reports and the subsequent NDA filing. As consideration, the Company has committed to pay fees of approximately $10.0 million in cash and stock over four years, including approximately $0.8 million for expert consultant fees and pass through costs to vendors, plus certain incentive-based regulatory milestone fees up to $1.0 million. As part of the aggregate payment, the Company issued 115,526 shares of common stock subject to quarterly vesting requirements related to performance of the services and achievement of budget timeline set forth in the Product Agreements. The Product Agreements can be terminated by either party

due to material breach or by the Company without cause with 90 days prior written notice. As of December 31, 2018, the Company recognized research and development expense of $0.4 million related to the shares issued under the Product Agreements. Additionally, as of December 31, 2018, the total unrecognized compensation expense related to unvested restricted shares was $0.7 million, which the Company expects to recognize over an estimated weighted-average period of 3.25 years.

Progeria Research Foundation (PRF) Collaboration Agreement

On May 15, 2018, the Company entered into a Collaboration and Supply Agreement (the "PRF Collaboration Agreement") with PRF. Under the PRF Collaboration Agreement, the parties agreed to collaborate with respect to the development and pursuit of regulatory approval of lonafarnib for the treatment of progeria and progeroid laminopathies in humans. PRF granted the Company a non-exclusive, world-wide, royalty-free, sub-licensable license pertaining to all intellectual property and data controlled by PRF to prepare and file any new drug application ("NDA") for a product containing lonafarnib for progeria and progeroid laminopathies. The Company is obligated to: (i) exclusively supply lonafarnib to PRF for use in clinical trials and non-clinical research in progeria and progeroid laminopathies at the Company's expense, (ii) prepare and be the sponsor of any NDA submission for lonafarnib for the treatment of progeria and progeroid laminopathies to the FDA, (iii) use commercially reasonable efforts to file a NDA for progeria and progeroid laminopathies by a specified date, (iv) submit a rare pediatric disease designation and a request for expedited approval in connection with a NDA filing, (v) establish a patient support program in progeria and progeroid laminopathies, and (vi) use commercially reasonable efforts to develop a pediatric formulation of lonafarnib for use in progeria and progeroid laminopathies.

Under the PRF Collaboration Agreement, the Company is solely responsible for any additional studies necessary for obtaining an NDA for progeria and progeroid laminopathies and is also responsible for any additional costs for such studies up to $2.0 million. The PRF Collaboration Agreement continues for an initial term of ten years and automatically renews for subsequent renewal terms of two years each unless either party terminates earlier.

Clinigen Master Service Agreement

On April 26, 2018, the Company entered into a master service agreement with Clinigen Healthcare Ltd. ("Clinigen") in anticipation of its obligations under the PRF Collaboration Agreement to establish an Expanded Access Program for children with progeria and progeroid laminopathies. On May 23, 2018, the Company entered into the first statement of work ("SOW") under the agreement. Pursuant to the SOW, Clinigen became an authorized non-exclusive worldwide distributor of lonafarnib, the unlicensed pharmaceutical product (the "Product"). The Company is responsible for supply of the Product to Clinigen, and Clinigen is responsible for providing the Product to patients as part of the patient support program. Clinigen is also obligated to set up, manage and close-out the patient support program. The agreement will continue on a country-by-country basis until the Product is commercially available in that country.

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 next potential milestone relating to this agreement is a $3.0 million payment, payable if and when the Company is able to successfully demonstrate proof of concept in a Phase 2 clinical trial.

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 lonafarnib for the treatment of all human viruses except certain specified viruses such as hepatitis B and hepatitis C alone. As consideration for such exclusive right, the Company issued Private Eiger convertible preferred stock with a fair value of $0.5 million when the agreement was executed in September 2010. This preferred stock was converted to 27,350 shares of common stock upon the Merger. In addition, the Company is obligated to pay Merck up to an aggregate of $27.0 million in development milestones and will be required to pay tiered royalties based on aggregate annual net sales of all licensed products ranging from mid-single to low double-digit royalties on net sales. The Company's obligation to pay royalties to Merck expires on a country-by-country and product-by-product basis on the later of the expiration of the last to expire patent assigned to the Company under the agreement, which is estimated to be 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. No additional milestones have been achieved as of December 31, 2018.

