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, 2020

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	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	**EIGR**	**The Nasdaq Stock Market LLC**

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 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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, 2020 totaled approximately $257,943,696 based on the closing price of $9.60 as reported by the Nasdaq Global Market. This calculation excludes 372,505 shares held by executive officers, directors and stockholders that the Registrant has concluded are affiliates of the Registrant. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the Registrant.

The number of outstanding shares of the registrant's common stock, par value $0.001 per share, as of March 5, 2021 was 33,901,386.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates certain information by reference from the registrant's proxy statement for the 2021 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, 2020.

Eiger BioPharmaceuticals, Inc.
Form 10-K
For the Fiscal Year Ended December 31, 2020

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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:

- our ability to support the launch of Zokinvy™ (lonafarnib) and our commercial development for Zokinvy;
- the potential approval of Zokinvy in jurisdictions outside of the U.S., including the European Union;
- our ability to maintain supply of our commercial and clinical trial materials;
- our ability to transition into a commercial stage biopharmaceutical company;
- our ability to finance the continued advancement of our development pipeline products;
- 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 U.S. 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

Overview

We are a commercial-stage biopharmaceutical company focused on the development and commercialization of foundational therapies for Hepatitis Delta Virus (HDV) infection, the most severe form of human viral hepatitis, for which there is currently no FDA-approved therapy.

Eiger has reported positive proof-of-concept clinical results across all our programs, and we have received Breakthrough Therapy designation for three programs in clinical development. Our programs have several aspects in common: the disease targets represent conditions of high unmet medical need; 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.

We are developing two complementary treatments for HDV. Lonafarnib is a first-in-class, oral farnesylation inhibitor in a global Phase 3 trial, and the only oral therapy in development for HDV. Peginterferon lambda (lambda) is a first-in-class, well-characterized, well-tolerated type III interferon entering Phase 3.

The pivotal Phase 3 D-LIVR study (N=400) of lonafarnib boosted with ritonavir in HDV is ongoing with completion of enrollment planned in 2021. The study spans twenty-two countries with over one hundred sites and has potential to generate data for two distinct lonafarnib-based ritonavir-boosted regimens for approval. An all-oral arm of lonafarnib boosted with ritonavir and a combination arm of lonafarnib boosted with ritonavir combined with pegylated interferon-alfa-2a will each be compared to placebo.

The FDA approved our first commercial product, Zokinvy (lonafarnib) to reduce the risk of mortality in Hutchinson-Gilford Progeria Syndrome (HGPS or Progeria) and to treat processing-deficient progeroid laminopathies, ultra-rare and rapidly fatal genetic conditions of accelerated aging in children, on November 20, 2020. Our Marketing Authorization Application (MAA) is under review with the European Medicines Agency (EMA), and we expect a decision in the second half of 2021.

Our pipeline is summarized in the table below. 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 licensed lonafarnib from Merck Sharp & Dohme Corp (Merck) in 2010 and licensed peginterferon lambda from Bristol-Myers Squibb (BMS) in 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 FDA and will rely on that data and information to support potentially pivotal clinical trials and any filings for regulatory approvals.

TARGETED INDICATION	DRUG	ORPHAN US / EU	BREAKTHROUGH THERAPY	RARE PEDIATRIC DISEASE	STATUS & UPCOMING MILESTONES
Hepatitis Delta Virus	Lonafarnib + Ritonavir	✓	✓	N/A	Phase 3 Enrollment Completion in 2021
	Peginterferon Lambda	✓	✓	N/A	Phase 3 Planned Start in 2021
Progeria and Progeroid Laminopathies	Zokinvy™ (lonafarnib) capsules 50 mg/75 mg	✓	✓	PRV sold for $95M	FDA APPROVED EMA Decision 2H21
Post-Bariatric Hypoglycemia	Avexitide	✓	✓	N/A	Phase 3 Ready
Congenital Hyperinsulinism		✓		✓	Phase 2

Our portfolio includes a late-stage clinical development pipeline with four clinical product candidates and one FDA-approved product.

Clinical Product Candidates

1. Lonafarnib (LNF) in HDV

LNF is a well-characterized, orally bioavailable, first-in-class farnesylation inhibitor in a Phase 3 clinical trial for HDV infection and is our lead program. HDV is the most severe form of viral hepatitis for which there is currently no FDA-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 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-dependent activity in reducing HDV viral load both as a monotherapy and in combination with ritonavir (RTV) and/or PEG IFN-alfa-2a. Phase 2 studies have identified two lonafarnib-based regimens, which have achieved clinically meaningful composite endpoints of HDV RNA decline ≥ 2 logs from baseline and normalized alanine aminotransferase (ALT), a key liver enzyme, at Week 24: all-oral regimen of LNF 50 mg boosted with 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.

Our Phase 3 registration program consists of a single, pivotal, global trial called D-LIVR that is designed to support U.S. regulatory approval. D-LIVR has the potential to generate data for two distinct 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. We plan to complete enrollment (N=400) in 2021.

LNF for treatment of HDV infection has been granted Orphan Drug designation by the FDA and EMA, Fast Track and Breakthrough Therapy designations 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

Lambda is our second program treating HDV. Lambda is a well-characterized, late-stage, first-in-class, type III, well-tolerated interferon (IFN), that stimulates immune responses that are critical for the development of host protection during viral infections.

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 (HBV), Hepatitis C Virus (HCV), Hepatitis D Virus (HDV), and SARS-CoV-2. Lambda has not been approved for any indication.

In 2020, following End of Phase 2 and Scientific Advice meetings with regulatory agencies, we gained agreement with FDA and EMA on a single pivotal Phase 3 trial for lambda as a monotherapy for treatment of HDV, which we expect to begin in the second half of 2021.

We have also generated data with lambda in a combination therapy with LNF + RTV. In November 2020, we reported positive end-of-study data from the LIFT study, 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) in 26 HDV-infected patients.

Lambda for treatment of HDV infection has received Orphan Drug designation from FDA and EMA and Fast Track and Breakthrough Therapy designations from FDA.

3. Avexitide in Post-Bariatric Hypoglycemia (PBH)

Avexitide is a well-characterized peptide that we are developing as a treatment for PBH, 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 including Roux-en-Y gastric bypass (RYGB) and Sleeve Gastrectomies (SG). PBH 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 (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 (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. Avexitide for the treatment of PBH has also been granted Breakthrough Therapy designation by FDA. Following End of Phase 2 and Scientific Advice meetings with regulatory agencies, we have agreement on a single pivotal Phase 3 study, including study design and endpoints with the FDA and EMA.

4. Avexitide in Congenital Hyperinsulinism (CHI)

Avexitide has also demonstrated clinical proof of concept for the treatment of congenital hyperinsulinism (CHI), an ultra-rare, pediatric metabolic disorder. CHI is the most frequent cause of persistent hypoglycemia in neonates and children and is characterized by fasting and protein-induced hypoglycemia and results in permanent brain damage with neurodevelopmental deficits in up to 50% of patients. Near-total pancreatectomy is often indicated and leads to life-long insulin-dependent diabetes (IDDM). Safe and effective therapies are urgently needed to prevent brain damage, IDDM and death.

Avexitide binds to the GLP-1 receptor on pancreatic beta-cells and behaves as a GLP-1 antagonist and inverse agonist, reducing fasting and amino-acid induced cAMP accumulation and thereby decreasing calcium-stimulated insulin secretion. Avexitide has been dosed in over 25 patients with congenital hyperinsulinism at Children's Hospital of Philadelphia (CHOP).

Avexitide has been granted Orphan Drug designation by the EMA for the treatment of CHI and Orphan Drug designation by the FDA for the treatment of hyperinsulinemic hypoglycemia, which includes CHI. Avexitide has also been granted Rare Pediatric Disease designation by FDA.

Approved Product

1. Zokinvy (LNF) in Progeria and Processing-Deficient Progeroid Laminopathies (PL)

In November 2020, we received FDA approval for Zokinvy to reduce risk of mortality in Progeria and to treat processing-deficient PL. Zokinvy is our first approved product, and the first approved therapy for these indications. There are approximately 20 identified patients in the U.S. who are eligible for treatment with Zokinvy.

In March 2020, we submitted our MAA for Zokinvy to the EMA, which is currently under review. We expect a decision in the second half of 2021.

Zokinvy is a disease-modifying agent that has demonstrated a statistically significant survival benefit in children and young adults with Progeria. In patients with Progeria, Zokinvy reduced the incidence of mortality by 60% (p=0.0064) and increased average survival time by 2.5 years. The most commonly reported adverse reactions were gastrointestinal (vomiting, diarrhea, nausea), and most were mild or moderate (Grade 1 or 2) in severity. Many Progeria patients have received continuous Zokinvy therapy for more than 10 years.

Progeria 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 called 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.

Processing-Deficient Progeroid Laminopathies are genetic conditions of accelerated aging caused by a constellation of mutations in the *LMNA* 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 believed to be approximately 200 patients.

In November 2020, we entered into an amendment to our license agreement with Merck to include, not only all uses of lonafarnib related to the treatment of Progeria, but also Progeroid Laminopathies.

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 develop an integrated 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, InterMune, Salix Pharmaceuticals, Inc., Onyx Pharmaceuticals, Aimmune Therapeutics, and Questcor, 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, BioDelivery Sciences, Inc., BioTime, Inc., Halozyme, Merck, Schering-Plough, Amylin, Zeneca, Jazz Pharmaceuticals, Rigel, Theravance and Amgen.

Our Strategy

Our strategy 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, primarily focused on the development of foundational therapies for HDV infection. 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:

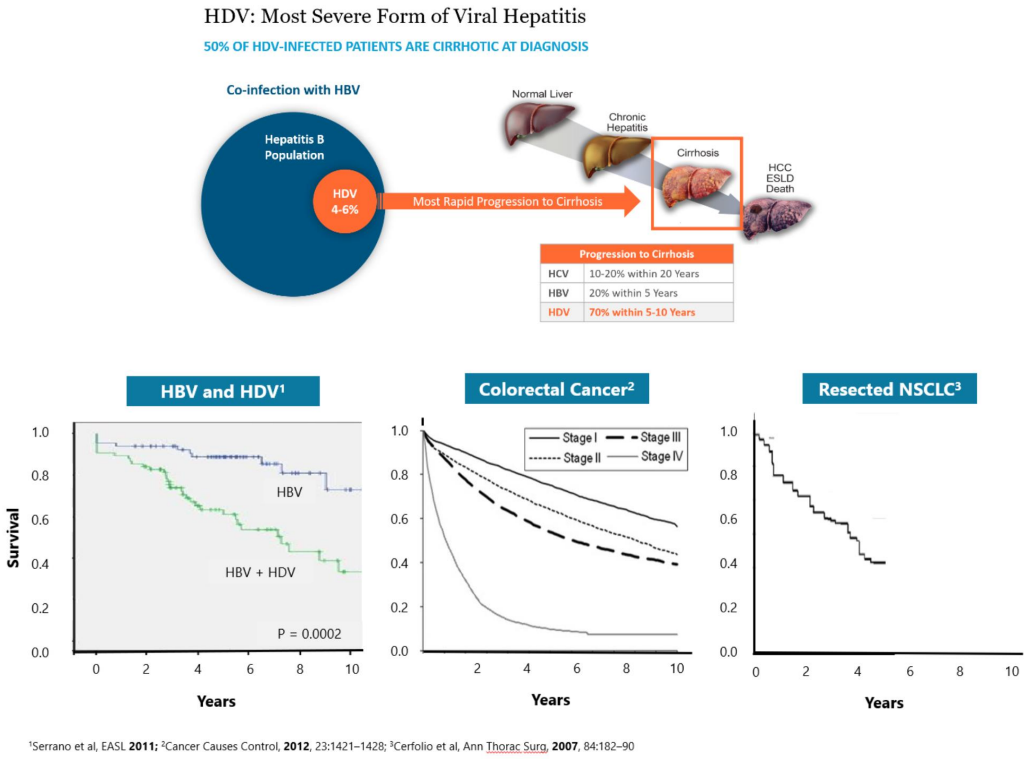
- Advance our existing product candidates through late-stage clinical trials, generating meaningful clinical results;
- Work with U.S. and international regulatory authorities for expeditious, efficient development pathways toward registration;
- Prepare for commercialization of each program;
- Use our 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.

Hepatitis Delta Virus Overview

About Hepatitis Delta Virus

Hepatitis delta infection is caused by HDV, a small circular ribonucleic acid (RNA) that expresses only one protein, the hepatitis delta antigen (HDAg). There are two forms of HDAg – small and large. These two forms of HDAg and the single-stranded RNA genome are surrounded by a lipid envelope, which is embedded with Hepatitis B Virus (HBV) surface antigen (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, 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, 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.



¹Serrano et al, EASL **2011;** ²Cancer Causes Control, **2012**, 23:1421–1428; ³Cerfolio et al, Ann Thorac Surg, **2007**, 84:182–90

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 10 to 14 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

Active HDV infections are best detected by reverse transcriptase-polymerase chain reaction (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 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. Commercially available assays will increase the number of assays performed and increase the number of identified patients who can potentially benefit from an HDV therapy such as LNF.

Current Therapy for HDV

Currently, there is no FDA-approved therapy for hepatitis delta virus infection. Hepcludex (buleviritide) was conditionally approved in Europe in 2020 for treatment of chronic HDV. The American Association for the Study of Liver Diseases (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 undetectable HDV RNA 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 in early stages and are not expected to eliminate extra-hepatic reservoirs of HBsAg. Given that HDV only requires small amounts of HBsAg for virion 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 (SHDAg) and large delta antigen (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 (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: Lonafarnib

Lonafarnib (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 designations from FDA for the treatment of chronic HDV infections. In the United States, we have issued patents, U.S. Patent No. 10,076,512 and 10,828,283, both 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, the Chinese Patent Office and the Japan Patent Office have also granted patents with claims covering a broad range of lonafarnib boosted with RTV dosing regimens for the treatment of HDV infection.

LNF Phase 2 Clinical Data

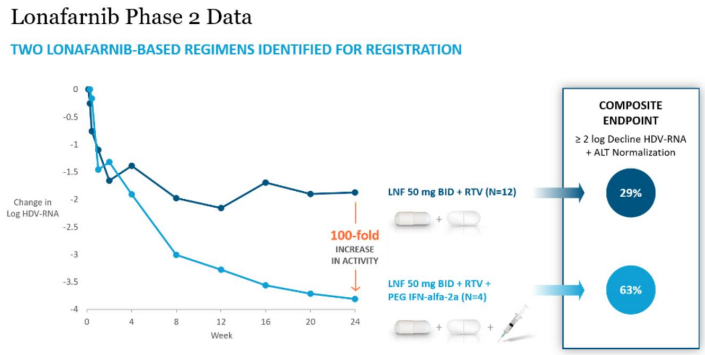
We licensed LNF from Merck in 2010, and have relied upon Merck's prior Phase 1, 2 and 3 clinical experience with LNF in over 2,000 patients to understand safety and pharmacokinetics.

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.

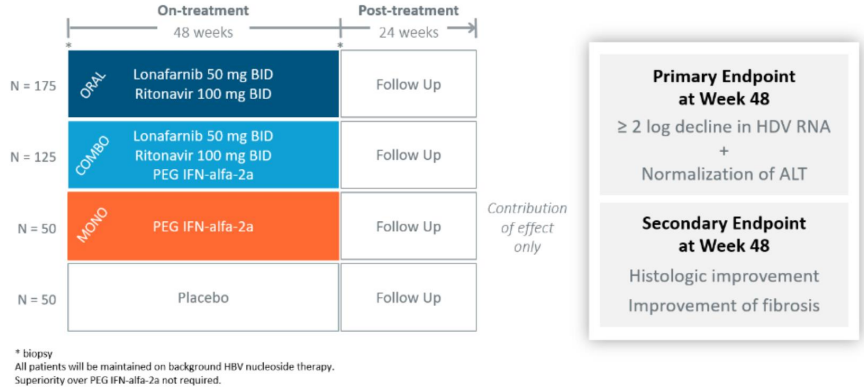
The Phase 2 LOWR studies demonstrated benefits of twice daily RTV-boosting of LNF for up to 24 weeks of dosing. RTV is a pharmacokinetic (PK) enhancer known to inhibit the metabolism of LNF, allowing lower doses of LNF to be administered, while resulting in higher systemic concentrations of LNF. The 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 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.

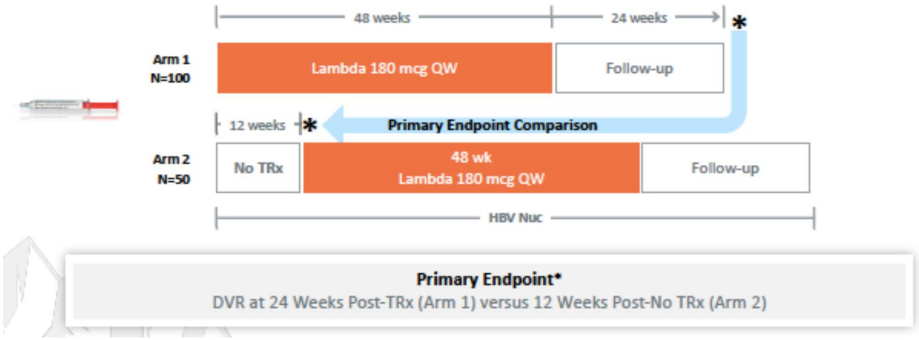
D-LIVR is a global study, enrolling across 22 countries and over 100 sites. We plan to complete enrollment (N=400) of D-LIVR in 2021.



Our Second HDV Therapeutic Approach: Lambda for HDV

Lambda is a well-characterized, late-stage, first in class, well-tolerated, type III interferon (IFN) that we in-licensed from Bristol-Myers Squibb in April 2016 for the treatment of HDV infection. Lambda is being developed as a well-tolerated interferon. 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, after 48-72 weeks of therapy, between 25% and 33% of HDV-infected patients were HDV RNA undetectable 24 weeks after stopping therapy. However, 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 are developing lambda as a monotherapy and in a combination therapy with LNF. In 2020, we gained agreement with FDA and EMA on study design and endpoints for a single pivotal Phase 3 of lambda as a monotherapy for treatment of HDV infection. The study, called LIMT-2, is depicted below, is a randomized, open-label, parallel-arm study and will include 150 patients randomized 2:1 to two different lambda-containing arms. The first arm is 48 weeks of treatment with lambda 180 mcg administered weekly and a 24-week off-treatment follow-up period. The second arm is 12-weeks of no therapy followed by 48 weeks of treatment with weekly lambda 180 mcg and a 24-weeks off-treatment follow-up period. The primary endpoint is a Durable Virologic Response (DVR), or HDV RNA below limit of quantitation (BLQ) or undetectable, 24-weeks post treatment of Arm 1 compared to placebo after 12-weeks of no treatment of Arm 2. All patients will be administered an anti-HBV nucleos(t)ide analog throughout the study.

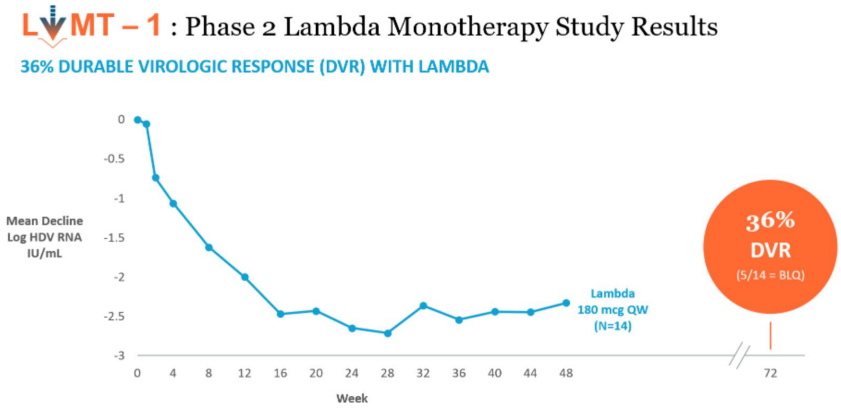


Lambda Clinical Data

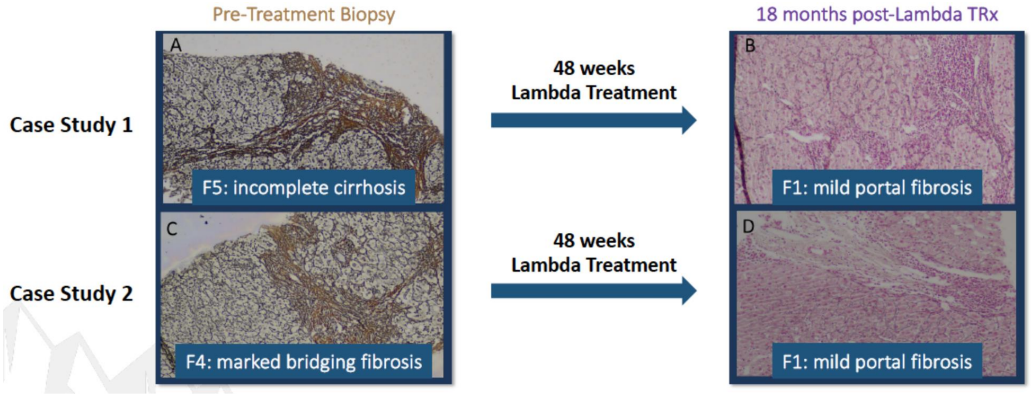
LIMT-1 Monotherapy Phase 2 Clinical Trial

LIMT-1 was a 1:1 randomized, open-label Phase 2 study of lambda 120 µg or 180 µg subcutaneous injections administered weekly for 48 weeks in 33 patients with chronic HDV. End of treatment was 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 in patients with chronic HDV infection. All patients were administered an anti-HBV nucleos(t)ide analog throughout the study. The trial was conducted at four international sites in New Zealand, Israel and Pakistan.

Week 48 end-of-treatment data were presented in November 2018 at AASLD. At Week 48, patients in the 180 µg lambda treated group experienced a 2.4 log mean decline in HDV-RNA, with 6 of 10 (60%) experiencing ≥ 2 log 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 mean decline in HDV RNA, with 6 of 14 (42.9%) experiencing ≥ 2 log 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. Observed ALT flares result from vigorous antiviral immunological response to treatment, not due to direct hepatotoxicity. End of 24-week follow-up data, presented in April 2019 at EASL, demonstrated that 36% of HDV infected patients were able to maintain HDV RNA below limit of quantitation (BLQ) 24-weeks post-treatment, or a Durable Virologic Response (DVR), and achieve ALT normalization. These data are illustrated below.



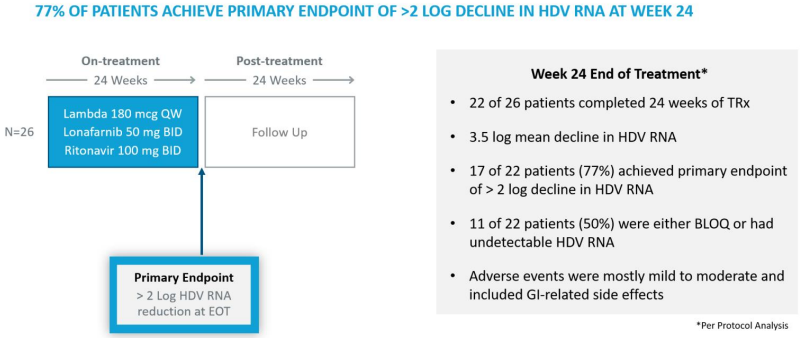
LIMT-1 study did not include per-protocol liver biopsies. However pre- and post-treatment liver biopsies were collected for two patients where regression in liver fibrosis from F5 to F1 and F4 to F1 was observed. This is the first demonstration of regression in liver fibrosis with a finite lambda treatment.

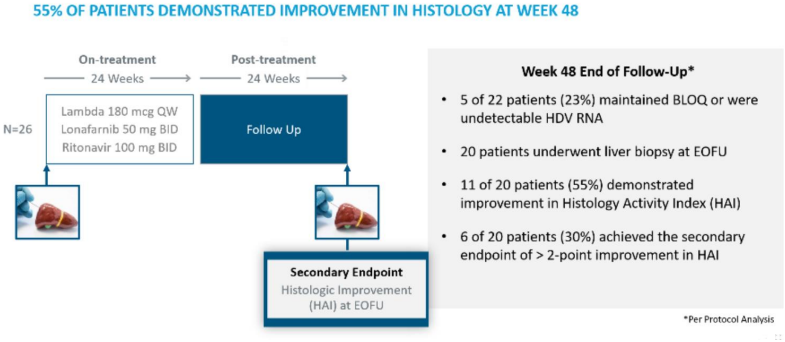


LIFT HDV Combination of Therapy Phase 2 Clinical Trial

LIFT (Lambda Interferon combination Therapy) was an open-label, Phase 2 study evaluating lambda in combination with lonafarnib boosted with ritonavir in 26 HDV-infected patients. Patients were dosed for 24 weeks and underwent off-treatment follow-up for 24 weeks. The primary endpoint was >2 log decline in HDV RNA at end of 24-weeks of treatment. Secondary endpoints included histology (>2-point improvement in histological activity index and no progression in fibrosis) at end of follow-up. LIFT was conducted within the National Institutes of Health (NIH) at the NIDDK. Study design and final end-of-treatment and end-of-study data were reported in November 2020 at the AASLD conference and are summarized in the pictures below.

The data demonstrated that after 24 weeks of treatment, by per protocol analysis, 77% of patients (17 of 22) achieved the primary efficacy end point of >2 log decline in HDV RNA, with 50% of patients (11 of 22) were either HDV RNA BLQ or undetectable. At Week 48 (24 weeks post-treatment), 5 of 22 patients (23%) maintained HDV RNA BLOQ or were HDV RNA undetectable, 11 of 20 patients (55%) demonstrated improvement in Histology Activity Index (HAI), and 6 of 20 patients (30%) achieved the secondary endpoint of > 2 point improvement in HAI.





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 BLQ, 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.

PBH Overview

As the use of bariatric surgical procedures has increased worldwide due to rising obesity and Type 2 diabetes, 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 (SG) 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, resulting from bariatric surgeries can cause early nutrient sensing by the intestinal “L” cells, leading to enhanced secretion of GLP-1 causing 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.

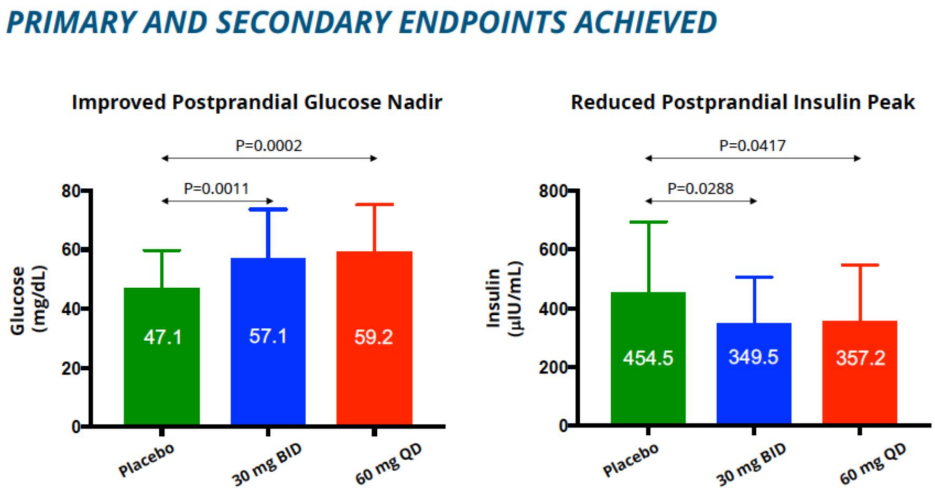
Approximately 240,000 bariatric surgical procedures are performed each year in the United States, and another 900,000 are performed each year in Europe. It is estimated that PBH can impact approximately 10% of Roux-en-Y gastric bypass and 2.5% of SG patients.

Clinical Data to Date

We have demonstrated in four clinical studies in 54 patients 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.

We completed our most recent Phase 2 study called PREVENT 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 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 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 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 MMTT was achieved with statistical significance with avexitide 30 mg BID and 60 mg QD, 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 and 60 mg QD. The primary and secondary endpoints are shown in the figure below.



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 and severe hypoglycemia during both dosing regimens of avexitide as compared to placebo as shown in the table below.

METABOLIC AND CLINICAL IMPROVEMENTS

Reduction in Rates[1] of Hypoglycemia, Clinically Important Hypoglycemia and Rescue by eDiary

	Number of Episodes in 14 Day Period		
	Placebo	Avexitide 30 mg BID	Avexitide 60 mg QD
Rate of Hypoglycemia[2]	4.03	2.81	1.56
Change from Placebo	*NA*	*-1.24 (p=0.0720)*	*-2.51 (p=0.0014)*
Rate of Clinically Important Hypoglycemia[3]	2.36	1.45	0.99
Change from Placebo	*NA*	*-0.89 (p=0.0267)*	*-1.35 (p=0.0020)*
Rate of Rescue	4.87	3.34	1.83
Change from Placebo	*N/A*	*-1.6 (p=0.0614)*	*-3.13 (p=0.0013)*

[1] Rate is defined as number of episodes in a 14 day period
[2] Hypoglycemia is defined as hypoglycemia symptoms confirmed by SBGM concentrations of <70 mg/dL
[3] Clinically important hypoglycemia is defined as neuroglycopenic symptoms confirmed by SBGM concentrations <55 mg/dL

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. Avexitide has been granted Breakthrough Therapy Designation by the FDA. In 2020, we received concurrence with FDA and EMA on a single Phase 3 for Avexitide for treatment of PBH.

CHI Overview

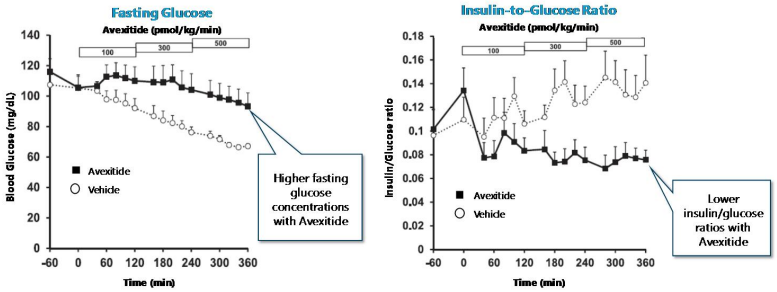
CHI is an ultra-rare pediatric metabolic disease. CHI presents with severe hypoglycemia in the neonatal period requiring intensive care hospitalization, administration of high rates of intravenous glucose through central lines, continuous intravenous administration of glucagon and in most instances surgical treatment by pancreatectomy during the neonatal period or during infancy. The most common and severe form of CHI is refractory to medical treatment with diazoxide and affects approximately 60% of all patients. Diazoxide unresponsive CHI arises out of inactivating mutations in the genes encoding the K_{ATP} channel, resulting in focal and diffuse forms of CHI. Focal disease, occurring in approximately 50% of patients with K_{ATP} CHI, resolves in 97% of cases after partial pancreatectomy. Diffuse disease persists in 41% of cases after subtotal (98%) pancreatectomy. However, by the age of 14 years old, 91% of patients undergoing subtotal pancreatectomy develop insulin-dependent diabetes, at which point hyperinsulinism is no longer present. Thus, CHI is a congenital, rare pediatric disease with life-threatening manifestations of severe hyperinsulinemic hypoglycemia occurring primarily during the neonatal period, infancy, childhood and adolescence.

Clinical Data to Date

To date, a total of 39 patients with K_{ATP} CHI enrolled in 3 clinical investigations at CHOP have received avexitide administered by continuous IV infusion: 10 adolescents and adults, 16 children, and 13 neonates. Data generated across all 3 clinical investigations suggest that treatment with avexitide may effectively reduce fasting and postprandial hypoglycemia in patients with diazoxide unresponsive CHI. Avexitide treatment was well tolerated, with no serious drug-related adverse events (AEs) reported. Data from each of the three studies are presented in the figures below. Avexitide for treatment of CHI has been granted Rare Pediatric Disease designation by the FDA.