On May 15, 2018, the Company entered into an amendment to the exclusive license agreement with Merck, which provides for expansion of the existing exclusively licensed field of use under the license agreement with Merck to include all uses of lonafarnib related to the treatment of Hutchinson-Gilford Progeria Syndrome ("HGPS" or "Progeria") in humans at no cost to the Company. The Company has the sole responsibility and the continuing obligation for the manufacture and supply of lonafarnib to The Progeria Research Foundation ("PRF"). Merck will not receive milestone payments in relation to lonafarnib for the treatment of progeria and progeroid laminopathies or any royalty payments for sales of a specified quantity of lonafarnib to treat the currently estimated progeria and progeroid laminopathies patient population worldwide.

Janssen License Agreement

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

In connection with this license agreement, the Company is obligated to make development milestone payments in aggregate of up to $38.0 million, sales milestone payments in aggregate up to $65.8 million and will be required to pay tiered royalties based on aggregate annual net sales of all licensed products ranging from mid-single to low double-digit royalties of net sales. As of December 31, 2018, the Company is not engaged in any product development related to this compound and does not perceive that it will pay any milestone payments in the near future.

7. Asset Purchase Agreements and Related License Agreements

EGI Asset Purchase Agreement

In December 2010, the Company entered into an asset purchase agreement with Eiger Group International, Inc. ("EGI"). Dr. Jeffrey Glenn, a founder and director of the Company, is the sole owner of EGI. Pursuant to the agreement, the Company purchased all of the assets including the intellectual property rights related to the use of farnesyl transferase inhibitors as anti-viral agents and methods to treat viral infections with those inhibitors and inhibitors of prenylation, prenyl cysteine methyltranferase and a protease as anti-viral agents and methods to treat viral infection with those inhibitors. The Company paid EGI an upfront payment of $0.4 million when the agreement was executed in December 2010. Additionally, the Company will pay EGI a low single-digit royalty based on aggregate annual net sales of products developed using the intellectual property. Within the first ten years after commercialization, the Company may make a one-time payment of $0.5 million for each contract for the three types of product related to such intellectual property that would reduce the payment term for the three products to the tenth anniversary of the first commercial sale. The obligation to pay royalties expires on a country-by-country and product-by-product basis on the later of either when the product is no longer sold in any country or the earliest of the tenth anniversary of the first commercial sale of the product. As of December 31, 2018, 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, 2018, the product has not achieved regulatory approval.

Avexitide 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 avexitide (formerly known as 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 share-based compensation expense as the awards vest over time. 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 fair value as of the ASU 2018-07 adoption date. During the years ended December 31, 2018, 2017 and 2016, the Company recognized $0.1 million, $44,000 and $0.3 million of compensation expense related to the time-vested options, respectively. No expense was recognized for the milestone vested options during the years ended December 31, 2018, 2017 and 2016.

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 avexitide, 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 avexitide. 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.

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. 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. As of December 31, 2018, the product has not reached commercialization and no milestones have been paid. In addition, as a result of this agreement, the Company has assumed the license agreements Eiccose had previously entered into. These include the PAH License Agreement, the Lymphedema License Agreement for the treatment of lymphedema and the license agreement with Nippon Kayaku Co., Ltd, ("Nippon"). As part of the agreement, Nippon is obligated to make a payment for royalties in the low single-digits of sales to the Company. In connection with the PAH License Agreement and the Lymphedema License Agreement, the Company is obligated to make development and commercial milestone payments of up to $0.5 million in the aggregate under each contract, increasing annual license maintenance fees ranging from $10,000 to $75,000 over the term of each license agreement and royalty payments in low single-digits on annual net sales after the first commercial sale of a product under each license. For the years ended December 31, 2018 and 2017, 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"). In May 2018, the Company entered into an amendment to the Oxford Loan (the "Amendment") and borrowed $5.0 million ("Amended Tranche B"). On August 3, 2018, the Company borrowed the remaining $5.0 million ("Amended Tranche C") under the Oxford Loan.

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, and starting on August 1, 2018, 36 equal monthly payments of principal and interest. Upon the receipt of Amended Tranche B, the interest only period for borrowed funds was extended by six months until February 1, 2019, 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, $0.4 million for Amended Tranche B and $0.4 million for Amended Tranche C. In addition, at the time of final payment of Amended Tranche B, the Company is required to pay an additional exit fee of $0.1 million 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 $0.4 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, excluding lonafarnib in progeria. 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, 2018 and 2017.

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 $1.7 million, $1.1 million, and $5,000 for the years ended December 31, 2018, 2017, and 2016, respectively. Long-term debt and unamortized discount balances are as follows (in thousands):

	December 31,	
	2018	2017
Face value of long term debt	$ 25,000	$ 15,000
Exit fee	1,960	1,125
Unamortized debt discount associated with exit fee, debt issuance costs and loan origination fees	(1,340)	(1,032)
Total long term debt	25,620	15,093
Less: current portion of long term debt[(1)]	—	(2,002)
Long term debt, net	$ 25,620	$ 13,091

[(1)] As of December 31, 2018, the Oxford Loan was classified as long-term as management had the intent and ability to refinance the borrowings on a long-term basis. The Oxford Loan was refinanced in March 2019, as discussed below in Note 17.

As of December 31, 2018, future minimum payments of principal, exit fee and interest expense under the Oxford Loan were as follows (in thousands):

Year ending December 31,		
2019	$	11,047
2020		11,002
2021		7,965
Total future payments		30,014
Less: unamortized interest		(3,054)
Less: exit fee		(1,960)
Face value of term loan	$	25,000

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.

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

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

10. 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 will equal $2.85 million. Additionally, the Company may exercise a put option at any time after the Proceeds Date, where upon written notice from 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 20th 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, 2018, 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, 2018, no dividends had been declared by the Board of Directors.

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

	December 31,	
	2018	2017
Options issued and outstanding	1,996,211	1,467,051
Options available for future grants	755,337	799,375
Warrants to purchase common stock issued and outstanding	—	10,180
Total	2,751,548	2,276,606

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. 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 with an exercise price of $84.15 per share. The Warrants expired 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 both the Company's stock-based compensation plans during the year ended December 31, 2018 (in thousands, except share and per share data):

	Shares Available for Grant	Number of Options	Weighted-Average Exercise Price Per Option	Weighted-Average Remaining Contractual Life (in Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2017	799,375	1,467,051	$ 12.70	8.41	$ 4,511
Additional options authorized	526,330				
Granted	(867,500)	867,500	$ 10.34		
Exercised		(41,208)	$ 7.52		
Forfeited or cancelled	297,132	(297,132)	$ 12.63		
Outstanding as of December 31, 2018	755,337	1,996,211	$ 11.80	7.54	$ 2,347
Vested and exercisable as of December 31, 2018		1,004,316	$ 12.36	6.52	$ 1,647

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 $10.16 as of December 31, 2018.

The aggregate intrinsic value of stock options exercised in 2018, 2017 and 2016 was $0.2 million, $0.1 million and $0.1 million, respectively.

During the years ended December 31, 2018, 2017 and 2016, the Company granted employee stock options for the purchase of 799,500, 579,700 and 902,028 shares of the Company's common stock, respectively, with a weighted-average grant date fair value of $7.50, $7.66 and $10.40 per share, respectively. During the years ended December 31, 2018, 2017 and 2016, the Company granted non-employee stock options for the purchase of 68,000, 72,500, and 48,544 shares of the Company's common stock, respectively. The total grant date fair value of options that vested during the years ended December 31, 2018, 2017 and 2016 was $4.7 million, $5.0 million and $2.0 million, respectively.

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

The fair value of stock options was estimated using the following weighted-average assumptions:

	Year Ended December 31,		
	2018	2017	2016
Expected term (in years)	5.27 - 6.08	5.27 - 6.08	5.27 - 6.08
Contractual term (in years)	9.67 - 9.84	6.00 - 10.00	6.75 - 10.00
Volatility	84.00% - 95.00%	79.00% - 80.00%	73.91% - 78.00%
Risk free interest rate	1.67% - 2.68%	1.63% - 2.23%	1.21% - 2.27%
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). Upon adoption of ASU 2018-07, the Company elected to use the contractual term to determine the non-employee award fair value at the grant date. The contractual term of options granted under the Plan is ten years.

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.