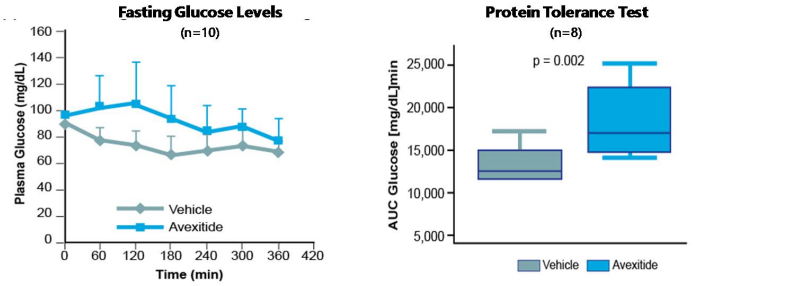
Adolescent and Adult Study Results (n=9)

Avexitide Increased Fasting Glucose; Decreased Requirement for Rescue



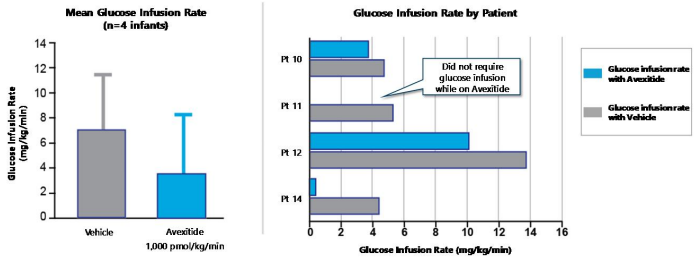
Child Study Results

Avexitide Raised Fasting Glucose and Significantly Reduced Protein-Induced Hypoglycemia



Neonate & Infant Study Results

Avexitide Reduced Mean Glucose Infusion Rates by 60%



Manufacturing

We currently contract with third parties for the manufacturing of all of our FDA-approved product, Zokinvy, and clinical product candidates 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 (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 for certain products. We have identified or 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. All of our third-party manufacturers are subject to periodic audits to confirm compliance with applicable regulations and must pass inspection before we can manufacture our drugs for commercial sales.

We have qualified and finalized or are in process of finalizing commercial supply agreements contract manufacturers for Zokinvy (lonafarnib) and have identified commercial manufacturers for lambda and plan to proceed with qualifications.

Lonafarnib

The drug product for completed lonafarnib (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. These manufacturers produce our commercial supply for progeria and processing-deficient progeroid laminopathies.

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 clinical drug product for avexitide for the treatment of PBH and CHI is manufactured by a third-party CMO.

Intellectual Property

We strive to protect and in-license those proprietary technologies, inventions, and improvements we believe are important to our business. We seek and maintain, where available, patent protection for our product candidates including: composition dosage, formulation, use, manufacturing process, among others. 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 on trade secrets, know-how, and continuing innovation to develop and maintain our competitive position. We cannot be certain that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents granted to us in the future will be commercially useful in protecting our technology.

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

We plan to continue to expand our intellectual property portfolio by filing patent applications for our product candidates. We file and prosecute patent applications in the United States and Europe and, when appropriate, additional countries, including Japan, Korea, Canada 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 (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 (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.

We own or in-license a number of patents in the U.S. and foreign countries that cover our products, product candidates, and methods of their use. With respect to our owned or in-licensed issued patents in the U.S. and Europe, we may be entitled to obtain an extension of patent term to extend the patent expiration date. For example, in the U.S., this extended coverage period is known as patent term extension (PTE) and can only be obtained provided we apply for and receive a marketing authorization for a product. The period of extension may be up to five years beyond the expiration of the patent, but cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent among those eligible for an extension may be extended. In Europe, Supplementary Protection Certificates (SPC) may also be available to patents, which would be available by applying to the member states. However, there is no guarantee that the applicable authorities, including the FDA, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. The exact duration of the extension depends on the time we spend in clinical studies as well as getting marketing approval from the FDA.

Patent Protection of Our Product Candidates

The exclusivity positions for our clinical-stage product candidates as of December 31, 2020 are summarized below.

LNF. We have licensed from Merck a portfolio of patents and know how 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 LNF in combination with RTV for the treatment of HDV infection. Eiger's U.S. Patent Nos. 10,076,512 and 10,828,283 entitled, Treatment of Hepatitis Delta Virus Infection, includes claims covering broad range of RTV-boosted LNF doses and durations. The patents have terms that extend to 2035. Additional claims are being pursued in a continuation application. The European Patent Office, the Chinese Patent office and the Japanese Patent Office have also granted 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, China and Japan, additional claims are being pursued in divisional applications. 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, China and Japan.

Corresponding patent applications claiming the use of lonafarnib boosted with ritonavir are pending in Korea and continuation applications are pending in the U.S., Europe, China and Japan.

Additionally, US Patent 10,835,496 and a European Patent issued claiming particular dosage regimens for ritonavir-boosted lonafarnib for the treatment of HDV infections. These patents extend protection until at least 2036. Applications are also pending in 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 in-licensed from The Progeria Research Foundation patents covering the methods of treating Hutchinson-Gilford Progeria Syndrome (HGPS or Progeria), and progeroid laminopathies. The patents provide protection until at least 2024 and an application for patent term extension (PTE) that could extend the protection for one of the patents until 2029 have been filed. We have also filed a patent application in the US related to method of treating progeria and progeroid laminopathies that if issued would provide further protection until 2039.

Lambda. We have in-licensed from BMS a portfolio of patents relating to the manufacture, use, and compositions of lambda modified by polyethylene glycol derivatization (lambda). The key United States composition of matter patent in this portfolio expires in 2025, but we expect to be eligible for the full 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 for 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 2037. The United States Patent and Trademark Office (the USPTO) and the European Patent Office (EPO) have both issued Notices of Allowance, and we expect the patent to issue in the US and Europe the first half of 2021 with claims covering the use of lambda to treat HDV.

We have also filed PCT applications relating to the use of lambda in HDV and to the use of lambda, lonafarnib and ritonavir to treat HDV, which will offer protection until 2039 and 2040, respectively, if issued.

***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 USPTO issued US 10,639,354 and US 10,660,937 which will provide protection until May 2036. The applications are filed 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 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 and the USPTO has issued a Notice of Allowance and we expect the patent to issue in the first half of 2021. Any patents that issue from this application will expire in 2037. We have also filed an additional PCT related to method of treating PBH and CHI, that if issued would provide protection until 2039.

We have in-licensed patents and patent applications from the Trustees of the University of Pennsylvania (UPenn) and CHOP, relating to hyperinsulemic hypoglycemia. The in-licensed patents and applications relate to multiple hyperinsulinemic disorders, including PBH and CHI. The patents, which are issued in the US and Europe, and provide protection until 2028. There are continuation applications pending from which we are pursuing additional claim coverage.

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 congenital hyperinsulinism, 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:

- HDV: Myr (being acquired by Gilead), conditional approval in Europe, Phase 3 ongoing; Replicor, Inc. (Phase 2); Janssen Research & Development, LLC (Phase 2)
- Progeria and Progeroid Laminopathies: none
- PBH: Xeris Pharmaceuticals (Phase 2)
- CHI: Zealand Pharmaceuticals (Phase 3); Xeris Pharmaceuticals (Phase 2); Rezolute, Inc (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, 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 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, 2020.

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 lonafarnib to treat the currently estimated progeria and progeroid laminopathies patient population worldwide. On November 3, 2020, we entered into an amendment to the exclusive license agreement with Merck which expanded the definition of progeria to also include progeroid laminopathies.

Asset Purchase Agreement with AbbVie Inc.

On November 20, 2020, we entered into an asset purchase agreement (the AbbVie Agreement) with AbbVie Inc. (AbbVie) to sell our Rare Pediatric Disease Priority Review Voucher, which was awarded the PRV on November 20, 2020 upon approval by the FDA of our new drug application for Zokinvy™ in Hutchinson-Gilford Progeria Syndrome and processing-deficient Progeroid Laminopathies (the PRV) to AbbVie. The AbbVie Agreement contains customary representations, warranties, covenants, and indemnification provisions subject to certain limitations.

In consideration for the PRV, AbbVie agreed to pay us $95.0 million. The transaction closed in January 2021. Such consideration was shared equally with The Progeria Research Foundation in accordance with the terms of our Collaboration and Supply Agreement, dated May 15, 2018, with The Progeria Research Foundation, pursuant to which we and The Progeria Research Foundation will equally share any proceeds from the sale of a priority review voucher that the Company may receive as the sponsor of a rare pediatric disease product application. We retained approximately $47.4 million of the proceeds from the sale of the PRF.

Asset Purchase Agreement with Eiger Group International, Inc.

In December 2010, we entered into an Asset Purchase Agreement with Eiger Group International, Inc. (EGI) dated December 8, 2010 (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. As of December 31, 2020, the product has not achieved regulatory approval.

Asset Purchase Agreement with Tracey McLaughlin and Colleen Craig

We entered into an Asset Purchase Agreement with two individuals, Dr. Tracey McLaughlin and Dr. Colleen Craig (the Sellers) dated September 25, 2015 (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 agreements related to the APA have expired. 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 (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, 2020, the product has not reached commercialization and no milestones have been paid. In the fourth quarter of 2020, we recorded a $3.0 million milestone expense that was triggered on successful demonstration of proof of concept in a Phase 2 clinical trial based on data presented from the Phase 2 LIFT trial. The next expected milestone is $5.0 million triggered on the initiation of a Phase 3 clinical trial.

License Agreement with the Trustees of the UPenn and CHOP

In May 2019, the Company entered into a license agreement (the UPenn/CHOP Agreement) with the Trustees of the UPenn and the CHOP, under which we obtained an exclusive, royalty-bearing, worldwide license to develop, manufacture and sell certain GLP-1 receptor antagonist(s) products to treat all human and animal conditions. We also obtained an exclusive, royalty-bearing, sublicenseable, worldwide license to certain data developed by CHOP. We are responsible for the development and commercialization of the licensed products at our sole cost and expense.

As part of the consideration for the rights granted to us under the UPenn/CHOP Agreement, we paid UPenn a one-time, non-refundable issue fee of $1.0 million, which is recorded in research and development expenses for the year ended December 31, 2019. In addition, we are obligated to pay UPenn a specified annual license maintenance fee, up to $2.5 million in certain regulatory milestones, and up to $18.0 million in commercial milestones. We will also

be required to pay UPenn a flat royalty in the low-single digits on our net sales of all licensed products, subject to specified reductions and offsets, and specified minimum annual royalty payments. Our obligation to pay royalties expires on a product-by-product and country-by-country basis, on the later of: (i) the expiration of the last valid claim in the licensed patents in any country, or (ii) the tenth anniversary of the first commercial sale of the product in such country. No milestones have been achieved as of December 31, 2020.

We may terminate the UPenn/CHOP Agreement in its entirety for any reason by providing prior written notice to UPenn and CHOP. UPenn or CHOP may terminate the UPenn/CHOP Agreement, upon a written notice, for our failure to achieve the specified diligence milestones within the specified periods, subject to our extension rights.

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 (FDC Act) and its 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 IND application, which must become effective before clinical testing may commence, approval by an independent institutional review board (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 (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 raises 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 (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 (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 (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 (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 (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 program user fees for any marketed products, 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 (RPD) designation by FDA enables priority review voucher (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 several 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. 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. 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 (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.

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 (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Covered manufacturers must submit reports by the 90th day of each calendar year. Beginning in 2022, such obligations will include payments and other transfers of value provided in the previous year to certain other healthcare professionals, including physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified nurse anesthetists, and certified nurse-midwives.

Many states have similar laws and regulations that may differ from each other and federal law in significant ways, thus complicating compliance efforts. For example, states have anti-kickback and false claims laws that may be broader in scope than analogous federal laws and may apply regardless of payer. In addition, state data privacy laws that protect the security of health information may differ from each other and may not be preempted by federal law. 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. Moreover, several states and local jurisdictions require the registration of sales representatives. These laws may adversely affect our sales, marketing and other activities with respect to any product candidate for which we receive approval to market in the United States by imposing administrative and compliance burdens on us.

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, imprisonment, 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.

To obtain regulatory approval of an investigational drug or biological product under EU regulatory systems, we must submit a marketing authorization application (MAA) either under the so-called centralized or national authorization procedures. The centralized procedure provides for the grant of a single marketing authorization by the European Commission following a favorable opinion by the EMA that is valid in all EU member states, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for medicines produced by specified biotechnological processes, products designated as orphan medicinal products, and products with a new active substance indicated for the treatment of specified diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative

disorders or autoimmune diseases, other immune dysfunctions and viral diseases. The centralized procedure is optional for other products that represent a significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public health or which contain a new active substance for indications other than those specified to be compulsory.

The EMA grants orphan drug designation to promote the development of products for the treatment, prevention or diagnosis of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 people in the EU. In addition, orphan drug designation can be granted if the drug is intended for a life threatening or chronically debilitating condition in the EU and without incentives it is unlikely that sales of the drug in the EU would be sufficient to justify the investment required to develop the drug. Orphan drug designation is only available if there is no other satisfactory method approved in the EU of diagnosing, preventing or treating the condition, or if such a method exists, the proposed orphan drug will be of significant benefit to patients. Orphan drug designation provides opportunities for free or reduced-fee protocol assistance, fee reductions for marketing authorization applications and other post-authorization activities and ten years of market exclusivity following drug approval, which can be extended to 12 years if trials are conducted in accordance with an agreed-upon pediatric investigational plan. The exclusivity period may be reduced to six years if the designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Foreign 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 information that we process, including, without limitation, personal information relating to clinical trial participants in the EU. The GDPR imposes significant obligations on controllers and processors of personal information, including, among other things, to implement administrative, physical, technical, and organizational safeguards to protect personal information, establish an appropriate legal basis for processing personal information, comply with transparency requirements regarding the processing of personal information, honor requests from data subjects regarding their personal information, provide data breach notifications, obtain explicit consent for collection of sensitive personal information such as health data, and comply with rules and restrictions on the transfer of personal data outside of the EU including to the U.S. The GDPR also requires businesses subject to the GDPR to make contractual privacy, data protection, and data security commitments. The GDPR allows EU member states to make additional laws and regulations further limiting the processing of personal information, including genetic, biometric and health data. Failure to comply with the GDPR and related EU member state 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 Zokinvy or any of our product candidates once approved could reduce physician utilization of such products 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.

We expect that 50% to 70% of patients eligible for treatment with Zokinvy will be covered by government insurance such as Medicaid, and the remaining patients will be covered by commercial insurance. We have had active engagement with payers that cover the lives of identified patients with Progeria and processing-deficient progeroid laminopathies.

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. Additionally, coverage policies and third-party reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained for one or more of our products, less favorable coverage policies and reimbursement rates may be implemented in the future.

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 third-party payors will pay for healthcare products and services, which could result in reduced demand for our products once approved or additional pricing pressures.

Healthcare Reform

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 (the ACA) was passed, which substantially changed the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. There remain judicial and Congressional challenges to numerous provisions of the ACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance and delaying the implementation of certain ACA-mandated fees. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing this case, although it is unclear when a decision will be made. It is also unclear how such litigation will impact the ACA and our business.

Also, there has been heightened governmental scrutiny recently over pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products For example, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out-of-pocket costs of drugs that contained proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out-of-pocket costs of drug products paid by consumers. In addition, the Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to drug pricing that seeks to implement several of the administration's proposals. As a result, the FDA released a final rule on September 24, 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs

from Canada. Further, on November 20, 2020, the U.S. Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

Research and Development Expenses

Our research and development expenses were $41.6 million, $51.8 million and $37.1 million for the years ended December 31, 2020, 2019 and 2018, respectively.

Employees and Human Capital

As of December 31, 2020, we had a total of 28 full-time employees in the United States, 13 of whom were primarily engaged in manufacturing and research and development activities, and 15 of whom were engaged in general management and administration. Six 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.

Our human capital objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards.

Corporate Information

We were originally incorporated in California in December 2000 as Celladon Corporation (Celladon). In April 2012, Celladon reincorporated in Delaware and had its initial public offering in February of 2014. On March 22, 2016, Eiger BioPharmaceuticals, Inc. (Private Eiger) completed its merger (Merger) with Celladon in accordance with the terms of the Merger Agreement. Pursuant to the Merger Agreement, Celladon Merger Sub, Inc., a wholly-owned subsidiary of Celladon (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.

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.

Risk Factor Summary

Below is a summary of material factors that make an investment in our common stock speculative or risky. Importantly, this summary does not address all of the risks and uncertainties that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, can be found under "Risk Factors" in Part I, Item 1A of this Annual Report. The below summary is qualified in its entirety by that more complete discussion of such risks and uncertainties. You should consider carefully the risks and uncertainties described under "Risk Factors" in Part I, Item 1A of this Annual Report as part of your evaluation of an investment in our common stock.

- We are a clinical development-stage biopharmaceutical company with a limited operating history. We have incurred net losses in each year since our inception. We have no drug candidates approved for commercial sale, we have never generated any revenue from product sales and we may never be profitable.
- We are dependent on the success of our product candidates, which are in various stages of clinical development. We cannot give any assurance that we will generate data for any of our product candidates sufficient to receive regulatory approval and without regulatory approval we will not be able to market our product candidates.
- Prior to the recent approval of our new drug application (NDA) for lonafarnib for the treatment of Progeria and Progeroid Laminopathies, we had not submitted an application for approval or obtained U.S. Food and Drug Administration (FDA) approval for any product. We may not be able to obtain FDA approval of our NDA or any future NDA for our product candidates, which would impede commercialization.
- Our business strategy is based upon obtaining and maintaining Orphan Drug designation for our product candidates. If we are unable to obtain Orphan Drug designation or regulatory approval, our business would be substantially harmed.
- 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.
- We rely on clinical studies of our product candidates in order to obtain regulatory approval. 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.
- If clinical studies of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- We rely on third parties to conduct our clinical studies, manufacture our product candidates and perform other services. Our ability to obtain regulatory approval or commercialize our product candidates and our business could be impaired if these collaborations are unsuccessful.
- If the market opportunities for our product candidates are smaller than we believe they are, we may not meet our revenue expectations. 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 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.

- We currently have limited marketing and sales capabilities for the commercialization of our product candidates.
- The commercial success of any of our current or future product candidates will depend upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community. Sales of our products depend substantially on the extent to which the costs of our product candidates will be paid for or reimbursed by healthcare management organizations or government authorities or third-party payors.
- We are currently conducting and will continue to conduct clinical trials for our product candidates outside the United States, which could expose us to risks that could have a material adverse effect on our business.
- We intend to rely on a combination of exclusivity from Orphan Drug designation and our patent rights for our product candidates. If we are unable to maintain exclusivity from the combination of these approaches, then our ability to compete effectively in our markets may be harmed.
- If we are unable to maintain effective proprietary rights for our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize product candidates similar or identical to ours.
- We may be unsuccessful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses. 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 may not be successful in any efforts to identify, license, discover, develop or commercialize additional product candidates.
- Healthcare legislative reform measures may have a material adverse effect on our business and 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.
- We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs.
- The current COVID-19 pandemic has and may continue to adversely affect our financial condition and our business as well as those of third parties on which we rely on significant manufacturing, clinical or other business operations.

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, 2020, 2019 and 2018, we reported a net loss of $65.1 million, $70.3 million, and $52.4 million, respectively. As of December 31, 2020, we had an accumulated deficit of $306.5 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 audited 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 regulatory reviews of our MAA of lonafarnib in Progeria and Progeroid Laminopathies progress towards potential approvals and as we advance our clinical development programs in various clinical studies, particularly the D-LIVR pivotal study to support the submission of an NDA for lonafarnib for use in a hepatitis D virus indication. We may need significant additional resources in order to aggressively move lonafarnib forward successfully based on the discussions with the FDA. 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. We have also agreed with The Progeria Research Foundation to make lonafarnib available to Hutchinson-Gilford Progeria Syndrome (HGPS or Progeria) and Progeroid Laminopathies patients under an Expanded Access Program that may not result in payment to us.

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

- continue the clinical development of our product candidates;
- in-license or acquire additional product candidates;
- undertake the manufacturing or have manufactured our product candidates;
- advance our programs into larger, more expensive clinical studies;
- initiate additional nonclinical, clinical, or other studies for our product candidates;
- identify 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 and CHI;
- 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;
- develop and educate HDV markets;
- 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 significant 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 and maintaining 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 (Oxford Finance) in December 2016 (the Oxford Loan). The Oxford Loan was 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. In August 2018, we drew the final $5.0 million upon achievement of certain clinical milestones. In March 2019, we entered into the third amendment to the Oxford Loan to refinance our outstanding principal balance of $23.3 million. Upon refinancing, the Oxford Loan was increased to $35.0 million in aggregate commitments, of which $30.0 million in principal is outstanding. The Oxford Loan is secured by perfected first priority liens on our assets, excluding intellectual property but including a commitment by us 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. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets

in the United States and worldwide resulting from the ongoing COVID-19 pandemic. We cannot assure you that we will be able to obtain additional funding if and when necessary to fund our entire portfolio of product candidates to meet our projected plans. If we are unable to obtain funding on a timely basis, we may be required to delay or discontinue one or more of our development programs or the commercialization of any product candidates or be unable to expand our operations or otherwise capitalize on potential business opportunities, which could materially affect our business, financial condition, and results of operations.

Covenants in 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 $35.0 million in term loans due on March 1, 2024, of which $30.0 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, restrict access to additional borrowings under the loan and security agreement, 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.

If the London Inter-Bank Offered Rate, or LIBOR, is discontinued, interest payments under the Oxford Loan may be calculated using another reference rate.

In July 2017, the Chief Executive of the United Kingdom Financial Conduct Authority (FCA), which regulates LIBOR, announced that the FCA intends to phase out the use of LIBOR by the end of 2021. In addition, the U.S. Federal Reserve, in conjunction with the Alternative Reference Rates Committee, a steering committee comprised of large U.S. financial institutions, is considering replacing U.S. dollar LIBOR with the Secured Overnight Financing Rate, or SOFR, a new index calculated by short-term repurchase agreements, backed by Treasury securities. Although there have been certain issuances utilizing SOFR, it is unknown whether this or any other alternative reference rate will attain market acceptance as a replacement for LIBOR. LIBOR is used as a benchmark rate throughout the Oxford Loan, and our credit agreement does not provide fallback language for all circumstances in which LIBOR ceases to be published. There remains uncertainty regarding the future utilization of LIBOR and the nature of any replacement rate, and any potential effects of the transition away from LIBOR on us are not known. The transition process may involve, among other things, increased volatility and illiquidity in markets for instruments that currently rely on LIBOR and may result in increased borrowing costs, the effectiveness of related transactions such as hedges, uncertainty under applicable documentation, including the Oxford Loan, or difficult and costly processes to amend such documentation. As a result, our ability to refinance our credit agreement or other indebtedness or to hedge our exposure to floating rate instruments may be impaired, which would adversely affect the operations of our business.

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. Our NDA for lonafarnib for treatment of Progeria and Progeroid Laminopathies was approved on November 20, 2020. Our MAA is currently under standard review with the EMA as well. Through December 31, 2020, we have not generated revenue from sales of any drugs and we may never be able to develop or commercialize additional product candidates. In addition, we have a commitment to provide access to Zokinvy for patients with Progeria and processing-deficient progeroid laminopathies for no or minimal cost to those patients.

With respect to potential commercial products, we currently have one product candidate that is in Phase 3 clinical development and two development programs focused on two separate indications that have we believe have completed Phase 2 and are advancing towards Phase 3. It may be years before our studies are initiated and completed, if at all.

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.

We may not be able to obtain FDA approval of any future NDA for our product candidates.

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, import, marketing and distribution and other possible activities relating to lonafarnib, lambda, avexitide and any other product candidate that we may develop in the future are subject to extensive regulation in the United States. Prior to the recent approval of our NDA for lonafarnib for the treatment of Progeria and Progeroid Laminopathies, we had not submitted an application for approval or obtained FDA approval for any product.

Approval of an NDA is not guaranteed, and the approval process is an expensive and uncertain process that may take several years. The FDA and foreign regulatory entities also have substantial discretion in the approval process. The number and types of preclinical studies and clinical trials that will be required for approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to target and the regulations applicable to any particular product candidate. Data are subject to varying interpretation and the FDA may not agree that our clinical data support that any of our product candidates are safe and effective for the proposed therapeutic use. Despite the time and expense associated with preclinical studies and clinical trials, failure can occur at any stage, and we could encounter problems that require us to repeat or perform additional preclinical studies or clinical trials or generate additional chemistry, manufacturing and controls data, including drug product stability data. In previous studies, ECG abnormalities were observed in our lonafarnib program. We do not expect that this will impact the conduct of the D-LIVR HDV study. The FDA and similar foreign authorities could delay, limit or deny approval of a product candidate, and may ultimately approve the product for narrower indications or with unfavorable labeling that would impede our commercialization of the drug.

Approval procedures vary among countries and can involve additional product testing and additional administrative review periods, including obtaining reimbursement and pricing approval in select markets. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks associated with FDA approval as well as additional, presently unanticipated, risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others, including the risk that our product candidates may not be approved for all indications requested and that such approval may be subject to limitations on the indicated uses for which the product may be marketed.

Our business strategy is based upon obtaining and maintaining 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 and maintain 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 and maintain 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 (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 five of our development programs 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.

Although the FDA has granted Rare Pediatric Disease designation to avexitide for the treatment of congenital hyperinsulinism, NDA approval for this program may not meet the eligibility criteria for a priority review voucher.

Our avexitide compound has received Rare Pediatric Disease (RPD) designation from the FDA for the treatment of Congenital Hyperinsulinism (CHI). The FDA defines a "rare pediatric disease" as a disease that affects fewer than 200,000 individuals in the United States primarily under the age of 18 years. Specifically, under this program, a sponsor who receives an approval for a drug or biologic for a "rare pediatric disease" may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product. The sponsor of a rare pediatric disease drug product receiving a priority review voucher may transfer (including by sale) the voucher to another sponsor. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted the application. The FDA may also revoke any priority review voucher if the rare pediatric disease drug for which the voucher was awarded is not marketed in the U.S. within one year following the date of approval. In addition, the priority review voucher is only awarded to an NCE, thus if a compound is approved first for an indication that is not a rare pediatric disease the compound may not be eligible to receive the voucher. While we obtained and sold the Priority Review Voucher issued upon approval of ZOVINKY, there can be no assurance that we will be successful in obtaining approval for avexitide for the treatment of CHI, or that a Priority Review Voucher will be issued at the time of any such approval.

Congress has only authorized the Rare Pediatric Disease Priority Review Voucher program until September 30, 2024. However, if a drug candidate receives Rare Pediatric Disease designation before September 30, 2024, it is eligible to receive a voucher if it is approved before September 30, 2026. Avexitide may not be approved by that date, or at all, and, therefore, we may not be in a position to obtain a priority review voucher prior to expiration of the program, unless Congress further reauthorizes the program.

There is no assurance we will receive a Rare Pediatric Disease Priority Review Voucher. Also, although Priority Review Vouchers may be sold or transferred to third parties, there is no guarantee that we will be able to realize any value if we were to sell a Priority Review Voucher.

Although we have received Breakthrough Therapy designations, this may not lead to a faster development, regulatory review or approval process, and it does not increase the likelihood of receiving marketing approval in the United States.

We have received Breakthrough Therapy designation for lonafarnib and lambda for the treatment of HDV, and for avexitide for the treatment of post-bariatric hypoglycemia. A breakthrough therapy is defined as a therapy that is intended, alone or in combination with one or more other therapies, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For therapies that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Therapies designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval. The Breakthrough Therapy designations we have obtained may not result in faster development processes, reviews or approvals compared to therapies considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, the FDA may later decide that any of our development programs no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

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 negative results from two of our Phase 2 clinical trials of ubenimex in two different indications 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. Additionally, we may experience delays in patient enrollment for our clinical trials as a result of the evolving COVID-19 global pandemic and competition for patients at our European clinical trial sites due to the recent conditional approval of Hepcludex in Europe. For example, certain clinical study sites that were scheduled to open have been delayed in activating and other sites have suspended randomization of subjects and if this continues longer than anticipated, the D-LIVR trial may be delayed further than anticipated. 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 (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 (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 (IND) or equivalent foreign application or amendment;
- delays in recruiting qualified patients, or patients dropping out of, in our clinical studies, including as a result of the evolving COVID-19 global pandemic;
- 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;
- 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. Our lonafarnib product candidate for HGPS and PL has been reported to cause ECG abnormalities, but these ECG abnormalities have not resulted in a risk of mortality for these patients. There is no guarantee that additional or more severe side effects or other properties will not be identified through ongoing clinical studies by other uses of lonafarnib for other indications or our own clinical trials. Our lambda product candidate is well-characterized and has been studied in thousands of HBV and HCV patients and the most common adverse events seen are moderate headache, pyrexia, fatigue, and myalgia. ALT flares that were seen result from vigorous antiviral immunological response to treatment, not due to direct hepatotoxicity. There is no guarantee

that additional or more severe side effects will not be identified through ongoing clinical studies for other uses of lambda. Undesirable side effects, other properties, and negative results for other indications may negatively impact the development and potential for approval of our product candidates for our proposed indications. For example, the ECG abnormalities seen with lonafarnib in HGPS and PL patients has the potential to impact the labeling for lonafarnib boosted with ritonavir for HDV. Our avexitide product candidate has been studied in 54 PBH patients and 39 CHI patients and the most common adverse events are injection site bruising, nausea, and headache. There is no guarantee that additional or more severe side effects will not be identified through ongoing clinical studies for other uses of avexitide in clinical trials.

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 (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 (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 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.

In addition, prescription drugs may be promoted only for the approved indications in accordance with the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label may be subject to significant liability. However, physicians may, in their independent medical judgment, prescribe legally available products for off-label uses. The FDA does not regulate the behavior of physicians in their choice of treatments, but the FDA does restrict manufacturer's communications on the subject of off-label use of their products.

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. The material used for lonafarnib HDV pivotal trials, ongoing Progeria clinical studies and expanded access program, and commercial Zokinvy supply are sourced from Eiger-controlled CMOs. These same vendors are currently under development for commercial qualification. Materials used for our avexitide clinical trials are also sourced from CMOs. Our vendors have successfully made GMP batches for our clinical studies. If these CMOs are not able to provide us with sufficient quantities of drug substance and drug product for our clinical trials or in support of our commercialization of potential products on a timely basis, or at all, whether due to production shortages or other supply interruptions resulting from the ongoing COVID-19 pandemic or otherwise, our clinical trials or regulatory approval may be delayed, or could impair our ability to generate revenue from the sale of such product candidate.

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 will be subject to pre-approval inspection by the FDA that will be conducted after we submit our marketing applications to the FDA or comparable foreign regulatory authorities. 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, our NDA and MAA for lonafarnib and future applications may not be approved by regulatory authorities, which would significantly delay our commercialization plans and increase our costs. 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 of any of our product candidates by the FDA or comparable foreign regulatory authorities 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 and ultra-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 and Progeroid Laminopathies, we expect that the sales 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, Xeris Pharmaceuticals, and Rezolute, Inc. 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, we have established an expanded access program in order to make lonafarnib available for patients with Progeria and Progeroid Laminopathies, which requires additional resources and costs to support.

The commercial success of any of our current or future product candidates 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 products 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, lonafarnib for patients with Progeria and Progeroid Laminopathies provided under an Expanded Access Program may not result in reimbursement.

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 (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.

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 Zokinvy or any of our product candidates once approved could reduce physician utilization of such products 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.

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. Additionally, coverage policies and third-party reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained for one or more of our products, less favorable coverage policies and reimbursement rates may be implemented in the future. If we are unable to obtain and maintain sufficient third-party coverage and adequate reimbursement, the commercial success of our products may be greatly hindered and our financial condition and results of operations may be materially and adversely affected.