Modification of Stock Awards

In December 2018, the Company entered into a Separation Agreement with its former Chief Financial Officer which resulted in the acceleration in the vesting of certain unvested stock options as well as the extension of the exercise period for all vested options. As a result of the modification, the Company recorded stock-based compensation expense of $0.3 million during the year ended December 31, 2018 to reflect the revised service period for the stock options and related vesting of shares that would otherwise not have vested.

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,		
	2018	2017	2016
Research and development	$ 1,500	$ 1,214	$ 737
General and administrative	3,507	3,029	2,453
Total stock-based compensation expense	$ 5,007	$ 4,243	$ 3,190

As of December 31, 2018, the total unrecognized compensation expense related to unvested options was $8.5 million, which the Company expects to recognize over an estimated weighted average period of 2.6 years.

13. Income Taxes

No provision for income taxes was recorded for the years ended December 31, 2018, 2017 and 2016. The Company has incurred net operating losses for all the periods presented. The Company has not reflected any benefit of such net operating loss carryforwards in the accompanying consolidated financial statements. The Company has established a full valuation allowance against its deferred tax assets due to the uncertainty surrounding the realization of such assets.

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

	Year Ended December 31,		
	2018	2017	2016
Federal statutory income tax rate	21.00%	34.00%	34.00%
Change in valuation allowance	(26.02)	(8.04)	(36.67)
Federal and state tax credits	5.52	5.10	4.68
State income taxes, net of federal benefit	0.27	0.36	(0.21)
Stock-based compensation	(0.77)	(1.06)	(1.26)
Other, net	—	—	(0.54)
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,	
	2018	2017
Deferred tax assets:		
Net operating loss carryforwards	$ 30,268	$ 20,230
Tax credits	12,536	9,514
Depreciation and amortization	1,526	1,700
Stock-based compensation	1,524	913
Accruals and reserves	381	245
Gross deferred tax assets	46,235	32,602
Valuation allowance	(46,235)	(32,602)
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, 2018 and 2017. The valuation allowance increased by $13.6 million and $3.4 million during the years ended December 31, 2018 and 2017, respectively.

As of December 31, 2018, the Company had approximately $136.3 million and $24.7 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. The 2018 federal net operating loss can be carried forward indefinitely.

As of December 31, 2018, the Company also had research and development tax credit carryforwards of approximately $0.3 million and $1.2 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, 2018, the Company had orphan drug tax credit carryforwards of approximately $15.9 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, 2018. 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.

In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act (SAB 118) (the "Act"), which allows companies to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. Since the Act was passed late in the fourth quarter of 2017, and ongoing guidance and accounting interpretation was yet to be issued, the Company's accounting of the transition tax and deferred tax re-measurements were incomplete as of December 31, 2017. The Company filed its 2017 Federal corporate income tax return in the third quarter of 2018. The Company's final analysis and impact of the Act is reflected in the tax provision and related tax disclosures for the year ended December 31, 2018. There was no change to the originally estimated $30.4 million re-measurement of deferred tax assets.

Uncertain Tax Positions

A reconciliation of the Company's unrecognized tax benefits for the years ended December 31, 2018, 2017 and 2016 is as follows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Balance at beginning of year	$ 3,218	$ 1,831	$ 404
Additions based on tax positions related to prior year	(61)	—	19
Additions based on tax positions related to current year	1,477	1,387	1,408
Balance at end of year	$ 4,634	$ 3,218	$ 1,831

If the $4.6 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, 2018, 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, 2018, 2017 and 2016.

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. Oral arguments were heard on August 28, 2018 before the Ninth Circuit Court of Appeals, and on September 17, 2018, the court ruled that the lower court ruling was re-affirmed. The plaintiff had two weeks to file a petition for a rehearing and such filing was not made within the allowed time, effectively terminating the shareholder lawsuit.

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 October 2017, the Company entered into a non-cancelable facility lease agreement for 8,029 square feet of office space located at 2155 Park Blvd in Palo Alto, California 94306. The lease commenced 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, 2018 and 2017.

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

Year ending December 31,	Amounts
2019	$ 593
2020	610
2021	629
2022	647
2023	109
Total minimum payments	$ 2,588

Rent expense was $0.8 million, $0.6 million and $0.3 million for the years ended December 31, 2018, 2017 and 2016, 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, and have been transferred to the previous shareholders of Eiccose.