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

Under the Orphan Drug Act, the FDA may designate a product as an Orphan Drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient

population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union (the EU), the EMA's Committee for Orphan Medicinal Products (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 designations for each of our development programs 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 the lonafarnib composition of matter 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. 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 (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 (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 (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 products in the Orange Book after approval by FDA, ANDAs and 505(b)(2) NDAs with respect to those products 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. 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, 2020, we had 28 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 the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH). Depending on the facts and circumstances, we could be subject to significant penalties if we obtain, use, or disclose individually identifiable health information in a manner that is not authorized or permitted by HIPAA.

Foreign data protection laws, including, without limitation, the EU General Data Protection Regulation (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 businesses, including requiring changes to informed consent practices and more detailed notices for clinical trial subjects and investigators, limitations on data processing, establishing a legal basis for processing personal information, notification of data processing obligations, notification of security incidents to appropriate data protection authorities or data subjects, protecting the security and confidentiality of the personal information and establishing means for data subjects to exercise rights in relation to their personal information.

The GDPR generally restricts the transfer of personal information from the European Economic Area (EEA) to the United States and most other countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal information. Data protection laws in the United Kingdom and Switzerland impose similar restrictions. One of the primary safeguards allowing United States companies to import personal information from Europe has been certification to the EU-U.S. Privacy Shield and Swiss-U.S. Privacy Shield frameworks administered by the United States Department of Commerce. However, the Court of Justice of the EU recently invalidated the EU-U.S. Privacy Shield. The same decision also raised questions about whether one of the primary alternatives to the EU-U.S. Privacy Shield, namely, the European Commission's Standard Contractual Clauses, can lawfully be used for personal information transfers from Europe to the United States or other countries. Similarly, the Swiss Federal Data Protection and Information Commissioner recently announced that the Swiss-U.S. Privacy Shield Framework is inadequate for personal information transfers from Switzerland to the United States, and also raised questions about the viability of the Standard Contractual Clauses. At present, there are few, if any, viable alternatives to the EU-U.S. Privacy Shield and Swiss-U.S. Privacy Shield frameworks and the Standard Contractual Clauses. Although we rely primarily on individuals' explicit consent to transfer their personal information from Europe to the United States and other countries, in certain cases we have relied or may rely on the Standard Contractual Clauses. Authorities in the United Kingdom, whose data protection laws are similar to those of the EU, may similarly invalidate use of the EU-U.S. Privacy Shield as a mechanism for lawful personal information transfers

from the United Kingdom to the United States and other countries. As such, if we are unable to rely on explicit consent to transfer individuals' personal information from Europe, which can be revoked, or implement another valid compliance solution, we will face increased exposure to substantial fines under European data protection laws as well as injunctions against processing personal information from Europe. Inability to import personal information from the European Economic Area, United Kingdom or Switzerland may also restrict our clinical trial activities in Europe; limit our ability to collaborate with CROs, service providers, contractors and other companies subject to European data protection laws; and require us to increase our data processing capabilities in Europe at significant expense.

Additionally, other countries outside of Europe have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating our business. For example, Brazil recently enacted the General Data Protection Law (Lei Geral de Proteção de Dados Pessoais or LGPD) (Law No. 13,709/2018), which broadly regulates the processing of personal information and imposes compliance obligations and penalties comparable to those of the GDPR.

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) and restrictions or prohibitions on data processing. 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.

In addition, in June 2018, California enacted the California Consumer Privacy Act (CCPA), which went into effect on January 1, 2020. The CCPA gives California residents expanded rights to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that may increase data breach litigation. The CCPA will be expanded substantially on January 1, 2023, when the California Privacy Rights Act of 2020 ("CPRA") becomes fully operative. The CPRA would, among other things, give consumers the ability to limit use of information deemed to be sensitive, increase the maximum penalties for violations concerning consumers under age 16, and establish the California Privacy Protection Agency to implement and enforce the new law and impose administrative fines. Aspects of the CCPA and CPRA, and their interpretation and enforcement, remain uncertain. The potential effects of the CCPA and CPRA are far-reaching and may require us to modify our data processing practices and policies and to incur substantial costs and expenses in an effort to comply. Although the CCPA includes exemptions for certain clinical trials data and HIPAA protected health information, the law may increase our compliance costs and potential liability with respect to other personal information we collect about California residents. The CCPA has prompted a number of proposals for new federal and state privacy legislation that, if passed, could increase our potential liability, increase our compliance costs and adversely affect our business.

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 (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, software vulnerabilities, ransomware attacks 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. 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.

The financial exposure from the events referenced above could either not be insured against or not be fully covered through any insurance that we maintain. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages as a result of the events referenced above.

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 (ACA) was passed, which substantially changed the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. There remains judicial and Congressional challenges to numerous provisions of the ACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance and delaying the implementation of certain ACA-mandated fees. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing this case, although it is unclear when a decision will be made. It is also unclear how such litigation will impact the ACA and our business. In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax.

Also, there has been heightened governmental scrutiny recently over pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government

program reimbursement methodologies for products For example, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out-of-pocket costs of drugs that contained proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out-of-pocket costs of drug products paid by consumers. In addition, the Trump administration's budget proposal for fiscal year 2021 includes a $135.0 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to drug pricing that seeks to implement several of the administration's proposals. As a result, the FDA released a final rule on September 24, 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the U.S. Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. 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. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

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 research, 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;
- 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 on certain covered entity healthcare providers, health plans, and healthcare clearinghouse and their business associates that perform certain services involving the use or disclosure of individually identifiable health information as well as their covered subcontractors, 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 (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations. Beginning in 2022, such obligations will include payments and other transfers of value provided in the previous year to certain other healthcare professionals, including physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified nurse anesthetists, and certified nurse-midwives;
- 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; state and local laws requiring the registration of pharmaceutical sales representatives; 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; and
- 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 United States.

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 significant civil, criminal and administrative penalties, damages, disgorgement, fines, sanctions, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, integrity oversight and reporting obligations, contractual damages, reputational harm, 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.

The withdrawal of the United Kingdom from the EU, commonly referred to as "Brexit," may adversely impact our ability to obtain regulatory approvals of our product candidates in the EU, result in restrictions or imposition of taxes and duties for importing our product candidates into the EU, and may require us to incur additional expenses in order to develop, manufacture and commercialize our product candidates in the EU.

On June 23, 2016, the U.K. held a referendum in which a majority of the eligible members of the electorate voted for the U.K. to leave the EU. The U.K's withdrawal from the EU is commonly referred to as Brexit. The U.K. and the EU agreed to a withdrawal agreement (the ***Withdrawal Agreement***) pursuant to which the U.K. formally left the EU on January 31, 2020. Under the Withdrawal Agreement, the U.K. is subject to a transition period until December

31, 2020 (the ***Transition Period***), during which EU rules will continue to apply. Due to the current COVID-19 global pandemic, negotiations between the U.K. and the EU scheduled for March are either being postponed or occurring in a reduced forum via video conference. There is, therefore, an increased likelihood that the Transition Period may need to be extended beyond December 31, 2020 (although it remains the position of the U.K. government that it will not be extended).

Since a significant proportion of the regulatory framework in the U.K. applicable to our business and our product candidates is derived from EU directives and regulations, Brexit, following the Transition Period, could materially impact the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the U.K. or the EU. For example, as a result of the uncertainty surrounding Brexit, the European Medicines Agency (EMA) relocated to Amsterdam from London. Following the Transition Period, the U.K. will no longer be covered by the centralized procedures for obtaining EU-wide marketing authorization from the EMA and, unless a specific agreement is entered into, a separate process for authorization of drug products, including our product candidates, will be required in the U.K., the potential process for which is currently unclear. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the U.K. or the EU and restrict our ability to generate revenue and achieve and sustain profitability. In addition, we may be required to pay taxes or duties or be subjected to other hurdles in connection with the importation of our product candidates into the EU, or we may incur expenses in establishing a manufacturing facility in the EU in order to circumvent such hurdles. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the U.K. or the EU for our product candidates, or incur significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the U.K. It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the EU.

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, Australia, Turkey, Germany, Pakistan, New Zealand, Mongolia, Spain, France, Bulgaria, Romania, Taiwan, Sweden, Italy, Belgium, Switzerland, United Kingdom, Greece, Moldova, Ukraine, Russia, and 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 Virus, 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. Certain countries have closed their borders due to COVID-19 preventing activation of clinical sites. 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, natural epidemics or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Earthquakes, health epidemics or other natural disasters could severely disrupt our operations and have a material adverse effect on our business. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, damaged critical infrastructure, such as the manufacturing facilities of our third-party CMOs, or otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. For example, in December 2019, an outbreak of a novel strain of coronavirus (COVID-19) originated in Wuhan, China. Since certain starting materials of certain of our products obtained from third-party chemical suppliers are manufactured in China and Japan, an outbreak of communicable diseases in the region, or the perception that such an outbreak could occur, and the measures taken by the governments of countries affected, could adversely affect our business, financial condition or results of operations by limiting our ability to manufacture product within or outside for example China, Japan, Italy, Canada, and the United States, forcing temporary closure of facilities that we rely upon or increasing the costs associated with obtaining starting materials and then clinical supplies of our product candidates. The extent to which the coronavirus impacts our results will depend on future developments, which are highly uncertain and cannot be accurately predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. In addition, our corporate headquarters is located in the San Francisco Bay Area, which has in the past experienced severe earthquakes and other natural disasters and is currently experiencing an outbreak of COVID-19. We do not carry earthquake insurance. We have limited 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.

Our business is currently adversely affected by and could be materially adversely affected in the future by the effects of disease outbreaks, epidemics and pandemics including the evolving effects of the COVID-19 outbreak. We have a significant number of clinical trial sites in countries that have been directly affected by COVID-19. We depend on manufacturing operations for various stages of our supply chain in countries that have been directly affected by COVID-19. COVID-19 continues to adversely affect our business and could materially and adversely affect our operations and those of our manufacturers and other third parties with whom we conduct business.

Our business has been adversely affected by COVID-19 and could be materially and adversely impacted by COVID-19 or other health epidemics in regions where we have significant manufacturing facilities, concentrations of clinical trial sites or other business operations.

The COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting employees, patients, community and business operations, as well as the U.S. economy and financial markets. The effects of the shelter-in-place order and our work-from-home policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

Additionally, some of our suppliers of certain materials used in the production of our drug products are located in China, Japan, Canada, Italy and the United States. While many of these materials may be obtained by more than one supplier, including suppliers outside of China, Japan, Canada, Italy and the United States, port closures and other restrictions resulting from the coronavirus outbreak in the region may disrupt our supply chain or limit our ability to obtain sufficient materials for our drug products.

In addition, our clinical trials have been and may continue to be affected by the COVID-19 pandemic. Site initiation and patient enrollment has been delayed, due to prioritization of hospital resources toward the COVID-19 pandemic, travel restrictions imposed by governments, and the inability to access sites for initiation and monitoring. In our D-LIVR trial, the COVID-19 pandemic has delayed enrollment in our global clinical trial, some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, we may be unable to obtain blood samples for testing, and we may not be able to provide study drug to patients.

Further, as a result of the COVID-19 pandemic, the extent and length of which is uncertain, we may be required to develop and implement additional clinical study policies and procedures designed to help protect study participants from the COVID-19 virus, which may include using telemedicine visits, remote monitoring of patients and clinical sites, and measures to ensure that data from clinical studies that may be disrupted as result of the pandemic are collected pursuant to the study protocol and consistent with good clinical practices (GCPs), with any material protocol deviation reviewed and approved by the site Institutional Review Board (IRB). Missed scheduled patient appointments, any interruption in study drug supply, or other consequences that may result in incomplete data being generated during a study as a result of the pandemic must be adequately documented and justified. For example, on March 18, 2020, the FDA issued guidance on conducting clinical trials during the pandemic, which describes a number of considerations for sponsors of clinical trials impacted by the pandemic, including the requirement to include in the clinical study report (or as a separate document) contingency measures implemented to manage the study, any disruption of the study as a result of the COVID-19 pandemic; a list of all study participants by unique subject identifier and by investigational site that were affected by the COVID-19 pandemic, and a description of how the individual's participation was altered; and analyses and corresponding discussions that address the impact of implemented contingency measures (e.g., participant discontinuation from investigational product and/or study, alternative procedures used to collect critical safety and/or efficacy data) on the safety and efficacy results reported for the study.

Further, the FDA may continue to suspend or delay certain foreign inspections, and the EMA may also, and if there continues to be a suspension or delay in inspections, our product application reviews and potential approvals could be impacted or delayed.

While we expect the COVID-19 pandemic to continue to adversely affect our business operations, the extent of the impact on our clinical development and regulatory efforts and the value of and market for our common stock will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the U.S. and in other countries, and the effectiveness of actions taken globally to contain and treat COVID-19. In addition, to the extent the evolving effects of the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described elsewhere in this ''Risk Factors'' section.

Risks Related to Ownership of our Common Stock

The market price of our common stock has been and may continue to 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, including very recently in connection with the ongoing COVID-19 pandemic, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. These broad market and industry factors, including potentially worsening economic conditions and other adverse effects or developments relating to the ongoing COVID-19 pandemic, 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.

Effective December 31, 2019, we ceased to be an "emerging growth company," and the reduced reporting requirements applicable to "emerging growth companies" no longer apply, which has increased our costs as a result of being a public company and places additional demands on management.

Effective December 31, 2019, we ceased to be classified as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act (the JOBS Act). We are now considered an Accelerated Filer and a Smaller Reporting Company, which will require accelerated deadlines of periodic reports. In March 2020, the definition of an Accelerated Filer was amended to exclude Smaller Reporting Companies from the requirements of the Sarbanes-Oxley Act Section 404(b).

We have previously taken advantage of the JOBS Act's reduced disclosure requirements applicable to "emerging growth companies" regarding executive compensation and exemptions from the requirements of holding advisory say-on-pay votes on executive compensation. Since we are no longer classified as an "emerging growth company," we are no longer eligible for such reduced disclosure requirements and exemptions and as such, we are required to hold a say-on-pay vote and a say-on-frequency vote at our 2019 annual meeting of stockholders. As a result, we expect that because we are no longer classified as an "emerging growth company," we will require additional attention from management with respect to our disclosures and will incur increased costs, which could include higher legal fees, accounting fees, consultant fees and fees associated with investor relations activities, among others.

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 RA Capital, Vivo Ventures Fund VI, L.P. and Adage Capital Partners, 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.

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

Our federal and state net operating loss (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. Under legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act, as modified by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), U.S. federal net operating loss carryforwards generated in tax years beginning after December 31, 2017 may be carried forward indefinitely but, in the case of tax years beginning after December 31, 2020, may only be used to offset 80% of taxable income annually. In addition, California recently enacted A.B. 85 which imposed limits on the usability of California state net operating losses and certain tax credits in tax years beginning after 2019 and before 2023. Such limitations could result in the expiration of portions of our net operating loss and tax credit carryforwards before utilization. Moreover, if a corporation undergoes an ownership change within the meaning of Section 382 of the Code (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. Our merger with Celladon 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. In addition, we assessed whether Eiger had an ownership change, as defined by Section 382 of the Code, as a result of the Merger and other stock issuances that occurred from our formation through December 31, 2020. Based upon this assessment, we have experienced ownership changes on April 20, 2016, October 18, 2018 and December 31, 2020. Due to these ownership changes, reductions were made to our NOL and tax credit carryforwards under these rules. Additional ownership changes in the future could result in additional limitations on our net operating loss and tax credit 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 5, 2021, there were approximately 25 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.

Securities Authorized for Issuance under Equity Compensation Plans

The following table summarizes our compensation plans under which our equity securities are authorized for issuance as of December 31, 2020:

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (1)	(b) Weighted-Average Exercise Price of Outstanding Options ($/share) (2)	(c) Number of Shares Remaining Available For Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (3)
Equity compensation plans approved by stockholders	3,734,575	$ 10.81	1,564,900
Equity compensation plans not approved by stockholders	—	—	—
Total	3,734,575	$ 10.81	1,564,900

(1) The amount shown in column (a) includes 3,697,075 outstanding options and 37,500 restricted stock units.

(2) The weighted average exercise price in column (b) includes options only as restricted stock units do not have exercise price.

(3) As of December 31, 2020, the number of securities remaining available for issuance in column (c) includes 1,021,109 share available for future issuance in the form of options or restricted stock units under our Amended and Restated 2013 Equity Incentive Plan and 543,791 shares remained available for future issuance under our 2013 Employee Stock Purchase Plan (ESPP).

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 indicated, 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.

Overview

We are a commercial-stage biopharmaceutical company focused on the development and commercialization of foundational therapies for Hepatitis Delta Virus (HDV), the most severe form of human viral hepatitis, for which there is currently no FDA-approved therapy. We have reported positive proof-of-concept clinical results across all our programs, and have received Breakthrough Therapy designation for three programs in clinical development.

Our programs have several aspects in common: the disease targets represent conditions of high unmet medical need; 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.

We are developing two complementary treatments for HDV. Lonafarnib is a first-in-class oral farnesylation inhibitor in a global Phase 3 trial, and the only oral therapy in development for HDV. Peginterferon lambda (lambda) is a first-in-class, well characterized, well-tolerated type III interferon entering Phase 3.

The pivotal Phase 3 D-LIVR study (N=400) of lonafarnib boosted with ritonavir in HDV is ongoing and enrolling patients. The study spans twenty-two countries and over one hundred sites and has potential to generate data for two lonafarnib-based ritonavir-boosted regimens for approval. An all-oral arm of lonafarnib boosted with ritonavir and a combination arm of lonafarnib boosted with ritonavir combined with pegylated interferon-alfa-2a will each be compared to placebo.

Lambda is our second program treating HDV and is entering Phase 3. We have agreement with the FDA and European Medicines Agency (EMA) on a single pivotal Phase 3 study design and endpoints. Lambda is a well-characterized, late-stage, first in class, type III interferon. We previously reported Phase 2 LIMT (lambda monotherapy) study results (n=33) that demonstrated a 36% durable virologic response (DVR), or below the limit of quantification (BLQ), at 24 weeks post-treatment. In the Phase 2 LIFT study, HDV patients were treated with a combination of our two proprietary products, lambda and lonafarnib boosted by ritonavir. The end-of-study results based on a per-protocol analysis reported in November 2020 showed that 77% of patients achieved the primary end-point of >2 log decline in HDV RNA at Week 24 and 50% of patients were HDV RNA BLQ or undetectable. Adverse events were mostly mild to moderate.

The FDA approved our first commercial product, Zokinvy (lonafarnib) to reduce risk of mortality of Hutchinson-Gilford Progeria Syndrome (HGPS or Progeria) and to treat processing-deficient progeroid laminopathies, ultra-rare and rapidly fatal genetic conditions of accelerated aging in children, on November 20, 2020. Our Marketing Authorization Application (MAA) is under review with the EMA, and we expect a decision in the second half of 2021.

We are also developing avexitide, a well-characterized peptide, as a treatment for post-bariatric hypoglycemia (PBH), a debilitating and potentially life-threatening condition for which there is currently no approved therapy. We have completed four clinical studies demonstrating proof of concept in 54 patients suffering from severe, refractory PBH, and have agreement with FDA and EMA on a single pivotal Phase 3 trial.

Avexitide has also demonstrated proof of concept for treatment of congenital hyperinsulinism (CHI), an ultra-rare pediatric metabolic genetic disorder.

We have not generated any revenue from product sales through 2020. 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 $65.1 million, $70.3 million and $52.4 million for the years ended December 31, 2020, 2019 and 2018, respectively. As of December 31, 2020, we had an accumulated deficit of $306.5 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, and potentially commercialize our product candidates and add personnel necessary to operate as a public company with an advanced clinical candidate pipeline of products. In addition, we will incur costs for additional personnel and upgrades to our information technology systems as we transition from an emerging growth 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 additional regulatory approvals.

Recent Developments

Publication of Phase 2 PREVENT Study Results of Avexitide in Post-Bariatric Hypoglycemia (PBH) in Journal of Clinical Endocrinology & Metabolism

On February 23, 2021, we announced that positive results from the Phase 2 PREVENT study of Avexitide in patients with PBH were published in *Journal of Clinical Endocrinology & Metabolism*. The study met its primary endpoints and we previously reported topline data from this study in March 2019.

Publication of ILIAD Study Results of Peginterferon Lambda (Lambda) in COVID-19 in Lancet Respiratory Medicine 2021

On February 8, 2021, we announced that final results from the Phase 2 ILIAD (Interferon Lambda for Immediate Antiviral Therapy at Diagnosis in COVID-19) study published in *Lancet Respiratory Medicine*. ILIAD, an investigator sponsored randomized trial of lambda in outpatients with mild to moderate COVID-19 conducted at Toronto General Hospital, University Health Network in Toronto, Canada, demonstrated a single dose of lambda accelerated clearance of SARS-CoV2 in newly diagnosed, non-hospitalized patients. We previously reported topline data from this study on October 15, 2020.

Completion of Sale of Priority Review Voucher

On November 23, 2020, we announced that we had entered into a definitive agreement to sell our Priority Review Voucher (PRV) for a lump sum payment of $95.0 million to AbbVie Inc. (AbbVie). The transaction was subject to customary closing conditions including anti-trust review. The PRV was granted to us in conjunction with the November 20, 2020 approval by the FDA of our new drug application for Zokinvy. On January 7, 2021, we announced that we had completed the sale to AbbVie following the early termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended. Eiger retained 50%, or approximately $47.4 million, of the PRV proceeds under the terms of the Collaboration and Supply Agreement with the Progeria Research Foundation.

Update on Impact of COVID-19 Pandemic on Clinical Development Activities and Business Operations

We have taken proactive steps to ensure the safety of patients and the integrity of our HDV Phase 3 D-LIVR trial, which is expected to complete enrollment in 2021. We have adequate clinical drug product supply for the D-LIVR study and do not anticipate any interruption in availability of study drug to patients.

We do not anticipate any impact to our planned U.S. commercial launch of Zokinvy, including availability of commercial drug supply. We previously announced that the EMA review of our MAA will follow a standard review timeline.

We have put into place remote operations and new policies, which are in-line with local, state and federal guidelines, to maintain the safety and well-being of our employees, while working to maintain business continuity as this unprecedented global situation continues to evolve. We continue to monitor the situation closely, including its potential effect on our clinical development plans and timelines.

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 clinical trials, including contract manufacturing arrangements, clinical trial material related costs and other 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, 2020, 2019 and 2018 (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Product candidates:			
Lonafarnib	$ 25,051	$ 37,775	$ 21,647
Avexitide	1,891	3,834	3,009
Lambda	6,128	1,935	1,945
Ubenimex	—	—	4,116
Internal research and development costs	8,520	8,247	6,374
Total research and development expense	$ 41,590	$ 51,791	$ 37,091

We expect research and development expenses will continue to be significant and may 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 fees 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. The COVID-19 pandemic presents additional risks and uncertainties associated with developing drugs, including:

- delays in trial activities and patient enrollment or diversion of healthcare resources as a result of the evolving effects of the COVID-19 pandemic or otherwise;
- production shortages or other supply interruptions in clinical trial materials resulting from the evolving effects of the COVID-19 pandemic or otherwise;
- our ability to hire and retain key research and development personnel;
- the scope, rate of progress, results and expense of our ongoing, as well as any additional, clinical trials and other research and development activities; and
- the timing and receipt of any regulatory approvals.

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, insurance, investor relations, banking fees and other administrative expenses and professional services. We expect our general and administrative expenses to increase in the future due to sales and marketing activities from the commercialization of Zokinvy.

Interest Expense

Interest expense consists of interest and amortization of the debt discount related to the Oxford Loan.

Interest Income

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

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 consolidated 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 sheets and within research and development expenses in the consolidated statements 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 and restricted stock units based on the estimated fair value of the awards on the date of grant. We estimate the grant date fair value of stock options, 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. We record forfeitures when they occur.

The Black-Scholes option-pricing model includes the following assumptions:

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. Beginning in the third quarter of 2019, as we had been publicly traded for four and a half years, we began to layer in our historical volatility in the calculation of expected volatility.

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.

We 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 10 years. 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.

We estimate the fair value of restricted stock units based on the closing market price of our common stock on the date of grant and the resulting stock-based compensation expense is recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the awards.

Results of Operations

Comparison of the Years Ended December 31, 2020 and 2019

The following table summarizes results of operations for the years ended December 31, 2020 and 2019 (in thousands):

	Year Ended December 31,		Increase / (Decrease)	% Change
	2020	2019		
Operating expenses:				
Research and development	$ 41,590	$ 51,791	$ (10,201)	(20)%
General and administrative	20,559	17,113	3,446	20%
Total operating expenses	62,149	68,904	(6,755)	(10)%
Loss from operations	(62,149)	(68,904)	6,755	(10)%
Interest expense	(3,594)	(3,406)	(188)	6%
Interest income	704	2,073	(1,369)	(66)%
Other expense, net	(12)	(15)	3	(20)%
Net loss	$ (65,051)	$ (70,252)	$ 5,201	(7)%

Research and development expenses

Research and development expenses decreased by $10.2 million to $41.6 million for the year ended December 31, 2020, from $51.8 million for the same period in 2019. The decrease was primarily due to a $11.7 million decrease in contract manufacturing and clinical expenditures due to decrease in clinical program activities. The decrease was partially offset by an increase of $0.7 million in regulatory expenses, an increase of $0.6 million in headcount related expenses and $0.3 million in other operating expenses.

General and administrative expenses

General and administrative expenses increased by $3.5 million to $20.6 million for the year ended December 31, 2020, from $17.1 million for the same period in 2019. The increase was primarily due to a $1.7 million increase in compensation and personnel related expenses, including stock-based compensation, due to an increase in headcount and a $1.7 million increase in outside services, including consulting, advisory and accounting services.

Interest expense

Interest expense increased by $0.2 million to $3.6 million for the year ended December 31, 2020, from $3.4 million for the same period in 2019. Interest expense primarily increased due to the additional funds borrowed under the Oxford Loan in 2019.

Interest income

Interest income decreased by $1.4 million to $0.7 million for the year ended December 31, 2020, from $2.1 million for the same period in 2019. The decrease was primarily due to a decrease in interest rates on money market funds and available-for-sale securities.

Sources of Liquidity

As of December 31, 2020, we had $128.9 million of cash, cash equivalents and investments, comprised of $28.9 million of cash and cash equivalents and $100.0 million of debt securities available-for-sale, and an accumulated deficit of $306.5 million.

In December 2019, we filed a shelf registration statement on Form S-3 (File No. 333-235655) with the Securities and Exchange Commission, which permits the offering, issuance and sale by us of up to a maximum aggregate offering price of $150.0 million of our common stock, preferred stock, debt securities and warrants. Up to a maximum of $50.0 million of the maximum aggregate offering price of $150.0 million may be issued and sold

pursuant to an at-the-market (ATM) financing facility (2019 ATM Facility) under a sales agreement with Jefferies LLC (Jefferies). In August 2020, we entered into a new sales agreement with Jefferies for up to $50.0 million of the remaining amount on the shelf registration statement which may be sold pursuant to an ATM financing facility (2020 ATM Facility).

As of December 31, 2020, we completed both the 2019 ATM Facility and the 2020 ATM Facility for a total of 9,267,760 shares resulting in $97.3 million in net proceeds, after deducting commissions.

On December 18, 2020, we filed a new shelf registration statement on Form S-3 (File No. 333-251497) with the Securities and Exchange Commission, which permits the offering, issuance and sale by us up to a maximum aggregate offering price of $200.0 million of our common stock, preferred stock, debt securities and warrants. Up to a maximum of $50.0 million of the maximum aggregate offering price of $200.0 million may be issued and sold pursuant to a new ATM financing facility under a sales agreement with Jefferies. We have not issued any shares under this facility.

We believe that the 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. However, if our anticipated operating results are not achieved in future periods, we believe that planned expenditures may need to be reduced or we would be required to raise funding in order to fund our operations. Additionally, our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic.

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 expect to generate revenues from product sales of Zokinvy beginning in 2021. 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, sales and marketing costs for commercialization of Zokinvy and other 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. As a result of economic conditions, general global economic uncertainty, political change and other factors, including the ongoing COVID-19 pandemic, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on reasonable terms. If we are unable to raise additional capital due to the volatile global financial markets, general economic uncertainty or other factors, we may need to curtail planned development or commercialization activities. 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,	
	2020	2019
Net cash provided by (used in):		
Operating activities	$ (63,185)	$ (63,614)
Investing activities	(44,787)	(16,471)
Financing activities	97,463	58,196
Net (decrease) increase in cash and cash equivalents	$ (10,509)	$ (21,889)

Cash flows from operating activities

Cash used in operating activities for the year ended December 31, 2020 was $63.2 million, which primarily consisted of a net loss of $65.1 million, partially offset by stock-based compensation expense of $6.0 million, non-cash interest expense of $0.8 million, amortization of operating lease right-of-use assets of $0.5 million and common stock issued under Product Development Agreement of $0.2 million. Additionally, cash used in operating activities reflected changes in net operating assets of $5.9 million due to an increase of $3.6 million in prepaid expenses and other current assets primarily due to the timing of payments, an increase of $1.4 million in other assets primarily related to long term deposits with clinical research organizations, a decrease of $0.4 million in accounts payable and accrued liabilities due to timing of payments and a decrease of $0.5 million in operating lease liabilities.

Cash used in operating activities for the year ended December 31, 2019 was $63.6 million and primarily consisted of a net loss of $70.3 million and amortization of debt securities discounts of $0.5 million, which was partially offset by $5.7 million of stock-based compensation expense, $0.7 million of non-cash interest related to amortization of debt discount and $0.4 million of amortization of operating lease right-of-use assets. Additionally, cash used in operating activities reflected changes in net operating assets due to an increase of $3.7 million in prepaid expenses and other current assets primarily due to the timing of payments and an increase of $2.1 million in other assets primarily due to an increase in long-term deposits to IQVIA, which was partially offset by an increase of $6.2 million in accounts payable and accrued liabilities primarily associated with increase in business activity.

Cash flows from investing activities

Cash used in investing activities was $44.8 million for the year ended December 31, 2020, primarily consisting of $128.3 million of purchases of debt securities, partially offset by $83.8 million of proceeds from maturities of debt securities.

Cash used in investing activities for the year ended December 31, 2019 was $16.5 million. The net cash decrease was primarily due to $96.3 million purchases of debt securities and $0.5 million purchases of property and equipment, which was partially offset by $80.3 million proceeds from maturities of debt securities.

Cash flows from financing activities

Cash provided by financing activities for the year ended December 31, 2020 was $97.5 million and primarily consisted of $96.8 million of net proceeds from the issuance of common stock under our ATM Facilities and $0.7 million of proceeds from the issuance of common stock upon stock option exercises and ESPP purchase.

Cash provided by financing activities for the year ended December 31, 2019 was $58.2 million and primarily consisted of $53.2 million of net proceeds from the issuance of common stock upon public offering, $4.0 million of proceeds from borrowings, net of repayments, in connection with the Oxford Loan, and $0.8 million of proceeds from the issuance of common stock upon stock option exercises.

Contractual Obligations and Other Commitments

Leases and Term Loan

Refer to Notes 7 and 12 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, 2020.

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. We have not included these potential payment obligations in our contractual obligations table as the amount and timing of such payments are not known.

Oxford Finance Term Loan

On December 30, 2016, we entered into an aggregate $25.0 million loan with Oxford Finance LLC (the Oxford Loan). We borrowed $15.0 million in December 2016 (Tranche A), $5.0 million in May 2018 (Tranche B), and $5.0 million in August 2018 (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 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. In addition, at the time of final payment of Tranche B, we were required to pay an additional exit fee of $0.1 million. On March 5, 2019, we entered into the third amendment to the Oxford Loan (the Amended Oxford Loan) to refinance the Oxford Loan. The Amended Oxford Loan increased the aggregate amount available to be borrowed to $35.0 million and extended the maturity date to March 1, 2024. On March 5, 2019, prior to entering into the Amended Oxford Loan, the outstanding balance of the Oxford Loan was $23.3 million. At the time of entering into the Amended Oxford Loan, we borrowed an additional $6.7 million in principal under the Amended Oxford Loan, which increased the total amount borrowed to $30.0 million (Amended Tranche A). The remaining $5.0 million (Amended Tranche B) will be available to us upon the latest to occur of (i) achievement of positive lonafarnib Phase 3 HDV topline data sufficient to file new drug application (Clinical Milestone) and (ii) January 1, 2021.

The Amended 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 6.64% or 9.15%. The Amended Oxford Loan has an interest only period until April 1, 2021, followed by 36 equal monthly payments of principal and interest. Upon the receipt of Amended Tranche B, the interest only period for borrowed funds will be extended by one year until April 1, 2022, followed by 24 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 borrowed funds, or $2.3 million. In addition, we are required to pay an additional exit fee of $1.0 million.

On February 23, 2021, we entered into the fifth amendment to the Oxford Loan. The amendment extended the interest only period by 17 months until September 1, 2022, followed by 19 equal monthly payments of principal and interest. Upon the receipt of Amended Tranche B, the interest only period for borrowed funds will be extended by six months until March 1, 2023, followed by 13 equal monthly payments of principal plus accrued interest. In addition, we paid the amendment fees of $0.2 million to the lenders on the effective date of the fifth amendment.

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, 2021, we were in compliance with all loan terms.

Manufacturing Service Agreement

In the first quarter of 2020, we entered into a Master Manufacturing Services Agreement (MMSA) and Product Agreement with Patheon, Inc. (Patheon) for the manufacturing of lonafarnib capsules and packaging of bottles for commercial sale. Under the terms of the agreements, we are required to provide Patheon with annual volume forecasts of capsules and Patheon will manufacture 80% of such annual forecasts. If we order less than 80% of such annual forecasts, we are required to pay 70% of purchase price for the shortfall. The initial terms of the MMSA and Product Agreement end on December 31, 2025 with automatic renewal for successive two-year terms, unless earlier terminated pursuant to the terms of each agreement, or upon either party’s notice of termination to the other.

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, 2020.

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, 2020 and 2019, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2020, 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.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

KPMG LLP

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

San Francisco, California

March 9, 2021

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

	December 31,	
	2020	2019
Assets		
Current assets:		
Cash and cash equivalents	$ 28,864	$ 39,373
Debt securities, available-for-sale	99,976	55,621
Prepaid expenses and other current assets	8,966	5,390
Total current assets	137,806	100,384
Property and equipment, net	709	590
Operating lease right-of-use assets	1,176	1,654
Other assets	3,903	2,511
Total assets	$ 143,594	$ 105,139
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,640	$ 6,414
Accrued liabilities	11,405	10,001
Current portion of operating lease liabilities	582	534
Total current liabilities	16,627	16,949
Long term debt, net	31,194	30,390
Operating lease liabilities	738	1,320
Total liabilities	48,559	48,659
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Common stock, $0.001 par value, 200,000,000 shares authorized as of December 31, 2020 and 2019; 33,878,486 and 24,523,381 shares issued and outstanding as of December 31, 2020 and 2019, respectively	34	24
Additional paid-in capital	401,509	297,863
Accumulated other comprehensive (loss) income	(8)	42
Accumulated deficit	(306,500)	(241,449)
Total stockholders' equity	95,035	56,480
Total liabilities and stockholders' equity	$ 143,594	$ 105,139

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,		
	2020	2019	2018
Operating expenses:			
Research and development	$ 41,590	$ 51,791	$ 37,091
General and administrative	20,559	17,113	13,956
Total operating expenses	62,149	68,904	51,047
Loss from operations	(62,149)	(68,904)	(51,047)
Interest expense	(3,594)	(3,406)	(2,329)
Interest income	704	2,073	997
Other expense, net	(12)	(15)	(12)
Net loss	$ (65,051)	$ (70,252)	$ (52,391)
Net loss per common share, basic and diluted	$ (2.31)	$ (3.08)	$ (3.84)
Weighted-average common shares outstanding, basic and diluted	28,143,391	22,785,611	13,634,152

See accompanying notes to the consolidated financial statements.

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

	Year Ended December 31,		
	2020	2019	2018
Net loss	$ (65,051)	$ (70,252)	$ (52,391)
Other comprehensive (loss) gain:			
Unrealized (loss) gain on available-for-sale debt securities, net	(50)	67	(22)
Comprehensive loss	$ (65,101)	$ (70,185)	$ (52,413)

See accompanying notes to the consolidated financial statements.

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

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Income (Loss)	Deficit	Equity
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 loss on available-for-sale 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
Issuance of common stock upon public offering, net of $3,731 of issuance costs	5,175,000	5	53,189	—	—	53,194
Issuance of common stock upon ESPP purchase	15,701	—	130	—	—	130
Issuance of common stock upon stock option exercise	120,921	—	844	—	—	844
Vesting of common stock under Product Development Agreement	—	—	226	—	—	226
Stock-based compensation expense	—	—	5,679	—	—	5,679
Unrealized gain on available-for-sale debt securities, net	—	—	—	67	—	67
Net loss	—	—	—	—	(70,252)	(70,252)
Balance at December 31, 2019	24,523,381	24	297,863	42	(241,449)	56,480
Issuance of common stock upon offering at-the-market, net of $3,231 of issuance costs	9,267,760	10	96,750	—	—	96,760
Issuance of common stock upon ESPP purchase	25,645	—	186	—	—	186
Issuance of common stock upon stock option exercise	61,700	—	520	—	—	520
Vesting of common stock under Product Development Agreement	—	—	217	—	—	217
Stock-based compensation expense	—	—	5,973	—	—	5,973
Unrealized loss on available-for-sale debt securities, net	—	—	—	(50)	—	(50)
Net loss	—	—	—	—	(65,051)	(65,051)
Balance at December 31, 2020	33,878,486	$ 34	$ 401,509	$ (8)	$ (306,500)	$ 95,035

See accompanying notes to the consolidated financial statements.

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

	Year Ended December 31,		
	2020	2019	2018
Operating Activities			
Net loss	$ (65,051)	$ (70,252)	$ (52,391)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	167	68	54
Amortization of debt securities premiums and discounts	124	(467)	(426)
Stock-based compensation	5,973	5,679	5,007
Non-cash interest expense	804	723	592
Amortization of operating lease right-of-use assets	478	418	—
Common stock issued under Product Development Agreement	217	226	428
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(3,563)	(3,698)	(780)
Other assets	(1,392)	(2,075)	(124)
Accounts payable	(1,899)	584	2,647
Accrued liabilities	1,491	5,610	2,110
Operating lease liabilities	(534)	(430)	—
Other long term liabilities	—	—	212
Net cash used in operating activities	(63,185)	(63,614)	(42,671)
Investing Activities			
Purchase of debt securities available-for-sale	(128,295)	(96,267)	(57,193)
Proceeds from maturities of debt securities available-for-sale	83,766	80,271	28,250
Purchase of property and equipment	(258)	(475)	(142)
Net cash used in investing activities	(44,787)	(16,471)	(29,085)
Financing Activities			
Issuance of common stock upon offering at-the-market, net of issuance costs	96,779	—	—
Proceeds from issuance of common stock upon stock option exercises	520	844	310
Proceeds from issuance of common stock upon ESPP purchase	186	130	96
Payment of deferred offering costs	(22)	(19)	—
Proceeds from issuance of common stock upon public offering, net of issuance costs	—	53,194	90,642
Proceeds from borrowings in connection with term loan, net of issuance costs	—	6,627	9,935
Repayment of accrued exit fee and second amendment fee	—	(913)	—
Repayment of term loan	—	(1,667)	—
Net cash provided by financing activities	97,463	58,196	100,983
Net (decrease) increase in cash and cash equivalents	(10,509)	(21,889)	29,227
Cash and cash equivalents at beginning of year	39,373	61,262	32,035
Cash and cash equivalents at end of year	$ 28,864	$ 39,373	$ 61,262
Supplemental disclosure of cash flow information:			
Interest paid	$ 2,791	$ 2,638	$ 1,652

See accompanying notes to the 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. Eiger is a commercial-stage biopharmaceutical company focused on the development and commercialization of foundational therapies for Hepatitis Delta Virus (HDV), the most severe form of human viral hepatitis, for which there is currently no FDA-approved therapy. Eiger has reported positive proof-of-concept clinical results across all of our programs and have received Breakthrough Therapy designation for three programs in clinical development.

Eiger's lead clinical programs are complementary treatments for HDV. Lonafarnib is a first-in-class oral farnesylation inhibitor in a global Phase 3 trial, and the only oral therapy in development for HDV. Peginterferon lambda is a first-in-class, well characterized, well-tolerated type III interferon entering Phase 3.

The FDA approved the Company's first commercial product, Zokinvy (lonafarnib) for treatment of Progeria and processing-deficient progeroid laminopathies, ultra-rare and rapidly fatal genetic conditions of accelerated aging in children, November 20, 2020. Eiger's Marketing Authorization Application (MAA) is under review with the European Medicines Agency (EMA), with a decision expected in the second half of 2021.

The Company is also developing avexitide, a well-characterized peptide, as a treatment for PBH, a debilitating and potentially life-threatening condition for which there is currently no approved therapy, and as a treatment CHI, an ultra-rare pediatric metabolic disorder.

The Company's principal operations are based in Palo Alto, California and it operates in one segment.

Liquidity

As of December 31, 2020, the Company had $128.9 million of cash, cash equivalents and investments, comprised of $28.9 million of cash and cash equivalents and $100.0 million of debt securities available-for-sale. The Company had an accumulated deficit of $306.5 million and negative cash flows from operating activities as of December 31, 2020. As the Company continues to incur losses, its transition to profitability will depend on the successful development, approval, and commercialization of product candidates and on the achievement of sufficient revenues to support its cost structure. The Company may never achieve profitability, and unless and until it does, the Company will need to continue to raise additional capital.

Management believes that the currently available resources will be sufficient to fund its operations for at least the next 12 months following the issuance date of these consolidated financial statements. However, if the Company's anticipated operating results are not achieved in future periods, the Company believes that planned expenditures may need to be reduced or it would be required to raise funding in order to fund the operations. Additionally, the Company's ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The consolidated financial statements include the accounts of Eiger BioPharmaceuticals, Inc. and its wholly owned subsidiaries, EBPI Merger Inc., EB Pharma LLC, Eiger BioPharmaceuticals Europe Limited, and EigerBio Europe Limited, have been prepared in accordance with accounting principles generally accepted in the United States of America, (U.S. GAAP) and following the requirements of the Securities and Exchange Commission (the SEC) for annual reporting. 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, operating lease liabilities 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.

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 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 income (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 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, 2020, 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 expenses 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.

Leases

The Company adopted Accounting Standards Codification ("ASC") Topic 842, "Leases" ("ASC 842") on January 1, 2019. Under ASC 842, the Company determines if an arrangement is or contains a lease at inception. Material leases with a term greater than one year are recognized in right-of-use ("ROU") assets and current and noncurrent lease liabilities, as applicable, in the Company's consolidated balance sheets.

The Company has a real estate lease for its office space in Palo Alto, California. The Company determines the initial classification and measurement of its right-of-use assets (ROU assets) and lease liabilities at the lease commencement date and thereafter if modified. The lease term includes any renewal options and termination options that the Company is reasonably assured to exercise. The present value of lease payments is determined by using the interest rate implicit in the lease, if that rate is readily determinable; otherwise, the Company uses its incremental borrowing rate. The incremental borrowing rate is determined by using the rate of interest that the Company would pay to borrow on a collateralized basis an amount equal to the lease payments for a similar term and in a similar economic environment.

Rent expense for operating leases is recognized on a straight-line basis, unless the operating lease ROU assets have been impaired, over the reasonably assured lease term based on the total lease payments and is included in operating expenses in the consolidated statements of operations. For operating leases that reflect impairment, the Company will recognize the amortization of the operating lease ROU assets on a straight-line basis over the remaining lease term with rent expense still included in general and administrative expenses in the consolidated statements of operations.

The Company has elected the practical expedient to not separate lease and non-lease components. The Company's non-lease components are primarily related to property maintenance and insurance, which varies based on future outcomes, and thus is recognized in general and administrative expenses when incurred.

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 and manufacturing activities on the Company's behalf. Amounts incurred in connection with license and asset purchase agreements are also included in research and development expenses. Manufacturing costs related to products undergoing regulatory approval are expensed as research and development costs until receipt of such approval.

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). Stock-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 for Black-Scholes option pricing model inputs. The Company accounts for forfeitures of stock-based awards when they occur.

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 experiences 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,		
	2020	2019	2018
Options to purchase common stock	3,697,075	2,767,617	1,996,211
Restricted stock units (unvested)	37,500	—	—
Total	3,734,575	2,767,617	1,996,211

Recently Adopted Accounting Pronouncements

In August 2018, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (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 adopted this guidance on January 1, 2020. The adoption did not have a material impact on the Company's consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-15, *Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That is a Service Contract (Subtopic 350-40)*. The standard adds certain disclosure requirements related to implementation costs incurred for internal-use software and cloud computing arrangements. The standard aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). The pronouncement is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years, with early adoption permitted. The amendments in ASU No, 2018-15 should be applied either using a retrospective or prospective approach. The Company adopted this guidance on January 1, 2020 using the prospective approach. The adoption did not have a material impact on the Company's consolidated financial statements.

Accounting Pronouncements Not Yet Adopted

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. In April 2019, the FASB issued ASU No. 2019-04, *Codification Improvements to Topic 326, Financial Instruments – Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments*, which clarifies and corrects certain unintended applications of the guidance contained in each of the amended Topics. Additionally, in May 2019, the FASB issued ASU No. 2019-05, *Financial Instruments – Credit Losses (Topic 326)*, which provides an option to irrevocably elect to measure certain individual financial assets at fair value instead of amortized cost. In November 2019, the FASB issued ASU No. 2019-10, *Financial Instruments – Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842)*, which defers the effective date for ASU No. 2016-13 for smaller reporting companies to fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company is evaluating the impact of the guidance on its consolidated financial statements.

In March 2020, the FASB issued ASU No. 2020-04, *Reference Rate Reform (Topic 848)*. The standard provides optional expedients for facilitating the effects of the reference rate reform on financial reporting. For the Company, there are two applicable optional expedients for contract modifications permitted for contracts that are modified because of the reference rate reform and meet the scope guidance. The modifications of contracts within the scope of ASC Topic 470 should be accounted for prospectively adjusting the effective interest rate. The modifications of contracts within the scope of ASC Topic 842 should be accounted for as a continuation of the existing contracts with no reassessments of the lease classification and the discount rate or remeasurements of lease payments that otherwise would be required under ASC Topic 842 for modifications not accounted for as separate contracts. The pronouncement is effective for all entities as of March 12, 2020 through December 31, 2022. The Company plans to adopt upon the occurrence of such contract modification, but not later than December 31, 2022. The Company engaged in early-stage discussions with its lender and will assess the impact of the adoption once the contract is modified.

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, 2020 and 2019, 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 its long term debt reflect current market conditions for an instrument with similar terms and maturity, therefore the carrying value of the Company's debt approximated its fair value.

Assets and liabilities recorded at fair value on a recurring basis in the consolidated balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined

as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

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

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

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

The Company's money market funds are classified as Level 1 because they are valued using quoted market prices. The Company's 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, 2020 and 2019.

There were no transfers in or out of 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, 2020			
	Level 1	Level 2	Level 3	Total
Financial Assets:				
Money market funds	$ 20,846	$ —	$ —	$ 20,846
Corporate debt securities	—	33,941	—	33,941
Commercial paper	—	21,980	—	21,980
U.S. treasury bills	—	39,995	—	39,995
U.S. government bonds	—	4,060	—	4,060
Total	$ 20,846	$ 99,976	$ —	$ 120,822

	December 31, 2019			
	Level 1	Level 2	Level 3	Total
Financial Assets:				
Money market funds	$ 35,854	$ —	$ —	$ 35,854
Corporate debt securities	—	16,644	—	16,644
Commercial paper	—	7,457	—	7,457
U.S. government bonds	—	31,520	—	31,520
Total	$ 35,854	$ 55,621	$ —	$ 91,475

There were no financial liabilities as of December 31, 2020 and 2019.

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, 2020			
	Amortized cost	Unrealized gain	Unrealized loss	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 20,846	$ —	$ —	$ 20,846
Total cash equivalents	$ 20,846	$ —	$ —	$ 20,846
Debt securities:				
Corporate debt securities	$ 33,952	$ 1	$ (12)	$ 33,941
Commercial paper	21,980	—	—	21,980
U.S. treasury bills	39,992	3	—	39,995
U.S. government bonds	4,060	—	—	4,060
Total debt securities	$ 99,984	$ 4	$ (12)	$ 99,976

	December 31, 2019			
	Amortized cost	Unrealized gain	Unrealized loss	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 35,854	$ —	$ —	$ 35,854
Total cash equivalents	$ 35,854	$ —	$ —	$ 35,854
Debt securities:				
Corporate debt securities	$ 16,633	$ 11	$ —	$ 16,644
Commercial paper	7,457	—	—	7,457
U.S. government bonds	31,489	31	—	31,520
Total debt securities	$ 55,579	$ 42	$ —	$ 55,621

As of December 31, 2020 and 2019, 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, 2020, 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 12 months.

4. Balance Sheet Components

Property and Equipment, Net

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

	December 31,	
	2020	2019
Computer equipment and software	$ 520	$ 160
Furniture	111	111
Leasehold improvements	80	61
Lab equipment	271	36
Construction in progress	69	436
Total property and equipment	1,051	804
Less: accumulated depreciation	(342)	(214)
Property and equipment, net	$ 709	$ 590

Depreciation expense for the years ended December 31, 2020, 2019 and 2018 was approximately $167,000, $68,000 and $54,000, respectively.

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	December 31,	
	2020	2019
Prepaid contract manufacturing costs	$ 6,126	$ 1,374
Prepaid research costs	1,177	1,627
Prepaid insurance	448	421
Other	1,215	1,968
Total prepaid expenses and other current assets	$ 8,966	$ 5,390

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2020	2019
Contract research costs	$ 6,062	$ 5,288
Contract manufacturing costs	1,167	2,510
Compensation and related benefits	3,169	1,707
Other	1,007	496
Total accrued liabilities	$ 11,405	$ 10,001

5. License, Collaboration, and Product Development Agreements

License Agreement with the Trustees of the University of Pennsylvania and the Children's Hospital of Philadelphia

In May 2019, the Company entered into a license agreement (the UPenn/CHOP Agreement) with the Trustees of the University of Pennsylvania (UPenn) and the Children's Hospital of Philadelphia (CHOP), under which the Company obtained an exclusive, royalty-bearing, worldwide license to develop, manufacture and sell certain Glucagon Like Peptide-1 (GLP-1) receptor antagonist(s) products to treat all human and animal conditions. The Company also obtained an exclusive, royalty-bearing, sublicenseable, worldwide license to certain data developed by CHOP. The Company is responsible for the development and commercialization of the licensed products at its sole cost and expense.

As part of the consideration for the rights granted to the Company under the UPenn/CHOP Agreement, the Company paid UPenn a one-time, non-refundable issue fee of $1.0 million, which is recorded in research and development expenses for the year ended December 31, 2019. In addition, the Company is obligated to pay UPenn a specified annual license maintenance fee, up to $2.5 million in certain regulatory milestones, and up to $18.0 million in commercial milestones. The Company will also be required to pay UPenn a flat royalty in the low-single digits on net sales of all licensed products by the Company, subject to specified reductions and offsets, and specified minimum annual royalty payments. The Company's obligation to pay royalties expires on a product-by-product and country-by-country basis, on the later of: (i) the expiration of the last valid claim in the licensed patents in any country, or (ii) the tenth anniversary of the first commercial sale of the product in such country. No milestones have been achieved as of December 31, 2020.

The Company may terminate the UPenn/CHOP Agreement in its entirety for any reason by providing prior written notice to UPenn and CHOP. UPenn or CHOP may terminate the UPenn/CHOP Agreement, upon a written notice, for the Company's failure to achieve the specified diligence milestones within the specified periods, subject to the Company's extension rights.

Product Development Agreement

On August 11, 2018, the Company entered into a Product Development Agreement and a First Project Agreement (the Product Agreements) with RDD International, LLC., 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 new drug application (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. For the years ended December 31, 2020, 2019 and 2018, the Company recognized research and development expense of $0.2 million, $0.2 million and $0.4 million, respectively, related to vesting of the shares issued under the Product Agreements. Additionally, as of December 31, 2020, the total unrecognized compensation expense related to unvested restricted shares was $0.2 million, which the Company expects to recognize over an estimated weighted-average period of 1.3 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 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 (EAP) 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 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 Company paid BMS $2.0 million and issued 157,587 shares of its common stock at an aggregate fair value of $3.2 million in April 2016. The BMS License Agreement also 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 fourth quarter 2020, the Company recorded in research and development expense a $3.0 million milestone, triggered on successful demonstration of proof of concept, as defined by the BMS License Agreement, in a Phase 2 clinical trial. The next milestone is $5.0 million triggered on the initiation of a Phase 3 clinical trial.

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 part of consideration, the Company issued 27,350 shares of common stock with a fair value of $0.5 million. 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. 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, 2020.

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. On November 3, 2020, the Company entered into an amendment to the exclusive license agreement with Merck which expanded the definition of progeria to also include progeroid laminopathies. The Company has the sole responsibility and the continuing obligation for the manufacture and supply of lonafarnib to the 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.

6. 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, 2020, 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 with the option 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 the Sellers 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 stock-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, 2020, 2019 and 2018, the Company recognized $0.1 million, $0.1 million and $0.1 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, 2020, 2019 and 2018.

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, 2020, the Company has paid a total of $0.1 million in milestone payments to each of the Sellers related to the successful completion of the Phase 2 trials.

Asset Purchase Agreement with AbbVie Inc.

On November 20, 2020, the Company entered into an asset purchase agreement (AbbVie APA) with AbbVie Inc. (AbbVie) to sell its Rare Pediatric Disease Priority Review Voucher, which was awarded the PRV on November 20, 2020 upon approval by the FDA of the NDA for Zokinvy in Hutchinson-Gilford Progeria Syndrome and processing-deficient Progeroid Laminopathies (the PRV) to AbbVie. The AbbVie Agreement contains customary representations, warranties, covenants, and indemnification provisions subject to certain limitations.

In consideration for the PRV, AbbVie agreed to pay the Company $95.0 million. The transaction closed in January 2021. Such consideration was shared equally with The Progeria Research Foundation ("PRF") in accordance with the terms of the PRF Collaboration Agreement, pursuant to which the Company and PRF will equally share any proceeds from the sale of a priority review voucher that the Company may receive as the sponsor of a rare pediatric disease product application. The Company retained approximately $47.4 million of the proceeds from the sale of the PRV.

7. Debt

In December 2016, the Company entered into an aggregate $25.0 million loan with Oxford Finance LLC (the Oxford Loan). The Company borrowed $15.0 million in December 2016 (Tranche A). In May 2018, the Company entered into an amendment to the Oxford Loan and borrowed $5.0 million (Tranche B). On August 3, 2018, the Company borrowed the remaining $5.0 million (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 interest only period for borrowed funds is 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 borrowed funds, or $1.9 million. In addition, at the time of final payment of 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.

On March 5, 2019, the Company entered into the third amendment to the Oxford Loan (the Amended Oxford Loan) to refinance the Oxford Loan. The Amended Oxford Loan increased the aggregate amount available to be borrowed to $35.0 million and extended the maturity date to March 1, 2024. On March 5, 2019, prior to entering into the Amended Oxford Loan, the outstanding balance of the Oxford Loan was $23.3 million. At the time of entering into the Amended Oxford Loan, the Company borrowed an additional $6.7 million in principal under the Amended Oxford Loan, which increased the total amount borrowed to $30.0 million (Amended Tranche A). The remaining $5.0 million (Amended Tranche B) is available to the Company provided that certain milestones are achieved by February 2021. The Company does not currently expect to draw down Amended Tranche B.

The Amended 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 6.64% or 9.15%. The Amended Oxford Loan has an interest only period until April 1, 2021, followed by 36 equal monthly payments of principal and interest. Upon the receipt of Amended Tranche B, the interest only period for borrowed funds will be extended by one year until April 1, 2022, followed by 24 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 borrowed funds, or $2.3 million. In addition, the Company is required to pay an additional exit fee of $1.0 million. The Company recorded as a liability and debt discount the exit fee for the Amended Oxford Loan. At the date of the Amended Oxford Loan, the Company paid $0.9 million for the accrued portion of the Oxford Loan exit fee and the Tranche B additional exit fee. The loan discount balance at the time of the Amended Oxford Loan was $0.2 million, which is being amortized over the remaining term of the Amended Oxford Loan.

The Company is also required to pay a 5.0% success fee of the total amount drawn under the Amended Oxford Loan within 30 days following the FDA’s approval of the Company’s first product, excluding lonafarnib in Progeria and Progeroid Laminopathies. This fee is enforceable within 10 years from the funding of Amended Tranche A. The Company determined that the success fee met the scope exemption from derivative accounting and should be accounted for under the guidance for contingencies. Accordingly, the Company will record a liability for the success fee upon receipt of approval from the FDA. The Amended Oxford Loan includes contingent interest features and mandatory prepayment features upon an event of default that meet the definition of a derivative but were not bifurcated from the debt instrument as their fair value was deemed to be insignificant. In connection with the execution of the Oxford Loan, the Company agreed to certain customary representations and warranties.

The refinancing of the term loan did not have a material impact on terms, conditions, representations, warranties, covenants or agreements set forth in the Oxford Loan. 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 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, restrict access to additional borrowings under the loan and security agreement, and accelerate the maturity of the debt. As of December 31, 2020, the Company was in compliance with all covenants.

The Company is permitted to make voluntary prepayments of the Amended Oxford Loan with a prepayment fee, calculated as of the loan origination date, equal to (i) 2.0% of the loan prepaid during the first 12 months and (ii) 1.0% of the loan prepaid in months 13-24. 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. Long-term debt and unamortized discount balances are as follows (in thousands):

	December 31,	
	2020	2019
Face value of long term debt	$ 30,000	$ 30,000
Exit fee	3,277	3,277
Unamortized debt discount associated with exit fee, debt issuance costs and loan origination fees	(2,083)	(2,887)
Total long term debt, net	$ 31,194	$ 30,390

As of December 31, 2020, future minimum payments of principal, exit fee and interest expense under the Oxford Loan were as follows (in thousands):

Year ending December 31,	
2021	10,051
2022	11,662
2023	10,734
2024	5,816
Total future payments	38,263
Less: unamortized interest	(4,986)
Less: exit fee	(2,083)
Face value of term loan	$ 31,194

On February 23, 2021, the Company entered into the fifth amendment to the Oxford Loan (Note 14). As the Company refinanced the short-term portion of the Oxford Loan on a long-term basis prior to the issuance of the financial statements, the current portion of long-term debt as of December 31, 2020 was reclassified as long-term at the balance sheet date.

8. 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, 2020, no dividends had been declared by the Board of Directors.

On April 17, 2019, the Company completed an underwritten public offering of 5,175,000 shares of its common stock, including 675,000 shares sold upon full exercise of the underwriters' option to purchase additional shares of common stock, at a price of $11.00 per share. The offering was made under the Company's effective shelf registration statement and resulted in net proceeds to the Company of $53.2 million, after deducting underwriting discounts and commissions and offering expenses.

In December 2019, the Company filed a shelf registration statement on Form S-3 (File No. 333-235655) with the Securities and Exchange Commission, which permits the offering, issuance and sale of up to a maximum aggregate offering price of $150.0 million of the company's common stock, preferred stock, debt securities and warrants. Up to a maximum of $50.0 million of the maximum aggregate offering price of $150.0 million may be issued and sold pursuant to an at-the-market (ATM) financing facility (2019 ATM Facility) under a sales agreement with Jefferies LLC (Jefferies). In August 2020, the Company entered into a new sales agreement with Jefferies for up to $50.0 million of the remaining amount on the shelf registration statement which may be sold pursuant to an ATM financing facility (2020 ATM Facility).

As of December 31, 2020, the Company has completed both the 2019 ATM Facility and the 2020 ATM Facility for a total of 9,267,760 shares resulting in $97.3 million in net proceeds, after deducting commissions.

In December 2020, the Company filed a new shelf registration statement on Form S-3 (File No. 333-251497) with the Securities and Exchange Commission, which permits the offering, issuance and sale by the Company up to a maximum aggregate offering price of $200.0 million of our common stock, preferred stock, debt securities and warrants. Up to a maximum of $50.0 million of the maximum aggregate offering price of $200.0 million may be issued and sold pursuant to a new ATM financing facility under a sales agreement with Jefferies.

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

	December 31,	
	2020	2019
Options issued and outstanding	3,697,075	2,767,617
Options available for future grants	1,021,109	823,598
Total	4,718,184	3,591,215

9. Equity Incentive Plans

Restated 2013 Equity Incentive Plan

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). 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. Under the terms of the Restated 2013 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 Rested 2013 Plan may not exceed ten years. The vesting schedule of newly issued option grants is generally four years. As of December 31, 2020, the Company is authorized to issue up to 4,705,442 shares under the Restated 2013 Plan.

The following table summarizes stock option activity under both the Company's stock-based compensation plans during the year ended December 31, 2020 (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, 2019	823,598	2,767,617	$ 12.14	7.94	$ 8,218
Additional options authorized	1,226,169	—			
Granted	(1,149,750)	1,149,750	$ 7.43		
Restricted stock units granted	(37,500)	—			
Exercised	—	(61,700)	$ 8.41		
Forfeited or cancelled	158,592	(158,592)	$ 10.27		
Outstanding as of December 31, 2020	1,021,109	3,697,075	$ 10.81	7.55	$ 9,048
Vested and exercisable as of December 31, 2020		2,041,834	$ 11.57	6.71	$ 4,125

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 $12.29 as of December 31, 2020.

The aggregate intrinsic value of stock options exercised in 2020, 2019 and 2018 was $0.3 million, $0.6 million and $0.2 million, respectively.

During the years ended December 31, 2020, 2019 and 2018, the weighted-average grant date fair value of options granted was $4.78, $8.98 and $7.50 per share, respectively. The total grant date fair value of options that vested during the years ended December 31, 2020, 2019 and 2018 was $5.6 million, $5.7 million and $4.7 million, respectively.

The Company records stock-based compensation on stock options 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,		
	2020	2019	2018
Expected term (in years)	5.00 - 6.08	5.27 - 6.08	5.27 - 6.08
Contractual term (in years)	10.00	10.00	9.67 - 9.84
Volatility	73.00% - 77.00%	73.14% - 83.19%	84.00% - 95.00%
Risk free interest rate	0.39% - 1.37%	1.42% - 2.57%	1.67% - 2.68%
Dividend yield	—	—	—

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). The Company uses the contractual term to determine the non-employee award fair value at the grant date. The contractual term of options granted under the Restated 2013 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. Beginning in the third quarter of 2019, as the Company had been publicly traded for four and a half years, the Company began to layer in its historical volatility in the calculation of expected volatility.

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.

2013 Employee Stock Purchase Plan

In 2013, the Company's board of directors adopted and in 2016, upon the merger with Celladon, the Company amended and approved the 2013 Employee Stock Purchase Plan (2013 ESPP). The 2013 ESPP is intended to qualify as an employee stock purchase plan under Section 423 of the U.S. Internal Revenue Code and is administered by the Company's board of directors.

The number of shares of common stock initially reserved for issuance under the 2013 ESPP was 100,000 shares with an automatic annual increase to the shares issuable under the 2013 ESPP to the lower of (i) 1% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, and (ii) 165,000 shares of common stock, unless a lower number determined by the board of directors. As of December 31, 2020, a total of 618,831 shares are reserved for issuance and 543,791 shares available for future issuance under the 2013 ESPP. During the years ended December 31, 2020 and December 31, 2019, employees purchased 25,645 shares for $0.2 million and 15,701 shares for $0.1 million, respectively, under the 2013 ESPP.

Restricted Stock Units

In the first quarter of 2020, the Company revised its non-employee director compensation policy to approve the granting of restricted stock units (RSUs) in accordance with the Restated 2013 Equity Incentive Plan (the Restated 2013 Plan). Each eligible director who has served for less than six months during the prior calendar year and continues to serve as a non-employee member of the board is granted RSUs, which are pro-rated for the period served during the prior calendar year.