17. Subsequent Events

On March 5, 2019, the Company entered into an amendment to the Oxford Loan (the "New Oxford Loan") to refinance its term loan. As amended, the New Oxford Loan has been increased to $35.0 million in aggregate commitments, maturing on March 1, 2024. The Company received gross proceeds of $30.0 million ("New Tranche A") at the amendment date. The remaining $5.0 million will be available to the Company upon achievement of certain clinical milestone. The New Oxford Loan will bear interest at a floating rate annum equal to the greater of either the 30-day U.S. Dollar LIBOR reported in the Wall Street Journal plus 6.64% or 9.15%. The interest only period for the borrowed funds is until April 1, 2021, followed by 36 equal monthly payments of principal plus accrued interest. If the Company receives the remaining funds, then the interest only period will be extended by one year followed by 24 equal monthly payments of principal plus accrued interest. There was no other material impact on terms, conditions, representations, warranties, covenants or agreements set forth in the Oxford Loan.

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, 2018, the end of the period covered by this report.

Management's Report on Internal Control over Financial Reporting.

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

As of December 31, 2018, 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, 2018, 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, 2018, 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 2019 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2018.

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

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

ITEM 11. Executive Compensation

The information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2019 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2018.

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 2019 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2018.

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 2019 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2018.

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 2019 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2018.

PART IV

ITEM 15. Exhibits and Financial Statement Schedules

(a) Financial Statements and Financial Statement Schedules

1. Financial Statements

See Index to Financial Statements at Item 8 herein.

2. Financial Statement Schedules

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

3. Exhibits

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	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).
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+	Celladon Corporation 2001 Stock Option Plan and Form of Notice of Grant of Stock Option, Stock Option Agreement and Stock Option Exercise Notice thereunder (incorporated by reference to Exhibit 10.2 to the Registration Statement on Form S-1, as amended (File No. 333-191688), originally filed with the SEC on October 11, 2013).
10.3+	Celladon Corporation 2012 Equity Incentive Plan and Form of Stock Option Grant Notice, Option Agreement and Notice of Exercise thereunder (incorporated by reference to Exhibit 10.3 to the Registration Statement on Form S-1, as amended (File No. 333-191688), originally filed with the SEC on October 11, 2013).

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 on 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 on December 14, 2015).
10.21†	License Agreement, dated as of May 1, 2015, by and between Eiccose, LLC and Nippon Kayaku Co., Ltd. (incorporated by reference to Exhibit 10.52 to the Registration Statement on Form S-4, as amended (File No. 333-208521), originally filed with the SEC on December 14, 2015).
10.22	Sublease Agreement, dated as of January 8, 2016, by and between Baker Hughes Oilfield Operations, Inc. and Eiger BioPharmaceuticals, Inc. (incorporated by reference to Exhibit 10.53 to the Registration Statement on Form S-4, as amended (File No. 333-208521), originally filed with the SEC on December 14, 2015).
10.23†	License Agreement, dated as of April 20, 2016, by and between Eiger BioPharmaceuticals, Inc. and Bristol-Myers Squibb Company (incorporated by reference to Exhibit 10.1 to the Registration Statement on Form S-3/A (File No. 333-212114), filed with the SEC on August 2, 2016).
10.24	Common Stock Purchase Agreement, dated as of April 20, 2016, by and between Eiger BioPharmaceuticals, Inc. and Bristol-Myers Squibb Company (incorporated by reference to Exhibit 10.2 to the Registration Statement on Form S-3, as amended (File No. 333-212114) filed with the SEC on June 17, 2016).
10.25	Controlled Equity Offering Sales Agreement, dated June 17, 2016, by and between Eiger BioPharmaceuticals, Inc. and Cantor Fitzgerald & Co. (incorporated by reference to Exhibit 1.2 to the Registration Statement on Form S-3, filed with the SEC on June 17, 2016).
10.26	Loan and Security Agreement, dated December 30, 2016, by and between Eiger BioPharmaceuticals, Inc. and Oxford Finance LLC (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. (incorporated by reference to Exhibit 10.27 to the Annual report on Form 10-K (File No. 001-36183) filed with the SEC on March 9, 2018).
10.28	Offer Letter, dated as of December 12, 2017, by and between Eiger BioPharmaceuticals, Inc. and David Apelian, M.D., Ph.D. (incorporated by reference to Exhibit 10.28 to the Annual report on Form 10-K (File No. 001-36183) filed with the SEC on March 9, 2018).
10.29	First Amendment to Lease, dated April 26, 2018, by and between Eiger BioPharmaceuticals, Inc. and the McDonald Family Co. LLC (incorporated by reference to Exhibit 10.2 to the Quarterly report on Form 10-Q (File No. 001-36183) filed with the SEC on May 11, 2018).
10.30	Master Services Agreement, dated April 26, 2018, by and between Eiger BioPharmaceuticals, Inc. and Clinigen Healthcare Ltd. (incorporated by reference to Exhibit 10.1 to the Quarterly report on Form 10-Q (File No. 001-36183) filed with the SEC on August 10, 2018).