The RSUs granted to non-employee directors will vest on the one-year anniversary of the grant date, subject to the eligible director's continuous services through the vesting date, and will vest in full upon a change in control, as defined under the Restated 2013 Plan. RSUs granted to employees during the year ended December 31, 2020, commence vesting on the one-year anniversary through the two-year anniversary of the grant date. The fair value of all RSUs is measured at the grant date based on the closing market price of the Company's common stock and is recognized as stock-based compensation expense on a straight-line basis over the vesting period.

During the year ended December 31, 2020, the Company granted 37,500 RSUs with a weighted-average grant date fair value of $6.95 per share. The Company recognized $0.2 million in stock-based compensation expense for the year ended December 31, 2020, which is included in general and administrative expenses. As of December 31, 2020, the total unrecognized compensation expense related to unvested RSUs was $0.1 million, which the Company expects to recognize over an estimated weighted-average period of 0.4 years.

Stock-Based Compensation Expense

Total stock-based compensation expense recognized was as follows (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Research and development	$ 1,494	$ 1,550	$ 1,500
General and administrative	4,479	4,129	3,507
Total stock-based compensation expense	$ 5,973	$ 5,679	$ 5,007

As of December 31, 2020, the total unrecognized compensation expense related to unvested options was $10.2 million, which the Company expects to recognize over an estimated weighted average period of 2.5 years.

10. Income Taxes

No provision for income taxes was recorded for the years ended December 31, 2020, 2019 and 2018. The Company has incurred net operating losses (NOL) for all the periods presented. The Company has not reflected any benefit of such NOL 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,		
	2020	2019	2018
Federal statutory income tax rate	21.00%	21.00%	21.00%
Change in valuation allowance	(26.75)	(27.42)	(26.02)
Tax credits	6.43	7.27	5.52
State income taxes, net of federal benefit	0.33	0.25	0.27
Stock-based compensation	(1.00)	(0.89)	(0.77)
Other, net	(0.01)	(0.21)	—
Provision (benefit) for income taxes	—%	—%	—%

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

	December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 54,523	$ 42,761
Tax credits	1,068	7,157
Depreciation and amortization	2,067	1,602
Stock-based compensation	2,452	1,912
Accruals and reserves	606	319
Lease liabilities	278	389
Gross deferred tax assets	60,994	54,140
Valuation allowance	(60,747)	(53,793)
Total deferred tax assets	247	347
Deferred tax liabilities:		
Right-of-use assets	(247)	(347)
Total deferred tax liabilities	(247)	(347)
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, 2020 and 2019. The net change in the valuation allowance for the years ended December 31, 2020 and 2019 increased by $7.0 million and $7.6 million, respectively.

As of December 31, 2020, the Company had approximately $251.7 million and $25.2 million, respectively, of federal and state NOL carryforwards available to reduce future taxable income that will begin to expire in 2030 and 2028, respectively, for federal and state tax purposes.

As of December 31, 2020, the Company also had research and development tax credit carryforwards of $1.8 million for state purposes, available to offset future taxable income tax. If not utilized, the state credits can be carried forward indefinitely.

The Company's ability to utilize NOL carryforwards or other tax attributes, such as research tax credits, in any taxable year may be limited if the Company has experienced an ownership change under Section 382 of the Internal Revenue Code (the Code) of 1986, as amended. The Company's merger with Celladon 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. The Company assessed whether it had an ownership change, as defined by Section 382 of the Code from its formation through December 31, 2020. Based upon this assessment, the Company experienced ownership changes on April 20, 2016, October 18, 2018 and December 31, 2020. Due to these ownership changes, reductions were made to the Company's NOL and tax credit carryforwards under these rules. Additional ownership changes in the future could result in additional limitations on the Company's NOL and tax credit carryforwards.

Tax benefits from uncertain tax positions are recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits. The amount recognized is measured as the largest amount of tax benefit that is greater than 50 percent likely of being realized upon effective settlement.

Uncertain Tax Positions

A reconciliation of the Company's unrecognized tax benefits for the years ended December 31, 2020, 2019 and 2018 is as follows (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Balance at beginning of year	$ 3,277	$ 4,634	$ 3,218
Additions based on tax positions related to prior year	—	—	(61)
Additions based on tax positions related to current year	81	2,443	1,477
Reductions based on tax positions related to prior year	(2,907)	(3,800)	—
Reductions based on tax positions related to current year	—	—	—
Balance at end of year	$ 451	$ 3,277	$ 4,634

If the $0.5 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. As of December 31, 2020, 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 consolidated statements 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, 2020, 2019 and 2018.

11. Legal Matters

From time to time in the ordinary course of business the Company becomes involved in various lawsuits, claims and proceedings, including those pertaining to the defense and enforcement of the Company's patent or other intellectual property rights and contractual rights. These proceedings are costly and time consuming. Additionally, successful challenges to the Company's patent or other intellectual property rights through these proceedings could result in a loss of rights in the relevant jurisdiction and may allow third parties to use the Company's proprietary technologies without a license from the Company or its collaborators. The outcome of such matters, which the Company believes, after consultation with legal counsel, will not have a material adverse effect on its financial condition, results of operations or liquidity. However, due to the risks and uncertainties inherent in legal proceedings, actual results could differ from current expected results. All legal costs associated with litigation are expensed as incurred.

12. Commitments and Contingencies

Lease Agreement

In October 2017, the Company entered into a non-cancelable operating 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 in February 2023. The lease has a three-year renewal option prior to expiration; however, the Company is not reasonably assured to exercise this option. The lease includes rent escalation clauses throughout the lease term. In October 2017, the Company provided a security deposit of $0.3 million. The Company also has additional operating leases that are included in its lease accounting but are not considered significant for disclosure.

The maturity of the Company's operating lease liabilities as of December 31, 2020 were as follows (in thousands):

Undiscounted lease payments	December 31, 2020
2021	$ 673
2022	662
2023	113
2024	1
Total undiscounted payments	1,449
Less: imputed interest	(129)
Present value of future lease payments	1,320
Less: current portion of operating lease liabilities	(582)
Operating lease liabilities	$ 738

Rent expense recognized for the Company's operating leases was $0.6 million, $0.6 million, and $0.8 million for the years ended December 31, 2020, 2019, and 2018, respectively. Under the terms of the lease agreements, the Company is also responsible for certain variable lease payments that are not included in the measurement of the lease liability. Variable lease payments for the operating leases were $0.1 million for each of the years ended December 31, 2020 and 2019.

The operating cash outflows for the operating lease liabilities were $0.7 million and $0.6 million for the year ended December 31, 2020 and 2019, respectively. As of December 31, 2020, the weighted-average remaining lease term and weighted-average discount rate were 2.1 years and 9.15%, 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. However, the amount and timing of these payments are not known.

Manufacturing Service Agreement

In the first quarter of 2020, the Company entered into a Master Manufacturing Services Agreement (MMSA) and Product Agreement with Patheon, Inc. (Patheon) for the manufacturing of lonafarnib capsules and packaging of bottles for commercial sale. Under the terms of the agreements, the Company is required to provide Patheon with annual volume forecasts of capsules and Patheon will manufacture 80% of such annual forecasts. If the Company order less than 80% of such annual forecasts, it is required to pay 70% of purchase price for the shortfall. The initial terms of the MMSA and Product Agreement end on December 31, 2025 with automatic renewal for successive two-year terms, unless earlier terminated pursuant to the terms of each agreement, or upon either party's notice of termination to the other.

13. Related Party Transactions

As disclosed in Note 6, the Company entered into license agreements with EGI, which is owned by the founder of the Company.

14. Subsequent Events

On February 23, 2021, the Company entered into the fifth amendment to the Oxford Loan. The amendment extended the interest only period by 17 months until September 1, 2022, followed by 19 equal monthly payments of principal and interest. Upon the receipt of Amended Tranche B, the interest only period for borrowed funds will be extended by six months until March 1, 2023, followed by 13 equal monthly payments of principal plus accrued interest. In addition, the Company paid the amendment fees of $0.2 million to the lenders on the effective date of the fifth amendment.

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

None

ITEM 9A. Controls and Procedures

(a) 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, 2020, the end of the period covered by this report.

(b) 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, not absolute 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.

There are inherent limitations to the effectiveness of any system of internal control over financial reporting. These limitations include the possibility of human error, the circumvention or overriding of the system and reasonable resource constraints. Because of its inherent limitations, our internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

As of December 31, 2020, 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, 2020, our internal control over financial reporting was effective based on those criteria.

(c) 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 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, 2020, 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 2021 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2020.

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 2021 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2020.

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 2021 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2020.

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 2021 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2020.

ITEM 14. Principal Accountant 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 2021 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2020.

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).
4.3	Description of Registrant's Securities (incorporated by reference to Exhibit 4.3 to the Annual Report on Form 10-K (File No. 001-36183), filed with the SEC on March 13, 2020).
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* **	Asset Purchase Agreement, dated September 25, 2015, by and between Eiger BioPharmaceuticals, Inc. and Tracey McLaughlin and Colleen Craig.
10.10* **	License Agreement, dated September 3, 2010, by and between Eiger BioPharmaceuticals, Inc. and Merck Corporation.
10.11	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).
10.12* **	License Agreement, dated as of April 20, 2016, by and between Eiger BioPharmaceuticals, Inc. and Bristol-Myers Squibb Company.
10.13	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).
10.14	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).
10.15	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).
10.16	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).
10.17* **	Amendment No. 6 to License Agreement, dated September 3, 2010, by and between Eiger BioPharmaceuticals, Inc. and Merck Sharp & Dohme Corp.
10.18* **	Collaboration and Supply Agreement, dated May 15, 2018, by and between Eiger BioPharmaceuticals, Inc. and The Progeria Research Foundation.

Exhibit Number	Description of Document
10.19	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).
10.20	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).
10.21	First Amendment to Loan and Security Agreement, dated August 24, 2017, by and between Eiger BioPharmaceuticals, Inc. and Oxford Finance LLC (incorporated by reference to Exhibit 10.38 to the Annual report on Form 10-K (File No. 001-36183) with the SEC on March 14, 2019).
10.22+	Amended and Restated Offer Letter Agreement, dated as of November 1, 2019, by and between Eiger BioPharmaceuticals, Inc. and David A. Cory (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 7, 2019).
10.23+	Amended and Restated Offer Letter Agreement, dated as of November 1, 2019, by and between Eiger BioPharmaceuticals, Inc. and Sriram Ryali (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 7, 2019).
10.24+	Amended and Restated Offer Letter Agreement, dated as of November 1, 2019, by and between Eiger BioPharmaceuticals, Inc. and Stephana E. Patton (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 7, 2019).
10.25+	Amended and Restated Offer Letter Agreement, dated as of November 1, 2019, by and between Eiger BioPharmaceuticals, Inc. and James Shaffer (incorporated by reference to Exhibit 10.4 to the Quarterly report on Form 10-Q (File No. 001-36183) filed with the SEC on November 7, 2019).
10.26*	License Agreement, dated as of May 10, 2019, by and among the Trustees of the University of Pennsylvania and The Children's Hospital of Philadelphia and Eiger BioPharmaceuticals, Inc (incorporated by reference to Exhibit 10.5 to the Quarterly report on Form 10-Q (File No. 001-36183) filed with the SEC on November 7, 2019).
10.27*	Third Amendment to Loan and Security Agreement, dated March 5, 2019, by and between Eiger BioPharmaceuticals, Inc. and Oxford Finance 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 May 9, 2019).
10.28+	Offer Letter Agreement, by and between Eiger BioPharmaceuticals, Inc. and Eldon Mayer, dated as of December 3, 2019 (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 7, 2020).
10.29+	Eiger BioPharmaceuticals, Inc. Non-Employee Director Compensation Policy, as amended. (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 7, 2020).
10.30*	Amendment No. 1, dated June 15, 2020, to the Collaboration and Supply Agreement, dated May 15, 2018, by and between Eiger BioPharmaceuticals, Inc. and the Progeria Research Foundation. (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q (File No. 001-36183) filed with the SEC on August 6, 2020).
10.31 **	Asset Purchase Agreement, by and between Eiger BioPharmaceuticals, Inc. and AbbVie Inc., dated as of November 20, 2020.
10.32 **	Amendment No. 7 to License Agreement, dated November 3, 2020, by and between Eiger BioPharmaceuticals, Inc. and Merck Sharp & Dohme Corp.

Exhibit Number	Description of Document
10.33 **	Amendment No. 5 to Loan and Security Agreement, dated February 23, 2021, 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**	Inline XBRL Instance Document- the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH**	Inline XBRL Taxonomy Extension Schema Document
101.CAL**	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF**	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB**	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	The cover page from the Company's Annual Report on Form 10-K for the year ended December 31, 2020, has been formatted in Inline XBRL.

+ 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.
* Portions of this exhibit have been omitted as being immaterial and would be competitively harmful if publicly disclosed.
** Filed herewith.

ITEM 16. Form 10-K Summary

None.

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: March 9, 2021

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

Eiger BioPharmaceuticals, Inc.

Date: March 9, 2021

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)*	March 9, 2021
/s/ Sriram Ryali Sriram Ryali	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 9, 2021
/s/ Thomas J. Dietz Thomas J. Dietz	Chairman of the Board of Directors	March 9, 2021
/s/ David Apelian David Apelian	Member of the Board of Directors	March 9, 2021
/s/ Evan Loh Evan Loh	Member of the Board of Directors	March 9, 2021
/s/ Jeffrey Glenn Jeffrey Glenn	Member of the Board of Directors	March 9, 2021
/s/ Christine Murray Christine Murray	Member of the Board of Directors	March 9, 2021
/s/ Amit K. Sachdev Amit K. Sachdev	Member of the Board of Directors	March 9, 2021

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

Exhibit 10.9

ASSET PURCHASE AGREEMENT

among:

EIGER BIOPHARMACEUTICALS, INC.,
a Delaware corporation;

and

TRACEY MCLAUGHLIN AND COLLEEN CRAIG

Dated as of September 25, 2015

ASSET PURCHASE AGREEMENT

THIS ASSET PURCHASE AGREEMENT is entered into, effective as of September 25, 2015 (the "***Effective Date***"), by and between EIGER BIOPHARMACEUTICALS, INC., a Delaware corporation ("***Purchaser***") and TRACEY MCLAUGHLIN AND COLLEEN CRAIG (each individually, "***Seller***", collectively, "***Sellers***"). Purchaser and Sellers are referred to herein collectively as the "***Parties***" and individually as a "***Party.***" Certain other capitalized terms used in this Agreement are defined in Exhibit A.

RECITALS

A. Purchaser and Sellers wish to provide for the sale by Sellers to Purchaser of the Designated Assets (as defined in Section 1.1) by Purchaser on the terms and subject to the conditions set forth in this Agreement.

B. In connection with the sale of the Designated Assets, Purchaser is entering into a Consulting Agreement with each Seller in substantially the form attached hereto as Exhibit B (the "***Consulting Agreement***").

C. This Agreement has received the requisite approvals by Purchaser and Sellers.

AGREEMENT

The Parties, intending to be legally bound, agree as follows:

SECTION 1. SALE OF DESIGNATED ASSETS; RELATED TRANSACTIONS.

1.1 Sale of Designated Assets. Each Seller hereby sells, assigns, transfers, conveys and delivers to Purchaser the entirety of their right, title and interest (if any) in and to the Designated Assets on the terms and subject to the conditions set forth in this Agreement. The "***Designated Assets***" shall mean the following assets (to the extent not previously or otherwise required to be assigned by Sellers to the Leland Stanford Junior University ("***Stanford***") under their existing employment agreements):

(a) All rights and interests in and to Patents, copyrights, trademarks, trade secrets, know-how, and documentation and related applications related to extending, including provisional patent application Docket No.: [*] filed by Sellers [*] (the "***HH Patents***"), if and to the extent any of the foregoing is the intellectual property of Sellers and not subject to a contractual obligation on the part of Sellers to assign the same to Stanford or not otherwise assigned and subject to the License Agreement (as defined below);

(b) All techniques, technology, trade secrets, inventions (whether patentable or not), methods, know-how, data and results (including pharmacological, toxicological and clinical data and results), analytical and quality control data and results, regulatory documents including investigational new drug applications (INDs) (other than the current IND designated as [*] involving [*]), and correspondence, as well as other information related to exendin and its uses in the possession of Sellers, if and to the extent any of the foregoing is the intellectual property of Sellers and not subject to a contractual obligation on the part of Sellers to assign the same to Stanford; and

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(c) The License Agreement between Stanford and Sellers dated May 4, 2015 (the "***License Agreement***"), pursuant to which Stanford granted to Sellers an exclusive, worldwide license to use, make, have made, market and sell products in all fields of use based upon, used or made in accordance with that certain invention described in Stanford Docket §12- 372, including as further described in the HH Patents, involving the use of exendin (the "***Invention***"). The License Agreement provides for making a product based on the Invention and any modifications, improvements or variations thereof (the "***Product***") "***available for public use and benefit***" and Purchaser acknowledges those obligations thereunder.

1.2 Purchase Price. The purchase price for the Designated Assets shall be (the "***Purchase Price***"):

(a) Within [*] of the Effective Date, the Purchaser shall issue to each of the Sellers: (i) shares of Common Stock of the Company pursuant to a customary Company common stock purchase agreement representing [*] of the total number of the Company's issued and outstanding shares of capital stock (excluding all shares reserved but unissued under the Plan and any issuances to the Sellers pursuant to this Section 1.2) as of immediately prior to the date of issuance of the shares of Common Stock, which shall not be subject to any vesting; (ii) non-qualified options to purchase Common Stock of the Company to each Seller under Purchaser's 2009 Equity Incentive Plan (the "***Plan***") equal to [*] of the total number of the Company's issued and outstanding shares of capital stock (excluding all shares reserved but unissued under the Plan and any issuances to the Sellers pursuant to this Section 1.2) as of immediately prior to the date of issuance of such options, which options shall have an exercise price equal to the fair market value on the date of grant, as reasonably determined by the Purchaser's Board of Directors and shall vest in increments of [*] per month from the date of grant for each month after the Effective Date, provided that such Seller is providing Continuous Service (as defined under the Plan) to the Company, it being understood that being on unpaid retainer shall satisfy such definition (collectively, the issuances under subclauses l.2(a)(i) and (ii), the "***Initial Time-Based Equity***") ; and (iii) non-qualified options to each Seller to purchase Common Stock of the Company to each Seller under the Plan to purchase [*] of the total number of the Company's issued and outstanding shares of capital stock (excluding all shares reserved but unissued under the Plan and any issuances to the Sellers pursuant to this Section 1.2) (the "***Milestone Options***"), which Milestone Options shall have a term of [*] and shall vest upon the earlier of: (A) [*] and (B) [*] (each, a "***Milestone Vesting Trigger***"), provided that for clarity, with respect to the option grants pursuant to this subclause (iii), vesting shall occur on the achievement of the Milestone Vesting Trigger by the Company regardless of whether Sellers are providing Continuous Service (as defined under the Plan) at the applicable time of achievement during the term of such Milestone Options. The occurrence of a Milestone Vesting Trigger shall be determined by Purchaser's Board of Directors in its reasonable discretion, which decision shall be binding upon the Parties and final;

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(b) At the closing of the first round of financing after the date of this Agreement pursuant to which Purchaser sells shares of its equity resulting in gross proceeds to the Company of at least [*], including a reverse merger whose primary purpose is financing (the "***Financing***"), Purchaser will issue to each Seller additional non-qualified options to purchase Common Stock of the Company (the "***Total Options***") to each Seller under the Plan (the "***Top-Up Options***") under the Plan pursuant to this Section 1.2(b) in an amount sufficient to ensure that the sum of the Initial Time-Based Equity plus the Milestone Options plus the Top-Up Options held by each Seller represents [*] of the total number of the Company's issued and outstanding shares of capital stock (excluding all shares reserved but unissued under the Plan and any issuances to the Sellers pursuant to this Section 1.2) as of immediately following the initial closing of the Financing. The Top-Up Options shall have an exercise price equal to the fair market value on the date of grant, as reasonably determined by the Purchaser's Board of Directors (or if the Company is publicly traded, pursuant to the terms of the Plan), and shall vest as follows: (i) [*] of the shares under the Top-Up Options (i.e., [*] of the of the total number of the Company's issued and outstanding shares of capital stock (excluding all shares reserved but unissued under the Plan and any issuances to the Sellers pursuant to this Section 1.2) as of immediately prior to the date of issuance of options) shall be vested on issuance and the remainder as of immediately prior to the date of issuance of options) shall vest in increments of [*] per month from the Effective Date, provided that such Seller is providing Continuous Service (as defined under the Plan) to the Company, it being understood that being on unpaid retainer shall satisfy such definition; and (ii) the other [*] of the Top-Up Options (i.e., [*] of the of the total number of the Company's issued and outstanding shares of capital stock (excluding all shares reserved but unissued under the Plan and any issuances to the Sellers pursuant to this Section 1.2), shall vest upon the occurrence of a Milestone Vesting Trigger, provided that for clarity, with respect to the Top-Up Option grants pursuant to this subclause (ii), vesting shall occur on the achievement of the Milestone Vesting Trigger by the Company regardless of whether Sellers are providing Continuous Service (as defined under the Plan) at the applicable time of achievement during the term of such Top-Up Options. The occurrence of a Milestone Vesting Trigger shall be determined by Purchaser's Board of Directors in its reasonable discretion, which decision shall be binding upon the Parties and final;

(c) [*] shall be payable to each Seller, within [*] following [*], as reasonably determined by Purchaser's Board of Directors;

(d) [*] shall be payable to each Seller, within [*] following [*], as reasonably determined by Purchaser's Board of Directors;

(e) [*] payable to each Seller, within [*] following [*], as reasonably determined by Purchaser's Board of Directors; and

(f) The Royalty Payments, payable if and to the extent provided in Section 1.4 below.

For clarity, the Parties contemplate that the Sellers shall each hold Initial Options and Top-Up Options totaling [*] of the outstanding shares of equity of the Company following the Financing. For further clarity, the payments in Sections 1.2(c), (d) and (e) of the Purchaser Price shall be payable only once to each Seller upon the first successful achievement by the Purchaser of such payment event with respect to the Product, as determined by Purchaser's Board of Directors, as aforesaid.

1.3 Assumed Liabilities. Purchaser shall not assume any Liabilities of Sellers (whether or not related to the Designated Assets), except for the continuing obligations under the terms of the License Agreement arising following the Closing Date, but solely to the extent not related to or arising from any fact, circumstance, act, breach or violation occurring prior to the Closing Date.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

1.4 Contingent Consideration.

(a) Commencing with the date the Product is first commercially sold and until the last to expire of any Valid Claim of any of the Patents licensed under the License Agreement, as applicable (the "***Royalty Period***"), each Seller shall be entitled to receive within [*] after the end of each calendar year during the Royalty Period a payment equal to [*] of the Annual Net Sales of such Product made during such calendar year (such payments collectively, the "***Royalty Payments***"). The determination as to the calculation of the Royalty Payments shall be reasonably made by Purchaser's Board of Directors, in its reasonable discretion.

(b) Concurrently with each Royalty Payment made hereunder, Purchaser shall submit to Sellers a written statement of account, which statement shall show (i) the Annual Net Sales in a manner consistent with the definition thereof, and (ii) the manner in which the Royalty Payment was calculated (the "***Royalty Statement***").

(c) For [*] following the submission of a Royalty Statement, Sellers and their agents and representatives shall have the right upon written request to conduct reasonable inspection and audit of Purchaser's relevant books and records for the sole purpose of verifying the accuracy of the Royalty Statements, provided that: (i) such written request must be reasonable; (ii) Purchaser shall receive reasonable advance notice of such request; (iii) such inspection or audit shall take place during Purchaser's regular business hours and at the place where such books and records are maintained; (iv) Purchaser may demand that the Sellers, their agents and representative will execute a nondisclosure agreement in a form reasonably satisfactory to Purchaser prior to such inspection or audit; and (v) in no event shall Purchaser be required to provide access to information that is subject to attorney-client privilege. Any such inspection or audit by Sellers shall be at their sole expense.

1.5 Transfer Taxes. Sellers shall be liable for any sales Taxes, use Taxes, transfer Taxes or similar Taxes, charges or fees that may become payable in connection with the sale of the Designated Assets to Purchaser. Purchaser and Sellers shall cooperate to reduce the amount of such Taxes to the extent permitted by applicable law.

1.6 Allocation. The consideration referred to in Section 1.2 shall be allocated among the Designated Assets pursuant to a purchase price allocation prepared by Purchaser, which shall be delivered to Sellers within [*] of the Effective Date, and no Party shall file any tax return or other document with, or make any statement or declaration to, any governmental body that is inconsistent with such allocation, except as required by applicable law.

1.7 Closing.

(a) The closing of the sale of the Designated Asset to Purchaser pursuant to this Agreement (the "***Closing***") shall take place concurrently with the execution and delivery of this Agreement (the "***Closing Date***").

(b) At the Closing:

(i) Purchaser and each Seller shall execute and deliver to each other a Consulting Agreement; and

(ii) Purchaser and each Seller shall execute and deliver to the other Party that certain instrument, titled "***Amendment No. 1 To License Agreement***" in the form attached hereto as Exhibit C, thereby effectuating the assignment of the License Agreement to Purchaser. (With reference to said Amendment No. 1 to License Agreement, in the interest of clarity, the Parties agree that obligations set forth in Section 13.3 of the amended License Agreement do not and shall not apply to Sellers hereunder.)

SECTION 2. REPRESENTATIONS AND WARRANTIES OF SELLER.

Sellers, severally and not jointly, each represent and warrant to Purchaser that, except as set forth in the Disclosure Schedule (it is hereby agreed that any information disclosed in any section or subsection of the Disclosure Schedule shall be deemed to relate to and qualify the corresponding numbered or lettered section or subsection of this Agreement and any other representation or warranty of Sellers where such disclosure would reasonably be deemed to apply) as of the Effective Date (for the avoidance of doubt and sake of clarity, in this Section 2, each Seller shall only make each representation with respect to itself, notwithstanding the fact that "***Sellers***" or "***each Seller***" may be referenced):

2.1 License Agreement. Sellers have delivered to Purchaser accurate and complete copies of the License Agreement. The License Agreement is valid and in full force and effect. Neither Seller nor any of the other parties to the License Agreement has violated or breached, or declared or committed any default under the License Agreement. No event has occurred, and no circumstance or condition exists, that might (with or without notice or lapse of time) result in a violation, breach or default by any Seller or any of the other parties to the License Agreement. Neither Seller has waiver any rights under the License Agreement. There are no material disputes regarding the License Agreement and, to the knowledge of Sellers, the relationship between Sellers and Stanford is good.

2.2 Authority; Binding Nature of Agreements. Each Seller has full power and authority to enter into, perform and comply with its obligations under this Agreement, and any other Transaction Agreement which such Seller is required to enter into hereunder and this Agreement constitutes and any such other Transaction Agreement when executed will constitute valid, legally binding and enforceable obligations on such Seller in accordance with its or their respective terms, subject to: (i) laws of general application relating to bankruptcy, insolvency and the relief of debtors; and (ii) rules of law governing specific performance, injunctive relief and other equitable remedies.

2.3 Non-Contravention. The execution and delivery by Sellers of the Transactional Agreements, and the consummation of the transactions contemplated by the Transaction Agreements, including the sale of the Designated Assets by Sellers to Purchaser will not result in the imposition or creation of any lien or Encumbrance upon or with respect to any of the Designated Assets. Sellers are not required to obtain any additional consent from any Person in connection with the execution and delivery of the Transactional Agreements or the consummation of the transactions contemplated thereby, including the sale of the Designated Assets to Purchaser.

2.4 Compliance with Law; Permits. As it relates to the Designated Assets: (a) each Seller has at all times been and is now in compliance with each Legal Requirement that is applicable to the ownership or use of the Designated Assets; (b) no event has occurred, and no condition or circumstance exists, that might (with or without notice or lapse of time) constitute or result in a violation by any Seller of, or a failure on the part of any Seller to comply with, any Legal Requirement; and (c) no Seller has received, at any time, any notice or other communication (in writing or otherwise) from any governmental body or

any other Person regarding any actual or alleged violation of, or failure to comply with, any Legal Requirement.

2.5 Title to Transferred Assets. Sellers own, and have good and valid title to, all of the Designated Assets, free and clear of any Encumbrances, subject to the qualifications pertaining thereto with respect to Stanford as set forth in Section 1.1, subparts (b) and (c).

2.6 Tax Matters. Each Tax with respect to the Designated Assets required to have been paid, or claimed by any governmental body to be payable, by Sellers has been duly paid in full on a timely basis. With respect to the Designated Assets, no claim or other Proceeding is pending or, to the knowledge of Sellers, has been threatened in respect of any Tax.

2.7 Restriction on Business Activities. There is no order to which Sellers are a party to or otherwise binding upon Sellers or any of their properties or assets (including the Designated Assets) which has or may reasonably be expected to have the effect of prohibiting or impairing the use of the Designated Assets or limiting the freedom of Purchaser to engage in any line of business or to compete with any Person. Sellers have not entered into any contract under which they are, or Purchaser will be after the Closing, restricted from using the Designated Assets to create products or services and sales, licensing, marketing, manufacturing or otherwise distributing or using any such products, services or any of the Designated Assets or from providing services to customers or potential customers or any class of customers, m any geographic area, during any period of time, or in any segment of the market.

2.8 No Liability. The Sellers have no Liability with respect to the Designated Assets.

2.9 Intellectual Property. The Sellers exclusively own or otherwise a valid right to use and practice (through the License Agreement) the Invention, under the HH Patent and the other intellectual property included in the Designated Assets (the "***Designated IP***"), free of any Encumbrances, including obligations to pay royalties or indemnification obligations (except as otherwise provided in the License Agreement). The Designated IP is valid, subsisting and enforceable. There are no outstanding options, licenses, or agreements of any kind relating to the Designated IP. To Sellers' knowledge, the Designated IP does not violate or infringe any intellectual property right of any other Person. Neither Seller has received any communication alleging that any Seller or that the Designated IP has violated or would violate any of the patents, trademarks, service marks, tradenames, copyrights, trade secrets or other proprietary rights or processes of any other Person. Neither the execution or delivery of this Agreement and the other Transaction Agreements, nor the use of the Designated Assets as currently proposed to be conducted will conflict with or result in a breach of the terms, conditions, or provisions of, or constitute a default under, any contract, covenant or instrument under which any Seller is obligated.

2.10 Proceedings. There is no pending or threatened Proceeding: (a) that involves or otherwise can affect any Seller or any of the Designated Assets; or (b) that challenges, or that may have the effect of preventing, delaying, making illegal or otherwise interfering with, the transactions contemplated by this Agreement or the other Transaction Agreements. No event has occurred, and no claim, dispute or other condition or circumstance exists, that will or could be expected to, give rise to or serve as a basis for the commencement of any such Proceeding. There is no order, writ, injunction, judgment or decree to which any Seller, or any Designated Asset, is subject.

2.11 No Brokers. Sellers are not obligated to pay any brokerage, commission, finder's fee or similar fee in connection with the transactions contemplated hereby.

2.12 Full Disclosure. Sellers have disclosed to Purchaser all facts known to them that are material to the Designated Assets, or may have material effect on Purchaser's consideration of the execution of

this Agreement or any other Transaction Agreement, or consummation of the transactions contemplated hereby or thereby. No representation or warranty by Sellers in this Agreement or any Schedule hereto contains any untrue statement of a material fact or omits to state any material fact necessary, in each case with respect to the Designated Assets, in order to make the statement made herein or therein, in light of the circumstances under which they were made, not misleading.

SECTION 3. REPRESENTATIONS AND WARRANTIES OF PURCHASER.

Purchaser represents and warrants to Sellers that:

3.1 Due Organization. Purchaser is a limited liability company duly organized, validly existing and in good standing under the laws of Delaware.

3.2 Authority; Binding Nature of Agreements. Purchaser has the requisite corporate power and authority to enter into and to deliver each of the Transactional Agreements to which it is a party and to perform its obligations under each such Transactional Agreement, and the execution, delivery and performance by Purchaser of each of the Transactional Agreements to which it is a party have been duly authorized by all necessary corporate action on the part of Purchaser. Each of the Transactional Agreements constitutes a legal, valid and binding obligation of Purchaser, enforceable against it or them in accordance with its terms, except to the extent that enforcement thereof may be limited by: (a) bankruptcy, insolvency, reorganization, moratorium, fraudulent conveyance or other similar laws now or hereafter in effect relating to creditors' rights generally; and (b) general principles of equity (regardless of whether enforceability is considered in a Proceeding at law or in equity).

3.3 Non-Contravention. The execution and delivery by Purchaser of the Transactional Agreements, and the purchase of the Designated Assets by Purchaser from Sellers will not result in a violation of the charter documents of Purchaser.

3.4 Capitalization Table. Exhibit D sets forth the true and correct capitalization of the Company as of the Effective Date.

SECTION 4. SURVIVAL AND INDEMNIFICATION.

4.1 Survival of Representations.

(a) The representations and warranties of Sellers shall survive the Closing and the sale of the Designated Assets to Purchaser and shall expire on the date that is [*] following the Closing Date (the "***Representation Termination Date***"); *provided*, *however*, that if Purchaser provides Seller a written notice relating to any representation or warranty prior to the applicable Representation Termination Date, then the claim(s) asserted in such Claim Notice shall survive the Representation Termination Date until such time as such claim is (or claims are) fully and finally resolved. The limitations set forth in this Section 4.l(a) shall not apply in the case of intentional misrepresentation, willful misconduct or fraud ("***Fraud***"). The covenants and obligations of each Party shall survive the Closing and the sale of the Designated Assets to Purchaser and shall expire upon the applicable statute of limitations, which statute shall start to run on the Closing Date, except in the case of Fraud.

(b) For purposes of this Agreement, a "***Claim Notice***" relating to a particular representation or warranty shall be deemed to have been given if Purchaser delivers to Sellers a written notice stating that Purchaser believes that there is or has been a breach of a representation or warranty, asserting a claim for

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

recovery under Section 4.2 based on such alleged breach and setting forth in reasonable detail: (i) the basis for, and a brief description of the circumstances supporting, Purchaser's belief that there is or has been such a breach; and (ii) to the extent practicable, a non-binding, preliminary estimate of the aggregate dollar amount of the actual and potential Damages that have arisen and may arise as a result of such breach.

4.2 Indemnification. From and after the Closing Date (but subject to the limitations set forth in this Section 4), each of the Sellers shall individually, and not jointly, hold harmless, reimburse and indemnify Purchaser and its agents and representatives from and against, any Damages that are suffered or incurred by Purchaser and that arise from or as a result of or relating to:

(a) Any inaccuracy in or breach of any of the representations or warranties made by the applicable Seller in this Agreement or in any other Transaction Agreement;

(b) Any breach of any covenant or obligation of the applicable Seller contained in this Agreement or any other Transaction Agreement; and

(c) Any Liability of such Seller, except for the Assumed Liabilities.

4.3 Cap. Notwithstanding anything to the contrary, each Seller's liability to Purchaser hereunder shall be capped at the value of such Seller's vested shares comprising the Purchase Price (with the value of such shares or options, to the extent necessary in determining the cap, as reasonably determined by Purchaser's Board of Directors based upon the available information pertaining thereto) for each of the Sellers pursuant to this Agreement; provided that, to the extent that the liability to Purchaser exceeds the value of the vested shares comprising the Purchase Price with respect to any claim of Purchaser, the liability shall be satisfied in part by any vested shares or options and shall remain in effect until there are no longer shares or options subject to vesting. It is further agreed that each Seller shall have the right to satisfy any liability to Purchaser hereunder by returning to Purchaser that portion of its vested shares or options whose value equals the amount of said liability, not to exceed the return of all of its shares or options comprising the Purchase Price (with the value of such shares or options, to the extent necessary in determining the cap, as reasonably determined by Purchaser's Board of Directors based upon the available information pertaining thereto). The limitation set forth in this Section 4.3 shall not apply in the case of Fraud and shall survive the termination or expiration of this Agreement.

4.4 Defense of Third-Party Claims. In the event of the assertion or commencement by any Person of any claim or Proceeding (whether against Purchaser or against any other Person) with respect to which Purchaser may be entitled to indemnification, compensation or reimbursement pursuant to this Section 4.4, Purchaser shall have the right, at its election, to proceed with the defense of such claim or Proceeding on its own with counsel reasonably satisfactory to Sellers (which consent may not be unreasonably withheld, delayed or conditioned). Purchaser shall have the right to settle, adjust or compromise such claim or Proceeding; *provided, however*, that if Purchaser settles, adjusts or compromises any such claim or Proceeding without the consent of Sellers (such consent not to be unreasonably withheld or delayed), such settlement, adjustment or compromise shall not be conclusive evidence of the amount of Damages incurred by Purchaser in connection with such claim or Proceeding. Purchaser shall give Sellers prompt notice after it becomes aware of the commencement of any such claim or Proceeding against Purchaser; *provided, however*, that any failure on the part of Purchaser to so notify Sellers shall not limit any of the obligations of Sellers, or any of the rights of Purchaser, under this Section 4.4 (except to the extent such failure materially prejudices the defense of such Proceeding). If Purchaser does not elect to proceed with

the defense of any such Proceeding, Sellers may proceed with the defense of such Proceeding with counsel reasonably satisfactory to Purchaser; *provided, however*, that Sellers may not settle or compromise any such Proceeding without the prior written consent of Purchaser.

SECTION 5. CERTAIN POST-CLOSING COVENANTS.

5.1 Further Assurances. From and after the Closing, each of Purchaser and Sellers will, to the extent reasonably requested by the other Party and at such other Party's sole expense, execute and deliver such documents and instruments and take such other actions as such other Party may reasonably request in order to consummate and make effective the transactions contemplated by this Agreement. On and after the Closing Date, each Seller shall execute such documents, further instruments of sale, transfer, conveyance, assignment and confirmation and other papers and take such further actions as may be reasonably required to transfer, convey and assign to Purchaser, and to confirm Purchaser's title to, all of the Designated Assets.

5.2 Publicity. Sellers agree that, on and at all times after the date of this Agreement: (a) no press release or other publicity concerning any of the transactions contemplated hereby shall be issued or otherwise disseminated by it or on its behalf without Purchaser's prior written consent; and (b) Sellers shall continue to keep the terms of this Agreement strictly confidential.

5.3 Tax Cooperation. Purchaser and Sellers agree to furnish or cause to be furnished to each other, upon request, as promptly as practicable, such information and assistance relating to the Designated Asset (including access to books and records) as is reasonably necessary for the filing of all tax returns, and making of any election related to taxes, the preparation for any audit by any taxing authority and the prosecution or defense of any claim, suit or Proceeding relating to any tax return.

5.4 Non-Competition.

(a) Non-Competition. Each Seller hereby covenants, acknowledges and agrees that it will not, at any time during [*] from the Closing Date, either directly or indirectly, as principal, agent, owner, partner, employee, consultant, shareholder, director or officer, as the case may be, in any manner whatsoever, own, be engaged in, be concerned with, be interested in, operate, have any financial interest in or advance, lend money to, guarantee the debts or obligations of, permit its name or any part thereof to be used or applied by any Person, firm or corporation engaged in or concerned with or interested in, directly or indirectly, in any Competitive Activity in any territory in which the Products are currently planned to be commercialized, except as a passive shareholder holding less than [*] percent of the outstanding shares of a corporation offering its shares to the public and whose shares are listed and posted for trading on a recognized stock exchange. Notwithstanding the foregoing covenant, Purchaser agrees that said covenant shall not be construed to preclude Sellers from continuing, during said [*] period following the Closing Date, their research and mechanistic studies relating to hyperinsulinemic hypoglycemia in connection with their employment at Stanford.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(b) Relief.

(i) Injunctive Relief. Sellers acknowledges that breach of Seller's covenants contained in this Section 5.4 may cause irreparable harm to the Business, which may not be compensable through monetary damages. Sellers therefore hereby acknowledges that in the event of a breach or a threatened breach by the them or their respective affiliates of such covenants, Purchaser will be entitled, in addition to any other rights, remedies or damages which may be available to Purchaser, at law or in equity, to obtain an interim and permanent injunction in order to prevent or restrain any breach or threatened breach of this Agreement by Sellers or their affiliates, partners, employers, employees, servants, agents, representatives, and other Persons directly or indirectly acting for, or on behalf of, or with, Sellers. Sellers further agree that Purchaser shall be entitled to injunctive relief without having to prove damages and shall be entitled to all of its costs and expenses incurred in order to obtain relief from any such breach under this Agreement.

(ii) Restrictions Reasonable. Purchaser and Sellers acknowledge and confirm that:

(1) they have been independently advised by their respective counsel with respect to the provisions of this Section 5.4;

(2) they have negotiated the provisions of Section 5.4 on an equal footing based on equal bargaining power at the Closing Date;

(3) neither Purchaser or Sellers were required or induced by force, threats, or other means of intimidation or in any other manner to enter into this Agreement or the Transaction Documents;

(4) the provisions of this Section 5 and the Transaction Documents are reasonable and do not go beyond what is necessary to protect the interests of Purchaser; and

(5) the Transaction Documents are supported by adequate consideration.

5.5 Commercially Reasonable Efforts. Purchaser hereby agrees to use Commercially Reasonable Efforts to pursue and complete [*].

SECTION 6. MISCELLANEOUS PROVISIONS.

6.1 Notices. All notices, requests, demands and other communications under this Agreement shall be in writing and shall be deemed to have been duly given or made as follows:

(a) if sent by registered or certified mail in the United States return receipt requested, upon receipt; (b) if sent designated for overnight delivery by nationally recognized overnight air courier (such as Federal Express), upon receipt; (c) if sent by facsimile transmission before 5:00 p.m. in California, when transmitted and receipt is confirmed; (d) if sent by facsimile transmission after 5:00 p.m. in California and receipt is confirmed, on the following business day; and (e) if otherwise actually personally delivered, when delivered, provided that such notices, requests, demands and other communications are delivered to the address set forth below, or to such other address as either Party shall provide by like notice to the other Party:

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

If to Sellers:

Tracey McLaughlin, MD
300 Pasteur Drive, Room S025
Stanford, CA 94305-5103
Facsimile: _____

and

Colleen Craig, MD
300 Pasteur Drive, Room S025
Stanford, CA 94305-5103
Facsimile: _____

With copies (which shall not constitute notice) to:

Blakely, Sokoloff, Taylor & Zafman LLP
12400 Wilshire Boulevard
Suite 700
Los Angeles, California 90025
Attention: Norman Zafman
Facsimile: (310) 820-5988

If to Purchaser:

Eiger BioPharmaceuticals, Inc.
350 Cambridge Avenue, Suite 350
Palo Alto, CA 94306
Attention: David Cory
Facsimile: (415) 203-0934

With copies (which shall not constitute notice) to:

Cooley LLP
3175 Hanover St.
Palo Alto, CA 94304
Attention: Glen Sato
Facsimile: (650) 849-7400

6.2 Headings. The bold-faced headings contained in this Agreement are for convenience of reference only, shall not be deemed to be a part of this Agreement and shall not be referred to in connection with the construction or interpretation of this Agreement.

6.3 Counterparts and Exchanges by Electronic Transmission or Facsimile. This Agreement may be executed in counterparts, each of which shall constitute an original and both of which, when taken together, shall constitute one agreement. The exchange of a fully executed Agreement (in counterparts or otherwise) by electronic transmission or facsimile shall be sufficient to bind the Parties to the terms and conditions of this Agreement.

6.4 Governing Law; Venue.

(a) This Agreement shall be construed in accordance with, and governed in all respects by, the internal laws of the State of California (without giving effect to principles of conflicts of laws).

(b) Any Proceeding relating to this Agreement or the enforcement of any provision of this Agreement shall be brought or otherwise commenced in any state or federal court located in the State of California. Each Party:

(i) expressly and irrevocably consents and submits to the jurisdiction of each state and federal court located in the State of California (and each appellate court located in the State of California) in connection with any such proceeding;

(ii) agrees that each state and federal court located in the State of California shall be deemed to be a convenient forum; and

(iii) agrees not to assert (by way of motion, as a defense or otherwise), in any such Proceeding commenced in any state or federal court located in the State of California, any claim that such Party is not subject personally to the jurisdiction of such court, that such Proceeding has been brought in an inconvenient forum, that the venue of such Proceeding is improper or that this Agreement or the subject matter of this Agreement may not be enforced in or by such court.

6.5 WAIVER OF TRIAL BY JURY. EACH PARTY WAIVES THE RIGHT TO A JURY TRIAL IN CONNECTION WITH ANY LAWSUIT, ACTION OR PROCEEDING SEEKING ENFORCEMENT OF SUCH PARTY'S RIGHTS UNDER THIS AGREEMENT.

6.6 Successors and Assigns; Parties in Interest. Except as otherwise expressly provided herein, the provisions hereof shall inure to the benefit of, and be binding upon the parties hereto and their respective successors, assigns, heirs, executors and administrators. Sellers may not assign any of their rights or delegate any of their obligations under this Agreement to any other Person without the prior written consent of Purchaser. Purchaser may freely assign any or all of its rights hereunder, in whole or in part, to any other Person without obtaining the consent or approval of any other Person.

6.7 Waiver. No failure on the part of either Party to exercise any power, right, privilege or remedy under this Agreement, and no delay on the part of either Party in exercising any power, right, privilege or remedy under this Agreement, shall operate as a waiver of such power, right, privilege or remedy; and no single or partial exercise of any such power, right, privilege or remedy shall preclude any other or further exercise thereof or of any other power, right, privilege or remedy.

6.8 Specific Performance. Each Party agrees that: (a) in the event of any breach or threatened breach by the other Party of any covenant, obligation or other provision set forth in this Agreement, such Party shall be entitled (in addition to any other remedy that may be available to it) to: (i) a decree or order of specific performance or mandamus to enforce the observance and performance of such covenant, obligation or other provision; and (ii) an injunction restraining such breach or threatened breach; and (b) neither Party shall be required to provide any bond or other security in connection with any such decree, order or injunction or in connection with any related legal proceeding.

6.9 Amendments. This Agreement may not be amended, modified, altered or supplemented other than by means of a written instrument duly executed and delivered on behalf of Sellers and Purchaser.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

6.10 Severability. In the event that any prov1s10n of this Agreement, or the application of any such provision to either Party or set of circumstances, shall be determined to be invalid, unlawful, void or unenforceable to any extent, the remainder of this Agreement, and the application of such provision to a Party or circumstances other than those as to which it is determined to be invalid, unlawful, void or unenforceable, shall not be impaired or otherwise affected and shall continue to be valid and enforceable to the fullest extent permitted by law.

6.11 Expenses. Each Party shall bear and pay all fees, costs and expenses that have been incurred or that are in the future incurred by, on behalf of or for the benefit of, such Party in connection with the negotiation, preparation and review of this Agreement and the other Transactional Agreements and the consummation and performance of the transactions contemplated herein; *provided*, *however*, that Purchaser shall reimburse the reasonable fees and expenses of Blakely, Sokoloff, Taylor & Zafinan LLP, as counsel to Sellers, not to exceed [*].

6.12 Entire Agreement. The Transactional Agreements set forth the entire understanding of the Parties relating to the subject matter thereof and supersede all prior agreements and understandings between the Parties relating to the subject matter thereof.

6.13 Construction.

(a) For purposes of this Agreement, whenever the context requires: the singular number shall include the plural, and vice versa; the masculine gender shall include the feminine and neuter genders; the feminine gender shall include the masculine and neuter genders; and the neuter gender shall include the masculine and feminine genders.

(b) The Parties agree that any rule of contractual construction to the effect that ambiguities are to be resolved against the drafting Party shall not be applied in the construction or interpretation of this Agreement.

(c) As used in this Agreement and Exhibit A, the words "include" and "including," and variations thereof, shall not be deemed to be terms of limitation, but rather shall be deemed to be followed by the words "without limitation**.**"

(d) Except as otherwise indicated, all references in this Agreement to "Sections," "Exhibits" and "Schedules" are intended to refer to Sections of this Agreement and Exhibits and Schedules to this Agreement.

[*Remainder of page intentionally left blank*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

The Parties have caused this Agreement to be executed and delivered as of the date above mentioned.

PURCHASER:

EIGER BIOPHARMACEUTICALS, INC.

By: /s/ David Cory
Name: David Cory
Title: President and CEO

SELLERS:

/s/ Tracey McLaughlin
Tracey McLaughlin

/s/ Colleen Craig
Colleen Craig

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

LIST OF EXHIBITS

Exhibit A - Certain Definitions

Exhibit B - Form of Consulting Agreement

Exhibit C - Amendment No. 1 To License Agreement Exhibit D - Capitalization Table of the Company

LIST OF SCHEDULES

Disclosure Schedule

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

EXHIBIT A

CERTAIN DEFINITIONS

For purposes of the Agreement (including this Exhibit A):

Affiliate. "Affiliate" shall mean, with respect to a Person, any other Person that directly or indirectly controls, is controlled by, or is under common control with such first Person. For the purpose of this definition, "control" (including, with correlative meaning, the terms "controlled by" and "under the common control") meaning direct or indirect ownership of fifty percent (50%) or more, including ownership by trusts with substantially the same beneficial interests, of the voting and equity rights of such Person, or the power to direct the management of such Person.

Agreement. "Agreement" shall mean the Asset Purchase Agreement (including the Disclosure Schedule), to which this Exhibit A is attached as it may be amended from time to time.

Annual Net Sales. "Annual Net Sales" shall mean the gross amount invoiced by Purchaser, its Affiliate and its sublicensees, for sales of the Product to a third party within a single calendar year, less the following deductions, to the extent accrued and directly allocable to the Product:

(a) cash discounts;

(b) returns (including recalls); price protection and shelf stock adjustments; reprocurement charges by customers and other similar charges; chargebacks, allowances, discounts, and rebates;

(c) other payments required by applicable Legal Requirements or agreed to be made under Medicaid, Medicare or other government special medical assistance programs (including, but not limited to, payments made under the new "Medicare Part D Coverage Gap Discount Program" and the "Annual Fee on Branded Prescription Pharmaceutical Manufacturers");

(d) relevant managed markets rebates; and

(e) sales, excise or other similar taxes (excluding income taxes).

For clarity, any subsequent adjustment to an accrual shall be reflected in the Annual Net Sales in the period in which such adjustment is made. Sales between Purchaser and its Affiliates shall be disregarded for purposes of calculating Annual Net Sales except if such Affiliates are end users. Annual Net Sales shall be accounted for in accordance with GAAP, consistent with Purchaser's books and records, and in any event consistent with all of its other branded pharmaceutical products.

Business. "Business" shall all activity related to Sellers' development, ownership and use of the Designated Assets.

Commercially Reasonable Efforts. "Commercially Reasonable Efforts shall mean that level of efforts and resources, with respect to a particular Party, at the relevant point in time, that is consistent with the usual practice followed by a similarly situated company, in the exercise of its reasonable scientific and business judgment relating to other prescription pharmaceutical products owned or licensed by it or to which it has exclusive rights, which have market potential and are at a stage of development or product life similar to the applicable Product, taking into account measures of patent coverage, length of any statutory period of exclusivity, relative safety and efficacy, product profile, the competitiveness of the marketplace, the proprietary position of the compound or product, the regulatory structure involved, the relative profitability of the products (including, without limitation, pricing and reimbursement status) and other relevant factors, including without limitation comparative technical, legal, scientific, and/or medical factors.

Competitive Activity. "Competitive Activity" shall mean the research or development of, sale, testing, marketing, commercialization or offer of the Product or any product or service that competes with the Product or that could be developed and commercialized for the same indications as the Product.

Damages. "Damages" shall mean any loss, damage, injury, decline in value, Liability, lost opportunity, claim, settlement, judgment, fine, penalty, tax, fee (including any reasonable legal fee), charge or expense of any nature.

Disclosure Schedule. "Disclosure Schedule" shall mean the disclosure schedule delivered by Sellers to Purchaser contemporaneously with the execution and delivery of the Agreement.

Equity Documents. "Equity Documents" shall mean the documents to be executed by the other purchasers in the Financing.

Encumbrance. "Encumbrance" shall mean any lien, pledge, hypothecation, charge, mortgage, security interest, encumbrance, equity, trust, equitable interest, claim, preference, right of possession, lease, tenancy, license, encroachment, covenant, infringement, interference, Order, proxy, option, right of first refusal, preemptive right, community property interest, legend, defect, impediment, exception, reservation, limitation, impairment, imperfection of title, condition or restriction of any nature (including any restriction on the transfer of any asset, any restriction on the receipt of any income derived from any asset, any restriction on the use of any asset and any restriction on the possession, exercise or transfer of any other attribute of ownership of any asset).

GAAP. "GAAP" shall mean United States generally accepted accounting principles and practices in effect from time to time, consistently applied.

Knowledge. Information shall be deemed to be known to or to the "knowledge" of the Sellers if that information is actually known, reasonably should be known or reasonably could be expected to be discovered in the course of conducting a reasonable investigation concerning the existence of such fact or other matter by any Seller.

Legal Requirement. "Legal Requirement" shall mean any federal, state, local, municipal, foreign or other law, statute, legislation, constitution, principle of common law, resolution, ordinance, code, edict, decree, proclamation, treaty, convention, rule, regulation, ruling, directive, pronouncement, requirement, specification, determination, decision, opinion or interpretation issued, enacted, adopted, passed, approved, promulgated, made, implemented or otherwise put into effect by or under the authority of any Governmental Body.

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Liability. "Liability" shall mean any debt, obligation, duty or liability of any nature (including any unknown, undisclosed, unmatured, unaccrued, unasserted, contingent, indirect, conditional, implied, vicarious, derivative, joint, several or secondary liability), regardless of whether such debt, obligation, duty or liability would be required to be disclosed on a balance sheet prepared in accordance with generally accepted accounting principles and regardless of whether such debt, obligation, duty or liability is immediately due and payable.

Patents. "Patents" shall mean all patents and patent applications (including inventor's certificates and utility models) in any country or jurisdiction, including all provisionals, substitutions, counterparts, continuations, continuations-in-part, divisionals, supplementary protection certificates, renewals, all letters patent granted thereon, and all reissues, reexaminations, extensions, confirmations, revalidations, registrations, patents of addition thereof, PCTs, pediatric exclusivity periods, and foreign equivalents to any of the foregoing.

Person. "Person" shall mean any individual, corporation, partnership, limited liability company, or other legal entity or governmental body other than Purchaser and Sellers.

Phase 2 Clinical Trial. "Phase 2 Clinical Trial" shall mean any controlled human clinical trial designed to: (a) evaluate the effectiveness of the intended use of the therapeutic agent for a particular indication or indications; (b) identify short-term side effects and risks that are associated with the therapeutic agent in the dosage range to be prescribed; and (c) satisfy the requirements of 21 CFR § 312.21(b).

Phase 3 Clinical Trial. "Phase 3 Clinical Trial" shall mean any human clinical trial designed to: (a) establish that the therapeutic agent is safe and efficacious for its intended use; (b) define warnings, precautions and adverse reactions that are associated with the therapeutic agent in the dosage range to be prescribed; and (c) support regulatory approval of the therapeutic agent, that would satisfy the requirements of 21 CFR § 312.21(c).

Proceeding. "Proceeding" shall mean any action, suit, litigation, arbitration, proceeding (including any civil, criminal, administrative, investigative or appellate proceeding and any informal proceeding), prosecution, contest, hearing, inquiry, inquest, audit, examination or investigation commenced, brought, conducted or heard by or before, or otherwise involving, any governmental body or any arbitrator or arbitration panel.

Securities Act. "Securities Act" means the Securities Act of 1933, as amended.

Tax. "Tax" shall mean any tax (including any income tax, franchise tax, capital gains tax, estimated tax, gross receipts tax, value-added tax, surtax, excise tax, ad valorem tax, transfer tax, stamp tax, sales tax, use tax, property tax, business tax, occupation tax, inventory tax, occupancy tax, withholding tax or payroll tax), levy, assessment, tariff, impost, imposition, toll, duty (including any customs duty), deficiency or fee, and any related charge or amount (including any fine, penalty or interest), that is, has been or may in the future be (a) imposed, assessed or collected by or under the authority of any governmental body, or (b) payable pursuant to any tax-sharing agreement or similar contract.

Transactional Agreements. "Transactional Agreements" shall mean the Agreement and the Consulting Agreements, the Amendment No. 1 to License Agreement and any other documents delivered by Sellers to Purchaser to complete the transactions contemplated hereby.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Valid Claim. "Valid Claim" shall mean a claim of any issued and unexpired Patent within the (a) HH Patents or (b) Patents licensed under the License Agreement, as applicable, that has not been held invalid or unenforceable by a final decision of a court or governmental agency of competent jurisdiction, which decision can no longer be appealed or was not appealed within the time allowed; *provided*, *however*, that if a claim of a pending patent application within the Patents licensed under the License Agreement, as applicable, shall not have issued within [*] after the earliest filing date from which such claim takes priority, such claim shall not constitute a Valid Claim for the purposes of this Agreement.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

EXHIBITS

FORM OF CONSULTING AGREEMENT

CONSULTING AGREEMENT

This Consulting Agreement ("***Agreement***") is made and entered into as of September , 2015, ("***Effective Date***") by and between Eiger BioPharmaceuticals, Inc., a Delaware corporation with an address of 350 Cambridge Avenue, Suite 350, Palo Alto, CA 94306 (the "***Company***"), and Colleen Craig, MD ("***Consultant***"), with an address of 300 Pasteur Drive, Room S025, Stanford, CA 94305. Both Company and Consultant are referred to herein, individually, as a "***Party***" and, collectively, as the "***Parties***".

WHEREAS, Company desires to retain Consultant to render consulting services to Company and Consultant desires to be so retained by Company and to perform such services further specified herein, all in accordance with the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the premises, conditions and representations set forth herein, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged by Company and Consultant, Company and Consultant agree as follows.

PROFESSIONAL SERVICES

Services. Company hereby retains Consultant to provide professional consulting services as set forth on Exhibit A (the "***Services***") to Company, which is attached hereto and incorporated herein by reference, and Consultant hereby accepts such engagement. Consultant agrees to perform for Company the professional Services and deliver to Company the work product agreed upon by the Parties, including the time commitments, deliverables and any relevant timetables and specifications set forth on Exhibit A hereto.

Best Efforts. Consultant will use best efforts to perform the Services hereunder for Company in a diligent, timely, and professional manner, in accordance with specifications reasonably requested by Company.

Location and Access. The consulting Services shall be performed at Consultant's premises or such other premises that Company and Consultant may mutually agree upon.

Payroll Taxes. Consultant will be solely responsible for paying all applicable payroll taxes of any nature, including social security and other social welfare taxes or contributions, that may be due on amounts paid to Consultant pursuant to this Agreement.

PAYMENT

Company agrees to compensate Consultant for the Services performed by Consultant pursuant to this Agreement in accordance with the payment terms set forth in Exhibit A. Payment will be made only for work that has been performed to the reasonable satisfaction of Company.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Definition. As used in this Agreement, the term "***Confidential Information*** " means (i) any technical or business information furnished by Company, or on behalf of Company by its affiliates, subsidiaries, contractors, advisors, partners, or agents, to Consultant in connection with the Services to be performed hereunder, (ii) any work product produced by Consultant as a result of work hereunder, as well as all work papers related thereto, regardless of whether such information is specifically designated as confidential and regardless of whether such information is in written, oral, electronic or other form, and (iii) Data and Inventions (as defined in Section 4.1 hereof).

Use and Non-disclosure. Consultant acknowledges that, in the course of performing or preparing to perform Services for Company under this Agreement, Consultant will become acquainted with certain of Company's Confidential Information, the protection of which is necessary to the successful conduct of Company's business and the preservation of the integrity of Company's relationships with its customers. Company will make a reasonable effort to mark media containing Confidential Information with notice of the same and, otherwise, to inform Consultant when the latter is provided, or given access to, Confidential Information. Consultant agrees to (i) maintain all Confidential Information in strict confidence; (ii) use all Confidential Information solely for the purposes of performing Consultant's obligations under this Agreement; and (iii) reproduce the Confidential Information only to the extent necessary to perform Consultant's obligations under this Agreement, with all such reproductions being considered Confidential Information. Consultant shall not disclose Confidential Information to any third party without Company's express written authorization.

Exceptions. The foregoing obligations of Consultant shall not apply to any Confidential Information that Consultant can demonstrate: (i) was already in the public domain prior to the time of its disclosure under this Agreement; (ii) entered the public domain through means other than an unauthorized disclosure resulting from an act or omission by Consultant; (iii) was independently developed or discovered by Consultant prior to the time of its disclosure under this Agreement, as evidenced by Consultant's written records; (iv) is or was disclosed to Consultant at any time, whether prior to or after the time of its disclosure under this Agreement, by a third party having no fiduciary relationship with Company and having no obligation of confidentiality with respect to such Confidential Information; or (v) is required to be disclosed to comply with applicable laws or regulations, or with a court or administrative order, provided that Company receives prior written notice of such disclosure and that Consultant takes all reasonable and lawful actions to obtain or to permit Company to obtain confidential treatment for such disclosure and, if possible, to minimize the extent of such disclosure.

No License. Consultant acknowledges that, as between Consultant and Company, Company is the sole owner of the Confidential Information disclosed by Company and all patent, copyright, trademark, trade secret, and other intellectual property rights in, or arising from, such Confidential Information or developed hereunder. No option, license, or conveyance of such rights to Consultant is granted or implied under this Agreement.

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OWNERSHIP OF WORK PRODUCT

Invention Disclosure. Consultant agrees to disclose promptly and in writing to Company any and all data, ideas, concepts, discoveries, inventions (whether patentable or not), developments, original works of authorship, trade secrets, and know-how that are developed, conceived, devised, invented, developed or reduced to practice or tangible medium by Consultant, under her direction or jointly with others, which arise from or in connection with this Agreement ("***Data and Inventions*** "). All work products hereunder shall be "work for hire", and Consultant shall have no interest in the Data and Inventions.

Assignment. Consultant hereby assigns to Company all of Consultant's right, title, and interest to the Data and Inventions and any and all related patent rights, copyrights, and applications and registrations therefor. During the Term (as defined in Section 8.1) and thereafter, Consultant shall cooperate with Company, at Company's expense, in obtaining proprietary protection for the Data and Inventions, and shall execute all documents which Company shall reasonably request to perfect Company's rights in the Data and Inventions. Consultant acknowledges and agrees that without Company's substantial investment of time and money, the Data and Inventions could not be developed. In the event that any Data or Invention cannot be assigned to Company as sole owner, and Consultant retains some right to use Data or Inventions, then Consultant agrees only to use the same only for internal, noncommercial research.

CONSULTANT REPRESENTATION, WARRANTIES, AND CERTAIN COVENANTS

Consultant represents, warrants, and covenants to Company throughout the Term as follows.

The execution and performance of this Agreement does not, and will not, constitute a breach or default under any contract to which Consultant is a party, or by which Consultant is bound, and Consultant is not, and shall not be, under any contractual or other obligation to any third party which conflicts with any obligations hereunder or prevents or limits the performance of Services under this Agreement.

Consultant is free to disclose to Company, without breach of any obligation to a third party, any and all information, ideas, suggestions, developments, or know-how that Consultant may develop, generate or otherwise create in performing the Services under this Agreement.

Consultant has complied and will comply with all applicable laws, rules, regulations, and guidelines in her conduct of the Services under this Agreement.

Consultant warrants and represents that Consultant is not now, nor has Consultant ever been debarred or disqualified as a clinical investigator or participant in clinical services by the United States Food and Drug Administration or by any other regulatory or governmental authority.