Exhibit Number	Description of Document
10.31†	Amendment No. 6 to License Agreement, dated September 2, 2010, by and between Eiger BioPharmaceuticals, Inc. and Merck Sharp & Dohme Corp. (incorporated by reference to Exhibit 10.2 to the Quarterly report on Form 10-Q (File No. 001-36183) filed with the SEC on August 10, 2018).
10.32†	Collaboration and Supply Agreement, dated May 15, 2018, by and between Eiger BioPharmaceuticals, Inc. and The Progeria Research Foundation (incorporated by reference to Exhibit 10.3 to the Quarterly report on Form 10-Q (File No. 001-36183) filed with the SEC on August 10, 2018).
10.33	Second Amendment to Loan and Security Agreement, dated May 11, 2018, by and between Eiger BioPharmaceuticals, Inc. and Oxford Finance LLC (incorporated by reference to Exhibit 10.4 to the Quarterly report on Form 10-Q (File No. 001-36183) filed with the SEC on August 10, 2018).
10.34†	Product Development Agreement, dated July 1, 2018, by and between Eiger BioPharmaceuticals, Inc. and RRD International, LLC (incorporated by reference to Exhibit 10.1 to the Quarterly report on Form 10-Q (File No. 001-36183) filed with the SEC on November 9, 2018).
10.35	Common Stock Purchase Agreement, dated September 19, 2018, by and between Eiger BioPharmaceuticals, Inc. and RRD International, LLC (incorporated by reference to Exhibit 10.2 to the Quarterly report on Form 10-Q (File No. 001-36183) filed with the SEC on November 9, 2018).
10.36†	Product Assignment 1, dated July 1, 2018, by and between Eiger BioPharmaceuticals, Inc. and RRD International, LLC (incorporated by reference to Exhibit 10.3 to the Quarterly report on Form 10-Q (File No. 001-36183) filed with the SEC on November 9, 2018).
10.37+	Separation Agreement dated as of November 30, 2018, by and between Eiger BioPharmaceuticals, Inc. and James Welch.
10.38	First Amendment to Loan and Security Agreement, dated August 24, 2017, by and between Eiger BioPharmaceuticals, Inc. and Oxford Finance LLC.
21.1	List of subsidiaries.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney. Reference is made to the signature page hereto.
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

+ Indicates management contract or compensatory plan.
† Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

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: 14 March, 2019

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

Eiger BioPharmaceuticals, Inc.

Date: 14 March, 2019

By: /s/ Sriram Ryali
Sriram Ryali
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 A. Cory and Sriram Ryali, 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 A. Cory	President and Chief Executive Officer *(Principal Executive Officer)*	14 March, 2019
/s/ Sriram Ryali Sriram Ryali	Chief Financial Officer *(Principal Financial and Accounting Officer)*	14 March, 2019
/s/ Thomas J. Dietz Thomas J. Dietz	Chairman of the Board of Directors	14 March, 2019
/s/ David Apelian David Apelian	Member of the Board of Directors	14 March, 2019
/s/ Evan Loh Evan Loh	Member of the Board of Directors	14 March, 2019
/s/ Jeffrey Glenn Jeffrey Glenn	Member of the Board of Directors	14 March, 2019
/s/ Eldon Mayer Eldon Mayer	Member of the Board of Directors	14 March, 2019
/s/ Christine Murray Christine Murray	Member of the Board of Directors	14 March, 2019