Consultant further warrants and represents that Consultant has no knowledge of any circumstances which may affect the accuracy of the foregoing. Consultant agrees to notify Company immediately if such party becomes aware of any change in circumstances that would render any of the foregoing untrue or misleading in any respect during the Term.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

SOLICITATION OF COMPANY EMPLOYEES

Consultant agrees that during the Term and for a period of [*] thereafter, Consultant shall not, without Company's prior written consent, recruit, solicit, or hire any employee of Company, or induce or attempt to induce any employee of Company to discontinue his or her employment relationship with Company.

INDEMNIFICATION

Indemnification of Consultant. Company shall indemnify and hold harmless each of Consultant and its affiliates, and the successors and assigns of any of the foregoing (the "***Consultant Indemnitees*** "), from and against any and all losses, liabilities, damages, penalties, fines, costs and expenses (including reasonable attorneys' fees and other expenses of litigation) ("***Losses***") from any claims, actions, suits or proceedings brought by a third party (a "***Third Party Claim***") incurred by any Consultant Indemnitee, arising from, or occurring as a result of (a) gross negligence or willful misconduct of Company and its Affiliates and (b) the research, development and regulatory activities relating to the exendin product conducted by or on behalf of Company in connection with the performance of the Services in accordance with this Agreement; except to the extent such Third Party Claims fall within the scope of the indemnification obligations of Consultant set forth in Section 7.2.

Indemnification of Company. Consultant shall indemnify and hold harmless each of Company and its Affiliates and the directors, officers, shareholders, employees and agents of such entities and the successors and assigns of any of the foregoing (the "***Company Indemnitees*** "), from and against any and all Losses from any Third Party Claims incurred by any Company Indemnitee, arising from, or occurring as a result of (a) gross negligence or willful misconduct of Consultant or its Affiliates; and (b) any material breach of any representations, warranties or covenants by Consultant under this Agreement, except to the extent such Third Party Claims fall within the scope of the indemnification obligations of Company set forth in Section 7.1(a) or (b).

Procedure. A Party that intends to claim indemnification (the "***Indemnified Party***") under this Section 7 shall promptly notify the indemnifying Party in writing of any Third Party Claim, in respect of which the Consultant Indemnitee or Company Indemnitee, as the case may be, intends to claim such indemnification. The Indemnified Party shall provide the Indemnifying Party with reasonable assistance, at the indemnifying Party's expense, in connection with the defense of the Third Party Claim for which indemnity is being sought. The indemnitee may participate in and monitor such defense with counsel of its own choosing at its sole expense; *provided*, *however*, the indemnitor shall have the right to assume and conduct the defense of the Third Party Claim with counsel of its choice. The indemnitor shall not settle any Third Party Claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld, unless the settlement involves only the payment of money. So long as the indemnitor is actively defending the Third Party Claim in good faith, the indemnitee shall not settle any such Third Party Claim without the prior written consent of the Indemnifying Party. If the Indemnitor does not assume and conduct the defense of the Third Party Claim as provided above, (a) the indemnitee may defend against, and consent to the entry of any judgment or enter into any settlement with respect to the Third Party Claim in any manner the indemnitee may deem reasonably appropriate, and (b) the indemnitor will remain responsible to indemnify the Indemnitee as provided in this Section 7. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any action with respect to a Third Party Claim shall only relieve the indemnitor of its indemnification obligations under this 7. if and to the extent the indemnitor is actually prejudiced thereby.

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TERM AND TERMINATION

Term. This Agreement shall be effective for the period set forth in Exhibit A hereof (the "***Term***").

Termination. This Agreement may be terminated (i) by either Party at any time in the exercise of its sole discretion upon [*] written notice to the other Party, (ii) by a Party upon the material breach of this Agreement by the other Party, which material breach continues unremedied for [*] after delivery to the breaching Party by the nonbreaching Party of notice of material breach, (iii) by a Party immediately in the event of bankruptcy (voluntary or otherwise), insolvency, or other similar financial distress of the other Party.

Return of Company Materials. Upon expiration or termination of this Agreement for any reason or at any time upon request by Company, Consultant will immediately return to Company all property belonging to Company, including without limitation all Confidential Information and Data and Inventions in Consultant's possession or control.

Survival. Termination or expiration of this Agreement shall not cancel or terminate any rights and/or obligations which arose prior to the effective date of termination or expiration and which must continue in order to give effect to their meaning at the time such right and/or obligation arose, including without limitation Sections 3 4, 7, 8.3, 8.4, 10 and 12.

NOTICES

Any notice or approval required or permitted under this Agreement will be delivered in writing and will be sent by (i) facsimile (followed by a copy sent by overnight courier or, if the delivery is international, by two-day courier) or (ii) by overnight courier or, if the delivery is international, by two-day courier to the address specified below or to any other address that may be designated by prior notice. Any notice or approval delivered by facsimile will be deemed to have been delivered the day it is sent, unless it arrives after 5:00 p.m. at the recipient address or on a day other than a business day at the recipient address, in which case it shall be deemed delivered on the next business day. Any notice or approval sent by courier will be deemed delivered on the next business day after its date of posting if domestic or two business days after the day of posting if international.

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If to Company:

Eiger BioPharmaceuticals, Inc.
350 Cambridge Avenue, Suite 350
Palo Alto, CA 94306
Attn: Matthew Bys
Telephone: 415-203-0934
Email: mbvs@eigerbio.com

If to Consultant:

Colleen Craig, MD
300 Pasteur Drive, Room S025
Stanford, CA 94305
Attn: Colleen Craig, MD
Telephone: 650-350-2153
Email: cmcraig@stanford.edu

NON-COMPETITION

Consultant hereby covenants, acknowledges and agrees that it will not, at any time during [*] from the Effective Date, either directly or indirectly, as principal, agent, owner, partner, employee, consultant, shareholder, director or officer, as the case may be, in any manner whatsoever, own, be engaged in, be concerned with, be interested in, operate, have any financial interest in or advance, lend money to, guarantee the debts or obligations of, permit its name or any part thereof to be used or applied by any person, firm or corporation engaged in or concerned with or interested in, directly or indirectly, in any competitive activity in any territory in which the exendin products are currently planned to be commercialized, except as a passive shareholder holding less than [*] percent of the outstanding shares of a corporation offering its shares to the public and whose shares are listed and posted for trading on a recognized stock exchange. Notwithstanding the foregoing covenant, Company agrees that said covenant shall not be construed to preclude Consultant from continuing, during said [*] period following the Effective Date, their research and mechanistic studies relating to hyperinsulinemic hypoglycemia in connection with their employment at Stanford (as defined below).

CONSULTANT'S OBLIGATIONS SUBJECT TO THE EMPLOYMENT TERMS AND POLICIES OF STANFORD

Company acknowledges that it is aware that Consultant is a full time employee of the Leland Stanford Junior University ("***Stanford***"), and that under Stanford's employment terms and policies, it is permissible for Consultant to provide the Services desired by Company under this Agreement; *provided, however*, in the event of a conflict between Stanford's employment terms and policies and Consultant's obligations hereunder, Stanford's employment terms and policies shall govern, it being agreed that the parties shall in good faith attempt to amend this Agreement to reflect the intent of the parties with respect to the conflicting provision. In this connection, for example, Company acknowledges that it is aware that Stanford currently limits outside consulting services by its employees to a maximum of eight (8) hours per week.

GENERAL

Entire Agreement. This Agreement embodies the entire agreement and understanding between the Parties with respect to the subject matter hereof and supersedes all prior oral or written agreements and understandings relating to the subject matter hereof.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Modifications and Amendments. The terms and provisions of this Agreement may be modified or amended only by written agreement executed by the Parties hereto.

Waivers and Consents. The terms and provisions of this Agreement may be waived, or consent for the departure therefrom granted, only by written document executed by the Party entitled to the benefits of such terms or provisions. No such waiver or consent shall be deemed to be or shall constitute a waiver or consent with respect to any other terms or prov1s1ons of this Agreement, whether or not similar.

Assignment. Company may assign its rights and obligations hereunder to any person who or entity which succeeds to all or substantially all of Company's business or that aspect of Company's business in which Consultant is principally involved. Consultant's rights and obligations under this Agreement may not be assigned without the prior written consent of Company.

Benefit. All statements, representations, warranties, covenants, and agreements in this Agreement shall be binding on the Parties hereto and shall inure to the benefit of their respective successors and permitted assigns. Nothing in this Agreement shall be construed to create any rights or obligations except among the Parties hereto, and no person or entity shall be regarded as a third party beneficiary of this Agreement.

Headings and Captions. The headings and captions of the various subdivisions of this Agreement are for convenience of reference only and shall in no way modify, or affect the meaning or construction of, any of the terms or provisions hereof.

No Waiver of Rights, Powers, and Remedies. No failure or delay by a Party hereto in exercising any right, power or remedy under this Agreement, and no course of dealing between the Parties hereto, shall operate as a waiver of any such right, power or remedy of the Party. No single or partial exercise of any right, power or remedy under this Agreement by a Party hereto, nor any abandonment or discontinuance of steps to enforce any such right, power or remedy, shall preclude such Party from any other or further exercise thereof or the exercise of any other right, power or remedy hereunder. The election of any remedy by a Party hereto shall not constitute a waiver of the right of such Party to pursue other available remedies. No notice to or demand on a Party not expressly required under this Agreement shall entitle the Party receiving such notice or demand to any other or further notice or demand in similar or other circumstances or constitute a waiver of the rights of the Party giving such notice or demand to any other or further action in any circumstances without such notice or demand.

Independent Contractor. Company and Consultant agree that the relationship of Consultant to Company is at all times that of an independent contractor and not that of an employee, partner or joint-venturer of or with Company.

Counterparts. This Agreement may be executed in one or more counterparts that together shall constitute one and the same legal instrument.

Governing Law. This Agreement and the rights and obligations of the Parties hereunder shall be construed in accordance with and governed by the laws of the State of California, without giving effect to the conflict of law principles thereof.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Jurisdiction and Service of Process. Any legal action or proceeding with respect to this Agreement shall be brought in the state and Federal courts in the City of San Francisco, California. By execution and delivery of this Agreement, each of the Parties hereto accepts for itself and in respect of its property, generally and unconditionally, the jurisdiction of the aforesaid courts. Each of the Parties hereto irrevocably consents to the service of process of any of the aforementioned courts in any such action or proceeding by the mailing of copies thereof by certified mail, postage prepaid, to the party at its address set forth in Section 9 hereof.

Severability. The Parties intend this Agreement to be enforced as written. However, (i) if any portion or provision of this Agreement shall to any extent be declared illegal or unenforceable by a duly authorized court having jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law; and (ii) if any provision, or part thereof, is held to be unenforceable because of the duration of such provision or the geographic area covered thereby, the Parties agree that the court making such determination shall have the power to reduce the duration and/or geographic area of such provision, and/or to delete specific words and phrases, and in its reduced form such provision shall then be enforceable and shall be enforced.

Subcontracting. All services or materials for which Consultant contracts, subcontracts, or purchases for purposes of this Agreement shall be subject to prior written approval by Company. Consultant agrees to provide to Company a copy of any such contract for services or materials prior to execution for comment, in particular regarding costs, source, payment schedule, early termination penalties, confidentiality, and patent rights. Consultant hereby unconditionally guarantees the timely performance of Services and delivery of deliverables in accordance with this Agreement by any affiliate or permitted subcontractor hereunder.

Injunctive Relief. Consultant acknowledges that breach of Consultant's covenants contained in Section 3 or Section 10 may cause irreparable harm to the Company, which may not be compensable through monetary damages. Consultant therefore hereby acknowledges that in the event of a breach or a threatened breach by the them or their respective affiliates of such covenants, the Company will be entitled, in addition to any other rights, remedies or damages which may be available to Company, at law or in equity, to obtain an interim and permanent injunction in order to prevent or restrain any breach or threatened breach of this Agreement by Consultant or their affiliates, partners, employers, employees, servants, agents, representatives, and other persons directly or indirectly acting for, or on behalf of, or with, Consultant. Consultant further agree that the Company shall be entitled to injunctive relief without having to prove damages and shall be entitled to all of its costs and expenses incurred in order to obtain relief from any such breach under this Agreement

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

IN WITNESS WHEREOF, the Parties the parties hereto have executed this Consulting Agreement on the Effective Date written above.

Eiger BioPharmaceuticals, Inc.

By: _____
David A. Cory
Chairman, President and CEO, Eiger BioPharmaceuticals

CONSULTANT:

By: _____
Name: Colleen Craig, MD

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1. Services and Documentation.

CONSULTANT'S SERVICES MAY INCLUDE: (I) PROVIDING CONSULTATIVE SERVICES SURROUNDING THE EXENDIN DEVELOPMENT AND CLINICAL PROGRAM; (II) SPEAKING WITH INVESTORS, BANKS AND OTHER OUTSIDE PARTIES REGARDING THE EXENDIN DEVELOPMENT AND CLINICAL PROGRAM; AND (III) OTHER SERVICES AS MUTUALLY AGREED. CONSULTANT SHALL BE AVAILABLE, SUBJECT TO RECEIVING REASONABLE NOTICE FROM COMPANY, FOR MEETINGS TO PARTICIPATE AND FACILITATE COMMUNICATION AND WORK FLOW.

2. Term.

This Agreement shall be effective for the period beginning on the Effective Date and shall continue in full force for one (1) year thereafter, unless earlier terminated as permitted herein. This Agreement shall automatically renew for an annual period thereafter unless either Party provides written notice not less than [*] days prior to the then applicable annual expiration date.

3. Fees.

Consultant shall be paid [*] the first month for the value of her Services associated with the transfer of information, documents, and know-how related to the Exendin development and clinical program into the Company, and then the Consultant shall be paid at the rate of [*] per month for the remaining eleven (11) months of the first year of the Term, for time spent by Consultant on providing consulting Services requested by Company. In the interest of clarity, it is understood and agreed that Consultant will be paid said monthly amount for being available to provide Services reasonably requested by Company, regardless of whether, or the extent to which, Company requests Services. After the first anniversary, the fees shall paid on a per hour basis on actual consulting services time provided to the Company at the rate of [*] per hour.

It is further understood and agreed that if this Agreement is terminated during the initial year of the Term for any reason, the monthly amount due and payable to Consultant for the month in which such termination occurs will be appropriately pro-rated.

4. Payment Terms.

Company shall pay consultant on a monthly basis at the end of each month. Company will reimburse Consultant for any reasonable, authorized travel, lodging and other out-of-pocket expenses incurred by personnel in the course of performing hereunder, provided that Consultant furnishes Company with specific documentation therefore and Company approves all such expenses in advance.

All invoices for the above-described out-of-pocket expenses shall be submitted by Consultant directly to Company. Payment of all undisputed amounts shall be made within [*] days after receipt of invoice by Company. If Company has a dispute with any charges set forth in an invoice, Company shall notify Consultant of the dispute and provide Consultant details of the dispute. The Parties shall negotiate in good faith to promptly resolve disputes related to any invoiced amounts. Consultant shall maintain records of all time and expenses under this Agreement and shall provide Company reasonable access to the same upon request.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

EXHIBIT C

AMENDMENT NO. 1 TO LICENSE AGREEMENT

AMENDMENT NO. 1 TO LICENSE AGREEMENT

This Amendment No. 1 to License Agreement (the "***Amendment***") is effective as of day of September 2015 (the "***Amendment Effective Date***"), and amends that certain License Agreement effective May 4, 2015 (the "***Agreement***") among The Board of Trustees of the

Leland Stanford Junior University ("***Stanford***"), an institution of higher education having powers under the laws of the State of California, and Tracey McLaughlin and Colleen Craig (the "***Original Licensees***"), individuals having a principal place of business at Stanford University School of Medicine, and Eiger BioPharmaceuticals, Inc. ("***Eiger***"), as assignee of the Original Licensees pursuant to this Amendment. Collectively, Stanford, Original Licensees and Eiger are referred to as the "***Parties***".

RECITALS

A. The Original Licensees are assigning to Eiger all but certain specified rights and interests in technology with respect to Exendin for any and all uses, including the technology described within Stanford Docket S12-372 under the License Agreement;

B. Eiger desires to become assignee of the Original Licensees as set forth in this Amendment in order to further develop Exendin; and

C. Stanford desires to accept Eiger as an assignee of the Original Licensees and to amend Sections 1 and 13 of the Agreement as set forth in this Amendment.

AGREEMENT

Now, therefore, for good and valuable consideration, the receipt of which the parties acknowledge, the parties hereby agree as follows:

1. Upon the Amendment Effective Date, the Agreement shall be amended as follows:

   a. Eiger shall replace and be deemed the sole Licensee and assume all of the rights and obligations under the Agreement, and the Original Licensees shall have no rights or obligations under the Agreement.

   b. Within [*] days after the Amendment Effective Date, Eiger shall pay to Stanford [*] to an account designated by Stanford.

   c. Section 1 of the Agreement is amended to add the following clause to the end of the first sentence:

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

", including one or more provisional applications to be filed by Licensee at Licensee's discretion between the Amendment Effective Date and the date a PCT patent application claiming priority to Serial No. [*] is filed, the PCT application, and any US or foreign patents that issue on or claim priority to any of the foregoing."

d. Section 13 of the Agreement is hereby amended and restated to read in its entirety as follows:

"13. Assignment.

13.1 Permitted Assignment by Licensee. Subject to Section 13.3, Licensee may assign this Agreement: (a) as part of a sale or change of control, regardless of whether such a sale or change of control occurs through an asset sale, stock sale, merger or other combination, or any other transfer of Licensee's entire business or that part of Licensee's business that exercises all rights granted under this Agreement;
or

(b) to an Affiliate provided that Licensee remains liable to Stanford for the performance by its Affiliate.

13.2 Any Other Assignment by Licensee. Except pursuant to Section 13.1, any attempt to assign this Agreement by Licensee without Stanford's prior written consent is null and void.

13.3 Conditions of Assignment. Prior to any assignment, the following conditions must be met:

(a) Licensee must make best efforts to give Stanford [*] prior written notice of the assignment, including the new assignee's contact information; and

(b) the new assignee must agree in writing to Stanford to be bound by this Agreement; and

(c) Stanford must have received a [*] assignment fee.

13.4 After the Assignment. Upon a permitted assignment of this Agreement pursuant to this Section 13, Licensee will be released of liability under this Agreement and the term "***Eiger***" in this Amendment and "***Licensee***" in the Agreement will mean the assignee.***"***

2. Stanford and the Original Licensees each represent and warrant to Eiger the following:

a. as of the Amendment Effective Date, the Agreement remains in full force and effect;

b. no notice of any termination, noncompliance or breach has been delivered or received by either of Stanford or Original Licensees; and

c. none of Stanford or the Original Licensees is aware of noncompliance or claim that would result in a breach or termination of the Agreement.

3. Except as expressly set forth herein, the Agreement remains in full force and effect and shall not otherwise be amended except in writing entered into by Eiger (as Licensee) and Stanford.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

In witness whereof, the Parties hereto have executed and delivered this Amendment in their personal capacity or through their duly authorized officers or representatives, as the case may apply.

Stanford:

The Board of Trustees of the Leland Stanford Junior University

Signature: _____

Name: _____

Title: _____

Original Licensees (with respect to the Amendment and as assignors):

Signature: _____
Tracey McLaughlin

Signature: _____
Colleen Craig, M.D.

Eiger:

Eiger BioPharmaceuticals, Inc.

Signature: _____

Name: _____

Title: _____

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

EXHIBIT D

CAPITALIZATION TABLE

Security Type	Shares
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

Exhibit 10.10

LICENSE AGREEMENT

THIS LICENSE AGREEMENT (this "Agreement"), dated as of September 3, 2010, is by and between SCHERING CORPORATION, a New Jersey corporation having its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033 (hereinafter referred to as "Schering") and Eiger Biopharmaceuticals, Inc., a corporation organized and existing under the laws of the state of Delaware and having its principal place of business at 3350 W Bayshore Road, Suite 120, Palo Alto, CA 94303 (hereinafter referred to as "Licensee"). Schering and Licensee are sometimes referred to herein individually as a "Party" and collectively as the "Parties".

WHEREAS, Schering has developed the compound known as Sarasar/Lonafarnib (SCH 66336) and Schering is seeking to out-license rights to develop and commercialize Sarasar/Lonafarnib (SCH 66336);

WHEREAS, Licensee desires to develop and commercialize Sarasar/Lonafarnib (SCH 66336); and

WHEREAS, Licensee and Schering desire to enter into a license arrangement whereby Licensee will develop and commercialize Sarasar/Lonafarnib (SCH 66336).

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, Licensee and Schering hereby agree as follows:

ARTICLE I - DEFINITIONS

As used in this Agreement, the following capitalized terms, whether used in the singular or plural, shall have the respective meanings set forth below:

1.1 "Additional Indication" means an indication in the Field for the treatment of a virus that is different from the virus or disease condition caused by the virus that is the subject of the First Indication and any indication previously granted Regulatory Approval in the Field.

1.2 "Affiliate" means any individual or entity directly or indirectly controlling, controlled by or under common control with a Party to this Agreement. For purposes of this Agreement, the direct or indirect ownership of fifty percent (50%) or more of the outstanding voting securities of an entity, or the right to receive fifty percent (50%) or more of the profits or earnings of an entity shall be deemed to constitute control. Such other relationship as in fact results in actual control over the management, business and affairs of an entity shall also be deemed to constitute control.

1.3 “Business Day” means a day on which banking institutions in New York, New York, United States are open for business.

1.4 “Bulk Licensed Product” means finished capsules of the Licensed Product to be used in clinical trials packaged in bulk.

1.5 “Calendar Quarter” means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31, for so long as this Agreement is in effect.

1.6 “Calendar Year” means each successive period of twelve (12) months commencing on January 1 and ending on December 31, for so long as this Agreement is in effect.

1.7 “Combination Product” means a Licensed Product which comprises two (2) or more active ingredients, at least one (1) of which is a Licensed Compound.

1.8 “Commercialization” means, with respect to Licensed Product, any and all activities directed to the marketing, promotion, distribution, offering for sale and selling such product, importing and exporting such product for sale, and interacting with Regulatory Authorities regarding the foregoing. Commercialization shall also include Commercialization Studies. “Commercialize” has a correlative meaning.

1.9 “Commercialization Studies” means a study or data collection effort for a Licensed Product that is initiated in the Territory after receipt of Regulatory Approval for such Licensed Product and is principally intended to support the Commercialization of such Licensed Product in the Territory; provided, that such study or data collection effort is not principally to support or maintain a Regulatory Approval or obtain a label change or maintain a label.

1.10 “Commercially Reasonable Efforts” means the performance of obligations or tasks in a continuous, sustained manner consistent with the resources and efforts typically used in the pharmaceutical and biotechnology industries for an ethical drug of similar commercial potential as the Licensed Product, at a similar stage in its lifecycle, taking into consideration its safety and efficacy, the cost to Develop and Commercialize the product, the risks inherent in the Development and Commercialization of the product, its competitiveness compared to alternative products, the proprietary position of the product, the scope, timing and likelihood of Regulatory Approvals.

1.11 “Compound Patent Rights” means all patents and patent applications which, as of the Effective Date, are Controlled by Schering (and/or any of its Affiliates), other than the Program Patents, that are reasonably necessary for Licensee to make, have made, use, sell, offer for sale or import Licensed Product in the Territory and in the Field and that are listed on **Schedule 1.11**, and all (a) substitutions, divisions, continuations, continuations-in-part, reissues, renewals, registrations, certificates of invention, confirmations, re-examinations, extensions, supplementary protection certificates or the like, or the provisional applications of any such patents and patent applications of any of the foregoing; or (b) foreign equivalents of any of the foregoing.

1.12 “Controlled” means, with respect to a Person, that such Person (or any of its Affiliates) has the legal authority to grant a license or sublicense of intellectual property rights to another Person or to otherwise disclose proprietary information to another Person without breaching the terms of any agreement with a Third Party, or misappropriating the proprietary or trade secret information of a Third Party.

1.13 “Cross-Field Net Sales” means the total Net Sales of Licensed Product that are attributable to Cross-Field Sales in any given calendar year.

1.14 “Cross-Field Cost of Goods” means the fully burdened cost to manufacture all Licensed Product sold by a Party in the relevant calendar year (including both bulk and secondary packaging) divided by the total number of units of Licensed Product sold by such Party in the relevant calendar year multiplied by the number of units of Licensed Product sold by such Party that constitute Cross-Field Sales.

1.15 “Cross-Field Sales” means sales of Licensed Products Commercialized by (a) Schering or its collaborators for indications in the Field after the launch of Licensed Product in the Field, or (b) Licensee or its collaborators for indications outside the Field after launch of Licensed Product by Schering outside the Field, in each case as may be applicable following the Commercialization by both Parties of Licensed Product.

1.16 “Development” or “Develop” means all preclinical research and development activities and all clinical drug development activities, including, among other things: drug discovery, toxicology, formulation, statistical analysis and report writing, conducting clinical trials for the purpose of obtaining and maintaining Regulatory Approval (including without limitation, post-marketing studies), and regulatory affairs related to all of the foregoing. Development shall include all clinical studies (including Phase III-B) that are primarily intended to support or maintain a Regulatory Approval, maintain a label or obtain any label change, but shall exclude Commercialization Studies.

1.17 “Effective Date” shall have the meaning set forth in Section 12.1.

1.18 “Field” means the use of the Licensed Compound or Licensed Product for all human antiviral applications, except for the treatment of Hepatitis C virus, Hepatitis B virus, or HIV infections; provided, however, that the Field specifically includes, without limitation, the treatment of Hepatitis D virus infections, including the treatment of patients co-infected with Hepatitis D virus and either or both of (i) Hepatitis C virus and (ii) Hepatitis B virus.

1.19 “First Commercial Sale” means, with respect to a country in the Territory, the date that commercial quantities of a Licensed Product are first sold in such country to a Third Party on arm’s length terms by Licensee, its Affiliate or sublicensee for use in the Field after the receipt of Regulatory Approval in such country. Sales for test marketing, sampling and promotional uses, clinical trial purposes or compassionate or similar use shall not be considered to constitute a First Commercial Sale.

1.20 “First Indication” means treatment of the Hepatitis D virus infections in humans.

1.21 “FTE” means a full time equivalent person year of professional, scientific and/or technical work. An FTE shall consist of a total of [*] hours per year, with any portion of an FTE calculated based upon hours worked divided by such annual total.

1.22 “FTE Rate” means [*].

1.23 “FTE Cost” means, for any period of time, the product of (i) the actual total FTEs during such period and (ii) the FTE Rate.

1.24 “Good Clinical Practices” means the then current Good Clinical Practices as such term is defined from time to time by the United States Food and Drug Administration (“FDA”) or other relevant Governmental Authority having jurisdiction over the Development, manufacture or sale of Licensed Product in the Territory pursuant to its regulations, guidelines or otherwise.

1.25 “Good Laboratory Practices” means the current good laboratory practice regulations of the FDA as described in the United States Code of Federal Regulations (“CFR”) or any comparable corresponding foreign regulations or their respective successor regulations.

1.26 “Good Manufacturing Practices” means the then current Good Manufacturing Practices as such term is defined from time to time by the FDA or other relevant governmental authority having jurisdiction over the Development, manufacture or sale of Licensed Product in the Territory pursuant to its regulations, guidelines or otherwise.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

1.27 "Governmental Authority" means any court, agency, authority, department, regulatory body or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city or other political subdivision of any such government or any supranational organization of which any such country is a member.

1.28 "IND" means an investigational new drug application with respect to Licensed Product filed with the FDA for beginning clinical trials in humans, or any comparable application filed with the regulatory authorities of a country other than the United States prior to beginning clinical trials in humans in that country, as well as all supplements or amendments filed with respect to such filings.

1.29 "Know-How" means any and all proprietary data, information and materials (whether patentable or not) necessary or useful to the Licensed Compound, formulations, the Licensed Product, any Licensed Product Improvements, or the Development, Commercialization, Manufacture or use of any of the foregoing, which are not in the public domain, including, without limitation, (a) ideas, discoveries, inventions, improvements, technology or trade secrets, (b) pharmaceutical, chemical and biological materials, products, components or compositions, (c) methods, procedures, formulas, processes, tests, assays, techniques, regulatory requirements and strategies, (d) biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, clinical, safety, Manufacturing and quality control data and information related thereto, (e) technical and non-technical data and other information related to the foregoing, (f) drawings, plans, designs, diagrams, sketches, specifications or other documents containing or relating to such information or materials and (g) all applications, registrations, licenses, authorizations, approvals and correspondence submitted to Regulatory Authorities.

1.30 "Licensed Compound" means that certain Schering compound currently known as Sarasar/Lonafarnib (SCH 66336) with the chemical structure described in **Schedule 1.29**, including any prodrug, metabolite, salt, ester, solvate, hydrate and crystalline form thereof.

1.31 "Licensed Product" means any pharmaceutical product or product candidate that contains the Licensed Compound, either alone or in combination with one or more other active pharmaceutical ingredients, including without limitation, all formulations, line extensions and modes of administration thereof.

1.32 "Licensed Product Improvement" means any enhancement to Licensed Compound or any Licensed Product, including without limitation, formulations thereof; the inclusion of any inactive ingredient; and any alternative preparation, presentation, means of delivery, dosage, packaging or manufacture.

1.33 "Major European Country" means any of France, Germany, Italy, Spain or the United Kingdom.

1.34 "Manufacture" means all activities related to the manufacturing of a pharmaceutical product, or any ingredient thereof, including but not limited to test method development and stability testing, formulation, process development, manufacturing scale-up, manufacturing Licensed Compound or Licensed Product quality assurance/quality control development, quality control testing (including in-process release and stability testing), packaging, shipment and release of product or any component or ingredient thereof, quality assurance activities related to manufacturing and release of product or any component or ingredient thereof, and regulatory activities related to all of the foregoing.

1.35 "NDA" means a New Drug Application or its equivalent filed with the FDA seeking approval to market and sell a Licensed Product in the United States or any comparable application filed with a Governmental Authority of a country other than the United States.

1.36 "Net Sales" means, with respect to each country in the Territory, the aggregate gross amount invoiced by Licensee, its Affiliates or sublicensees (other than Schering and its Affiliates) on all sales of Licensed Product to an unaffiliated Third Party (including distributors) in an arm's length transaction, and exclusive of intercompany transfers or sales in the Territory, less the reasonable and customary deductions from such gross amounts, including: (i) normal and customary trade, cash and quantity discounts, allowances and credits; (ii) credits or allowances actually granted for damaged goods, returns or rejections of Licensed Product and retroactive price reductions; (iii)

sales, use, tariff or similar taxes (including duties or other governmental charges levied on, absorbed or otherwise imposed on the sale of Licensed Product including, without limitation, value added taxes or other governmental charges); (iv) transportation, freight, postage, shipping, customs duties and insurance charges; (v) charge back payments and rebates granted to managed health care organizations or their agencies, and purchasers and reimbursers or to trade customers, including but not limited to, wholesalers and chain and pharmacy buying groups; (vi) commissions paid to Third Parties other than sales personnel and sale representatives or sales agents; (vii) bad debt [*]; and (viii) rebates (or equivalents thereof) granted to or charged by national, state or local Governmental Authorities in a country in the Territory. Each of the deductions set forth above shall be reasonable and customary, and shall be determined on an accrual basis in accordance with United States Generally Accepted Accounting Principles (GAAP). Sales made in connection with test marketing, sampling and promotional uses, clinical trial purposes or charitable or compassionate use shall not be included in Net Sales.

In the event that Licensed Product is sold in the form of a Combination Product, Net Sales for such Combination Product will be calculated by multiplying actual Net Sales of such Combination Product by the fraction A/(A+B) where: A is the invoice price of the Licensed Product if sold separately by Licensee, or its Affiliate or sublicensee; and B is the invoice price of any other pharmaceutical product containing an active component or components (not including the Licensed Compound) in the Combination Product if sold separately by Licensee, or its Affiliate or sublicensee.

In the event that the Licensed Product is sold in the form of a Combination Product containing one or more active ingredients other than Licensed Compound and one or more such active ingredients of the Combination Product are not sold separately, then the above formula shall be modified such that A shall be the reasonable fully allocated manufacturing cost to Licensee, and/or its Affiliates or sublicenses of the Licensed Compound and B shall be the reasonable fully allocated manufacturing cost to Licensee, and/or its Affiliates or sublicenses of any other active component or components in the combination that is not the Licensed Compound.

To the extent that any discounts or other similar deductions that are based on sales to the customer of Combination Products are excluded from Net Sales of Licensed Products, such discounts or deductions shall be allocated to Licensed Products and the other relevant products on a pro rata basis based on the invoiced prices for such multiple products, which allocation in any event shall not disproportionately be applied to the Licensed Product.

1.37 “Person” means any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, governmental authority or agency, or any other entity not specifically listed herein.

1.38 “Phase II Study” means a controlled dose ranging clinical study in humans of a Licensed Product that would fall within the description set forth in 21 C.F.R. Part 312.21(b) (as amended from time to time) or other comparable regulation imposed by an applicable regulatory authority in any country other than the United States, to evaluate the efficacy and safety in the targeted patient population and to attempt to define an appropriate dosing regimen. For clarity, Phase II Study may include a Proof-of-Concept Trial.

1.39 “Phase III Study” means a large scale, pivotal clinical study of a Licensed Product that would fall within the description set forth in 21 C.F.R. Part 312.21(c) (as amended from time to time) or other comparable regulation imposed by an applicable regulatory authority in any country other than the United States performed after evidence suggesting effectiveness and safety of such Licensed Product and establishing a dose has been obtained in Phase II Study(ies) and adequacy of Phase II Study data has been confirmed by the applicable Regulatory Authority in a successful end of Phase II meeting. Phase III Studies are intended to evaluate the therapeutic efficacy and safety of a Licensed Product for the particular indication in question for purposes of submission to a Governmental Authority to obtain Regulatory Approval of the Licensed Product. Phase III Studies have a sufficient number of patients needed to evaluate the overall benefit-risk relationship of the Licensed Product, to provide an adequate basis for extrapolating the results to the general population, and to transmit that information in physician labeling.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

1.40 "Price Approvals" means, with respect to a Licensed Product, pricing or pricing reimbursement approval granted in each country in the Territory by the applicable Regulatory Authorities necessary for the commercial sale of such Licensed Product in such regulatory jurisdiction.

1.41 "Program IP" means the Program Know-How and Program Patents, collectively.

1.42 "Program Know-How" means any Know-How that is generated by or on behalf of one or more of the Parties and/or their respective Affiliates as a result of the Development of the Licensed Compound and/or the Licensed Product during the Term. For clarity, Program Know-How shall not include Schering Know-How.

1.43 "Program Patents" means (a) all patents and patent applications (other than the Compound Patent Rights) that claim discoveries, inventions, developments and/or innovations related to the Licensed Compound, including without limitation, Licensed Product Improvements, made by or on behalf of one or more of the Parties and/or their respective Affiliates during the term of this Agreement; (b) all substitutions, divisions, continuations, continuations-in-part, reissues, renewals, registrations, certificates of invention, confirmations, re-examinations, extensions, supplementary protection certificates or the like, or the provisional applications of any such patents and patent applications; or (c) are foreign equivalents of any of the above.

1.44 "Proof of Concept Trial" shall have the meaning set forth in Section 3.2(a).

1.45 "Proprietary Information" means, with respect to each of the Parties, any and all proprietary data, information or materials disclosed or otherwise made available by a Party or its Affiliates to the other Party or any of its Affiliates, including, without limitation, any such data, information or materials related to substances, formulations, devices (and/or any components thereof), techniques, technology, regulatory requirements and strategies, equipment, study results, reports, know-how, sources for manufacture and supply, patent position and business plans.

1.46 "Regulatory Application" means (a) the single application or set of applications for approval and/or pre-market approval to Manufacture and sell commercially a pharmaceutical therapeutic product submitted to the FDA including, without limitation, any related registrations with or notifications to the FDA, and (b) any foreign equivalents to such applications filed with any other national or supranational Regulatory Authority in the Territory, and (c) all supplements and amendments that may be filed with respect to any of the foregoing.

1.47 "Regulatory Approval" means any and all approvals (including Price Approvals), licenses, registrations, or authorizations of any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity necessary for the Manufacture, use, storage, import, export, transport, promotion, marketing or sale of a Licensed Product in the applicable country in the Territory.

1.48 "Regulatory Authority" means any United States federal, state, or local government, or any foreign government, or political subdivision thereof, or any multinational organization or authority or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof), or any governmental arbitrator or arbitral body with responsibility for granting licenses or approvals, including Regulatory Approvals, necessary for the marketing and sale of the Licensed Product in the applicable country in the Territory.

1.49 "Schering Know-How" means any and all Know-How owned or controlled by Schering and/or any of its Affiliates as of the Effective Date.

1.50 "[*]" means the earlier of [*] or [*].

1.51 "[*]" means the earlier of [*] or the date [*].

1.52 "Territory" means the entire world.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

1.53 "Third Party" means any Person other than a Party or its Affiliates.

1.54 "Valid Claim" means a claim of an issued and unexpired patent included within the Compound Patent Rights, which has not been (a) revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, (b) finally cancelled, withdrawn, abandoned or rejected by any administrative agency or other body of competent jurisdiction, (c) disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise, or (d) lost through an interference proceeding.

1.55 Additional Definitions. Each of the following definitions is set forth in the Section of this Agreement indicated below.

Definition	Section
AAA	13.2(a)
AEs	4.3(a)
Agents	9.1(b)
Agreement	Preamble
Annual Commercialization Report	3.4
CFR	1.21
Change of Control	14.1(c)
Data Services	3.7(c)(ii)
Development Plan	3.2(a)
Development Report	3.3
Effective Date	Preamble
FDA	1.20
Force Majeure	15.8
GAAP	1.36
Liability	11.1
LIBOR	7.5(e)
Licensee Field Product	3.7(c)(i)
Licensee Indemnified Party	11.2
Non- Licensee Field Product	3.7(c)(i)
Other Technology	2.5(d)
Phase II Completion Date	2.5(d)
Reacquisition License	2.5(b)
ROFN Notice	2.5(b)
ROFN Period	2.5(b)
Sales Tracking Methodology	3.7(c)(ii)
Schering Indemnified Party	11.1
Schering Prosecution Patents	8.3
Sublicense Agreement	2.5(e)
Term	12.1
Third Party Patent License	7.3(d)
Third Party Sublicense Agreement	2.5(b)

ARTICLE II - LICENSE

[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

2.1 License Grant. Subject to the terms and conditions of this Agreement, Schering hereby grants to Licensee an exclusive (even as to Schering), sublicensable (subject to the obligations and restrictions in Section 2.5), royalty bearing license, under the Compound Patent Rights, the Schering Know-How and Schering's interest in any solely or jointly owned Program IP to Develop, make, have made, use, import, export, Commercialize, sell, offer for sale, and market the Licensed Product in the Field in the Territory.

2.2 No Non-Permitted Use. Licensee hereby covenants that it shall not, nor shall it cause any Affiliate or sublicensee to knowingly use or practice, directly or indirectly, any Schering Know-How or Compound Patent Rights in conflict with the license granted under Section 2.1 above.

2.3 Retained Rights; Covenants. Schering retains any and all other rights under the Compound Patent Rights and Schering Know-How that are outside the scope of the license granted under Section 2.1. Licensee shall not grant any Third Party any license or right under any Compound Patent Rights and/or Schering Know-How, other than as expressly permitted in this Agreement.

2.4 No Other Licenses. Neither Party grants to the other Party any rights or licenses in or to any intellectual property, whether by implication, estoppel, or otherwise, other than the license rights that are expressly granted under this Agreement.

2.5 Sublicense Agreements; Right of First Negotiation.

(a) Except as provided in Section 2.5(b) and (c) and subject to the obligations and restrictions set forth in this Section 2.5, Licensee may grant sublicenses of the rights granted to it under Section 2.1 without Schering's consent.

(b) In the event Licensee intends to solicit bids from or determine the interest of a Third Party in connection with a sublicense to such Third Party of all rights to the Licensed Product granted by Schering to Licensee in Section 2.1 in the US, the Major European Countries, five or more countries in Asia Pacific (except Japan) and/or Japan in the Field, Licensee shall notify Schering of such intent in writing ("ROFN Notice"). In such an event, Licensee shall grant to Schering an exclusive right to enter into good faith negotiations with Licensee for an exclusive license to Schering for the rights to the Licensed Product that Licensee intends to sublicense to a Third Party ("Reacquisition License") for a period commencing on the date Schering receives the ROFN Notice and expiring [*] days thereafter (the "ROFN Period"). In the event that the Parties are in active negotiations, they will discuss in good faith an extension to such ROFN Period. During the ROFN Period, the Parties will negotiate in good faith the Reacquisition License on commercially reasonable terms and on financial terms that reasonably reflect Licensee's actual reasonably documented expenditures and investment Developing and Commercializing the Licensed Product. During the ROFN Period, if [*] that [*], Schering shall promptly notify Licensee [*] and the obligations of Licensee pursuant to this Section 2.5(b) and Section 2.5(c) shall terminate and Schering's right of first negotiation shall be deemed terminated, whether or not notification from Schering is provided hereunder.

(c) In the event that (i) Schering waives its exclusive right to enter into good faith negotiations with Licensee, (ii) Schering fails to notify Licensee that Schering elects to exercise its exclusive right to enter into good faith negotiations with Licensee within [*] of receipt of the ROFN Notice or (iii) the Parties are unable to agree upon terms of an agreement for the Reacquisition License within the ROFN Period, then Licensee shall be free to enter into a sublicense agreement with a Third Party for the rights that were the subject of the ROFN Notice ("Third Party Sublicense Agreement"); provided, however, that [*]. If [*], Licensee [*].

(d) In the event that Licensee receives Consideration (as defined herein) from its sublicensees in connection with any sublicense of the rights granted to Licensee in Section 2.1, Licensee shall pay to Schering, within [*] of the date Licensee receives such Consideration, a portion of such Consideration equal to the following: (i) [*] of the Consideration if the agreement for such sublicense is executed prior to [*]; (ii) [*] of the Consideration if the agreement for such sublicense is executed after [*] and prior to the date that [*]; and (iii) [*] if the agreement for such sublicense is executed after the date that [*]. For purposes of this section, "Consideration" means any and all amounts received by Licensee from its sublicensee in consideration for granting such sublicensee a sublicense of any of the rights granted by Schering to Licensee in Section 2.1, including any and all payments, including without

limitation, up-front payments and milestone payments; provided, however, that the following payments shall be specifically excluded from the calculation of Consideration: (1) all past and future research and development funding, (2) any loan amounts, (3) the fair market value of all equity issued by Licensee to a sublicensee (calculated according to the good faith determination of the board of directors of Licensee), (3) royalty payments, and (4) Development milestone payments for the corresponding milestones set forth in Section 7.2 up to the amounts that are payable as Development milestone payments due under Section 7.2 of this Agreement. In the event that Licensee grants a sublicense to sublicensee under the rights granted to Licensee in Section 2.1 above in conjunction with a license to other technology or products independently developed by Licensee that is not comprised of Compound Patent Rights or Schering Know-How ("Other Technology"), the amounts that are allocable to the inclusion of such Other Technology, as reasonably established by Licensee and sublicensee and set out in the applicable Sublicense Agreement (as defined below), or if no such allocation is made in the Sublicense Agreement, then the prorated portion of any fees or payments (not otherwise excluded or deducted pursuant to this Section 2.5(d)) made to Licensee under the applicable Sublicense Agreement in consideration for such Other Technology shall be excluded from the definition of Consideration. In the event that Licensee receives non-cash consideration as part of any Consideration paid under an applicable Sublicense Agreement, the fair market value of such non-cash consideration on the date of the transfer will be the cash amount used to calculate Schering's percentage share of such Consideration under this Section 2.5(d).

(e) Licensee shall, in each agreement under which it grants a sublicense under the license set forth in Section 2.1 (each, a "Sublicense Agreement"), require the sublicensee to transfer to Schering, if this Agreement terminates for breach by sublicensee, and to Licensee, if only such sublicense terminates, (i) all regulatory filings and Regulatory Approvals held, possessed or Controlled by such sublicensee and (ii) all patent rights and Know-How Controlled by such sublicensee relating to a Licensed Product or its use, Manufacture, sale, or importation (which patent rights and Know-How shall be transferred either by assignment or by a freely sublicensable exclusive license). In the event that this Agreement terminates other than for breach by a sublicensee, Schering shall enter in an agreement with each sublicensee on the same terms as the existing Sublicense Agreement. All Sublicense Agreements shall be consistent with the terms and conditions of this Agreement. Licensee shall use reasonable efforts to (I) procure the performance by any sublicensee of the terms of each applicable Sublicense Agreement, and (II) ensure that any sublicensee will comply with the applicable terms and conditions of this Agreement. Licensee hereby guarantees the performance of its sublicensees that are party to a Sublicense Agreement as permitted herein, and the grant of any such sublicense will not relieve Licensee of its obligations under this Agreement, except to the extent they are satisfactorily performed by such sublicensee.

2.6 Third Party Agreements. Schering shall remain responsible for the payment of royalty, milestone and other payment obligations under all agreements entered into by Schering prior to the Effective Date. In the event that Licensee reasonably determines that rights to intellectual property owned or Controlled by a Third Party are required in order to lawfully perform any activities under this Agreement, Licensee shall have the right to negotiate and acquire such rights through a license or otherwise and to deduct from the payments due to Schering under this Agreement [*] of the royalties paid by Licensee to such Third Party; provided, however, that such reduction shall not reduce the royalty rates otherwise applicable to the Net Sales of such Licensed Product by more than [*]. Licensee shall ensure that each Third Party clinical trial, contract Manufacturing, or service agreement entered into by Licensee or its Affiliates with respect to the Development of Licensed Product contains provisions obligating such Third Party contractor to assign and/or convey the appropriate intellectual property rights relating to Licensed Product to Licensee so that Licensee can assign and/or convey such rights to Schering as necessary under the terms and conditions of this Agreement.

2.7 Schering Assistance. Subject to all applicable provisions of this Agreement, Schering shall, promptly following the Effective Date, provide copies to Licensee of all information, including without limitation, Schering Know-How, except to the extent that such Schering Know-How has been previously disclosed to Licensee, that are in Schering's actual possession as of the Effective Date and are reasonably necessary for Licensee to use, make, have made, sell, offer to sale or import Licensed Product in the Field. Each Party shall bear its own costs in performing any activities pursuant to this Section 2.7.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

2.8 Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code. Each Party shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code or equivalent legislation in any other jurisdiction. Upon the bankruptcy of either Party, the other Party shall further be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property, and such, if not already in its possession, shall be promptly delivered to such other Party, unless the Party in bankruptcy elects to continue, and continues, to perform all of its obligations under this Agreement.

ARTICLE III – DEVELOPMENT AND COMMERCIALIZATION

3.1 Overview. As of the Effective Date, Licensee shall be solely responsible for the Development and Commercialization of the Licensed Product in the Field in the Territory. Licensee shall perform all of its Development activities in accordance with each IND for each applicable Licensed Product and with all applicable laws, rules and regulations.

3.2 Development and Commercialization Plans.

(a) Proof of Concept. Not later than the Effective Date, the Parties shall have agreed on the initial proposed protocol for a proof of concept trial for the Licensed Product in the Field, which shall be incorporated as part of this Agreement as **Schedule 3.2(a)** (the **"Proof of Concept Trial"**). The Parties acknowledge that the Proof of Concept Trial protocol may change in light of regulatory and clinical developments affecting the Licensed Product.

(b) Initial Development Plan. Not later than the Effective Date, the Parties shall have agreed on the initial Development plan and related timelines for the Licensed Product in the Field in the Territory, which shall be incorporated as part of this Agreement as **Schedule 3.2(b)** (as may be amended and updated annually in accordance with this Agreement, the "Development Plan"). Schering shall have the right to review and comment on the clinical protocols for studies conducted in accordance with the Development Plan, including review of the design and endpoints of such studies so that such studies will lead to an outcome that is credible and reproducible, which comments Licensee shall consider and incorporate as Licensee deems appropriate in good faith. At Schering's written request, the President of Schering's research division, or his designee, and the President of Licensee's research division or equivalent position, or his designee, shall meet to discuss such comments. Any revision of the clinical protocols shall be submitted to Schering promptly after their completion.

(c) Annual Development Plan. Not later than thirty (30) days after December 31 of each Calendar Year, Licensee shall submit to Schering an updated Development Plan for the pending Calendar Year. Such update shall take into account completion, commencement, changes in or cessation of Development activities not contemplated by the then-current Development Plan in sufficient detail to reflect the continued diligence of Licensee and shall reflect effort and resources consistent with other priority projects of Licensee. Schering shall have the right to comment on such annual plan. In the event Schering reasonably disagrees with the plan, Licensee shall consider Schering's comments for revising the plan. At Schering's written request, the President of Schering's research division, or his designee, and the President of Licensee's research division or equivalent position, or his designee, shall meet to discuss such comments. Any revision of the annual plan shall be submitted to Schering promptly after its completion.

(d) Commercial Launch. Licensee shall give Schering prior written notice of at least sixty (60) days of its intent to file an NDA for the Licensed Product and at that time shall further provide Schering with the anticipated date of First Commercial Sale for the Licensed Product in the country of filing. Licensee shall promptly provide Schering with notice of any Regulatory Approval of Licensed Product.

(e) Performance. Licensee shall perform, and shall ensure that its Affiliates, sublicensees, and Third Party contractors perform, the activities described in the Development Plan in a professional manner and in compliance with, to the extent applicable, Good Laboratory Practices, Good Clinical Practices and/or Good Manufacturing Practices and in compliance with all other applicable laws, rules, and regulations.

(f) Program Know-How. Each Party shall share Program Know-How owned or Controlled by it with the other Party in a reasonably detailed annual report ("Know-How Report"). Such Know-How Reports will be exchanged by the Parties prior to January 31st of each Calendar Year of the Term.

3.3 Development Reports. Licensee shall provide Schering with reasonably detailed reports describing its progress with respect to its Development efforts under this Agreement (hereinafter "Development Reports"). Such Development Reports shall be furnished annually until the First Commercial Sale. Each Development Report shall include the following information for the Licensed Product: a description of the Development work to be conducted during the year in reasonable detail, including, to the extent applicable, clinical studies, formulation work, Manufacturing work, other testing work and regulatory activity; timelines for such work; and key decision gates and milestones for such work.

3.4 Commercialization Reports. Commencing with the First Commercial Sale and thereafter on an annual basis, Licensee shall provide Schering with a written non-binding estimate of annual Net Sales for the Licensed Product in the Territory ("Annual Commercialization Report"). The Annual Commercialization Report shall also list all ongoing Commercialization Studies and the status of such studies in the United States, the Major European Countries and Japan.

3.5 Contract Sales Force. Notwithstanding anything to the contrary in this Agreement, Licensee shall not use the services of sales representatives employed by a Third Party as a contract sales force for Licensed Product without the prior written consent of Schering, such consent not to be unreasonably withheld.

3.6 Development and Commercialization Costs. Licensee shall be solely responsible for all costs related to the Development and/or Commercialization of the Licensed Product in the Field in the Territory following the Effective Date.

3.7 Commercialization of Licensed Product in the Field.

(a) Sales in the Field. Licensee hereby covenants that it shall not, nor shall it authorize any Affiliate, permitted sublicensee or Third Party contractor to Commercialize Licensed Product in the Territory for any use outside the Field. Schering hereby covenants that it shall not, nor shall it authorize any Affiliate, permitted sublicensee or Third Party contractor to Commercialize Licensed Product in the Territory for any use in the Field. Each Party acknowledges and understands that the other Party cannot control the ultimate use of the Licensed Products it sells and that the purpose of the foregoing covenant is to prevent such Party and its Affiliates and sublicensees from facilitating or encouraging uses in the other Party's Field. To the extent either Party can prove the other Party materially breached this Section 3.7(a), such material breach shall permit such non-breaching Party to terminate this Agreement for cause under Section 12.4.

(b) Licensed Product Packaging. Each Party shall use reasonable efforts to ensure that Licensed Product it is Commercializing (in the Field with respect to Licensee and outside the Field with respect to Schering) is packaged and identified in a manner such that it is distinguishable from Licensed Product that the other Party is Commercializing in its respective Field, including not using trademarks, trade dress, product appearance, product packaging, and other such distinguishing characteristics that the other Party is using or is planning to use. The Parties shall cooperate in good faith to share information about each Party's respective Licensed Product (which information shall constitute the Proprietary Information of the disclosing Party) in order to allow each Party to comply with its obligations under this Section 3.7(b).

(c) Lost Sales. The Parties recognize that Schering has the right to Commercialize Licensed Products for indications outside the Field. As a result, the Parties acknowledge and desire to address the potential for Cross-Field Sales such that the Parties agree as follows:

(i) If at any time during the Term of this Agreement, Schering, its Affiliate, or licensees (other than Licensee) is Commercializing a product containing a Licensed Compound approved by the relevant Regulatory Authority for an indication outside the Field (a "Non-Licensee Field Product") and Licensee is at the same time Commercializing a Licensed Product approved by the relevant Regulatory Authority for an indication in the Field (a "Licensee Field Product"), and a Party reasonably believes that (1) sales of a Non-Licensee Field Product are occurring or will occur for use in the approved indication in the Field; or (2) sales of the Licensee Field Product are occurring or will occur for use in the approved indication outside the Field, then such Party may provide notice to the other Party of its desire to track sales of Licensed Product for the relevant indications either in the Field or outside the Field, as applicable.

(ii) Upon receipt of notice under Section 3.7(c)(i), Schering and Licensee shall meet and agree upon a method of tracking sales of each possible Cross-Field Sale (a "Sales Tracking Methodology") including (1) the acquisition of one or more prescription data products or services (including, by way of example, IMS Xponent, NDC, or DDD data, data from the UNOS database or other data from organizations tracking transplant surgeries or patients) or other relevant pharmaceutical sales tracking research services (including, for example, use of random sampling, use of data regarding distribution channels as a proxy for indication-specific sales or development of mathematical models for approximating indication-specific sales) generally recognized in the pharmaceutical industry as having a reasonably high degree of accuracy and reliability in the tracking of sales of pharmaceutical products that have a similar nature as and are prescribed by similar physicians as the applicable License Product (collectively, the "Data Services"), and (ii) the methodology for applying any such resulting data and information provided by such Data Services to determine the extent of Cross-Field Sales.

(iii) In the event that Schering and Licensee are unable to agree on a Sales Tracking Methodology pursuant to Section 3.7(c)(ii), then the following default methodologies shall apply:

(1) With respect to each of the U.S., the Major EU Countries and Japan (collectively, the "Major Regulatory Jurisdictions"), in which a Licensee Field Product and a Non-Licensee Field Product have received Regulatory Approval and in which Data Services are available at a reasonable cost (evaluated in light of the anticipated accuracy of such data and anticipated magnitude of Cross-Field Sales in such country), sales in the approved indications in the Field in such country and sales in the approved indications outside the Field in such country shall be calculated for each Licensee Field Product and each Non-Licensee Field Product based on the sales levels reported by the Data Services for such country.

(2) For all countries other than Major Regulatory Jurisdictions, the percentage of sales of each Licensee Field Product attributable to use in the approved indications outside the Field and the percentage of sales of each Non-Licensee Field Product attributable to use in the approved indications in the Field shall be calculated from total sales of such products based on the assumption that the ratio of Cross-Field Sales to total sales in such country is equal to the ratio of Cross-Field Sales to total sales calculated across all Major Regulatory Jurisdictions in which Cross-Field Sales are evaluated pursuant to Section 3.7(c)(iii)(1). In the event that there are no Major Regulatory Jurisdictions in which Cross-Field Sales are evaluated pursuant to Section 3.7(c)(iii)(1), then no Sales Tracking Methodology shall apply unless and until the Parties agree on a Sales Tracking Methodology pursuant to Section 3.7(c)(ii).

(3) All costs associated with the acquisition and application of such Data Services and Sales Tracking Methodology shall be shared equally by the Parties. In addition, the Parties shall also meet and confer with respect to: (A) how to account for prescriptions to patients with multiple afflictions that are both within and outside the Field (i.e., approved indications in the Field and approved indications outside of the Field); (B) the right for each Party to audit, on a periodic basis, the application of the Data Services and Sales Tracking Methodology; and (C) a mechanism for addressing prescriptions that are tracked back to sole source purchasing agreements.

(iv) If in the course of applying the foregoing Data Services and methodologies to track sales of the Licensee Field Product and Non- Licensee Field Product pursuant to this Section 3.7, or in the course of performing an audit of such application by the other Party, a Party determines that Cross-Field Sales by the other Party are occurring at more than the greater of (A) [*] or (B) [*] of such Party's total Net Sales of the Licensed Product, then the Parties shall compensate each other as follows:

(1) In the event that there are Cross-Field Sales by Licensee, Licensee shall make a payment to Schering equal to the amount of Licensee's Cross-Field Net Sales less Licensee's Cross-Field Sales Cost of Goods; and

(2) In the event that there are Cross-Field Sales of Schering, Schering shall make a payment to License equal to the amount of Schering's Cross-Field Net Sales less Schering's Cross-Field Cost of Goods.

(v) Both Parties acknowledge that in order to respect confidentiality, it may not be possible to share non-publicly available data with each other. Therefore, any discussion or dispute in relation to the compensation for Cross-Field Sales under Section 3.7(iv) will be submitted to an independent auditor acceptable to both Parties and that is subject to appropriate confidentiality obligations.

ARTICLE IV - REGULATORY

4.1 Regulatory Filings Transfer.

(a) Schering covenants that, as of the Effective Date, it does not have any INDs or other Regulatory Applications covering the Licensed Product in the Field in the Territory. After the Effective Date, Licensee or its Affiliates or sublicensee, as applicable, shall hold all INDs and other Regulatory Applications and Regulatory Approvals for Licensed Product in the Field throughout the Territory. Schering shall be the exclusive owner of all INDs and other Regulatory Applications related to the Licensed Compounds and/or Licensed Product outside the Field in the Territory.

(b) As soon as practicable after the Effective Date (or such other date as mutually agreed by the Parties), Schering shall provide to Licensee one (1) electronic copy in Microsoft Word or Adobe Acrobat (whichever format the document is currently available) of (i) all material documents and records that have been generated by or on behalf of Schering with respect to any existing INDs and other Regulatory Applications covering the Licensed Product in the Territory sufficient for Eiger to file an IND in its own name; and (ii) any documents and records (not provided pursuant to (b)(i)) between Schering and Regulatory Authorities related to Licensed Product in the Field, if any.

(c) Licensee shall oversee, monitor and coordinate all regulatory actions, communications and filings with, and submissions to, the FDA and other Regulatory Authorities in the Territory with respect to Licensed Product in the Field.

(d) Licensee shall be solely responsible for interfacing, corresponding and meeting with the FDA and other Regulatory Authorities throughout the Territory with respect to Licensed Product in the Field. Each Party shall provide the other Party with copies of any material correspondence with FDA or other Regulatory Authorities in the United States, the Major European Countries and Japan relating to Regulatory Approval of Licensed Product, and respond to all reasonable inquiries by the other Party with respect thereto. Each Party shall also provide the other Party in a timely manner with meeting minutes from any material meetings with Regulatory Authorities in the United States, the Major European Countries and Japan concerning the Regulatory Approval of Licensed Product in the Field.

(e) Each Party shall provide to the other Party a table report on an annual basis that contains the status of Regulatory Approvals for the Licensed Product in the Territory.

(f) In the event that any Regulatory Authority (a) threatens or initiates any action to remove a Licensed Product from the market in any country in the Territory or (b) requires a Party, its Affiliates, or its sublicensees to distribute a "Dear Doctor" letter or its equivalent regarding use of Licensed Product in the Territory, such Party shall notify the other Party of such event within one (1) Business Day after such Party becomes aware of the action, threat, or requirement (as applicable). The Parties shall consult prior to initiating a recall or withdrawal of Licensed Product in the U.S., Japan, or a Major European Country; provided, however, that the final decision as to whether to recall or withdraw a Licensed Product in the Territory shall be made by (i) Licensee in the Field in its sole discretion, or (ii) Schering outside the Field in its sole discretion. A Party initiating a recall shall be responsible, at its sole expense, for conducting such recalls or taking such other necessary remedial action.

(g) Schering's obligations to provide assistance and support under this Section 4.1 shall not extend beyond Licensee's initial IND filing date with respect to the Licensed Product in the Field.

(h) Schering shall also provide copies of all safety reports with respect to Licensed Product outside of the Field in the Territory.

4.2 Right of Reference. Schering grants to Licensee, the right to reference its Regulatory Application(s) or Regulatory Approval(s) covering the Licensed Product outside the Field in the Territory only to the extent required for Licensee to Develop, Manufacture and obtain and maintain Regulatory Approvals for the Licensed Product in the Field in the Territory; provided, however, that (a) such right of reference shall be used solely for purposes of this Agreement and (b) all information which is subject to the right of reference shall be treated by Licensee as Proprietary Information of Schering in accordance with Article 9. Except with the prior written consent of Licensee, which shall not be unreasonably withheld, conditioned or delayed, Schering shall not withdraw any Regulatory Application or Regulatory Approval that is subject to reference by Licensee hereunder.

4.3 Pharmacovigilance.

(a) After the Effective Date, Licensee shall be solely responsible for the collection, review, assessment, tracking and regulatory submission of safety-related information with respect to adverse events ("AEs") associated with Licensed Product developed and commercialized by the Licensee in the Field, in accordance with 21 CFR 312.32, 314.80 and comparable applicable law governing AEs outside of the United States.

(b) Within a reasonable period of time following the Effective Date, Schering will provide Licensee with all AEs for Licensed Product to the extent not previously provided to Licensee. In addition to the foregoing, Schering shall transfer to Licensee in an agreed upon format, all relevant information (sufficient for Licensee to comply with its obligations to regulatory authorities and Investigators) regarding AEs that have been observed during any clinical trials conducted with the Licensed Product prior to the Effective Date.

(c) Within a reasonable period of time following receipt of all such information described in this Section 4.3, Licensee shall assume responsibility for maintaining a safety database for the Licensed Product developed and commercialized by the Licensee consistent with industry practices.

(d) During the Term of this Agreement, Schering shall notify Licensee of all information coming into its possession concerning AEs associated with commercial or clinical uses, studies, investigations or tests with Licensed Products in the Territory, involving the Licensed Product. In addition, Licensee shall forward to Schering, completed AE case reports associated with commercial or clinical uses, studies, investigations or tests with Licensed Products in the Field, within 5 business days for any death/fatal-life threatening assessed AEs or, within 10 business days for all other serious AEs, to assure Schering remains in compliance with Investigator notifications outside the Field. Such AE information should be faxed to Schering at (US) 973-921-7422. If deemed necessary by both Parties, within a reasonable period of time following the Effective Date, the Parties can begin to negotiate a pharmacovigilance agreement between the Parties to revise this mutual exchange of AE reports and safety information associated with the Licensed Product. Such pharmacovigilance agreement shall be implemented at a time sufficient to permit compliance, and shall supersede this Section 4.3(d).

ARTICLE V - DILIGENCE

5.1 Generally. Licensee shall use Commercially Reasonable Efforts to Develop the Licensed Product in the Field in accordance with the Development Plan and to Commercialize the Licensed Product in the Field in the Territory. The activities of any Affiliate or sublicensee of Licensee will be treated as activities of Licensee in any determination whether Licensee has satisfied its obligation with respect to this Article V.

5.2 Failure. Any failure by Licensee to comply with the obligations set forth in this Article V shall be deemed to be a material breach for which Schering may exercise its termination rights under Section 12.4(b).

ARTICLE VI – MANUFACTURING

6.1 Manufacturing Responsibility. With the exception of the supplies of Bulk Licensed Product to be supplied by Schering to Licensee pursuant to Section 6.2, Licensee will be responsible for the Manufacture of Licensed Product for Development and Commercialization of Licensed Product by Licensee, its Affiliates, and its sublicensees in the Field in the Territory. Schering shall, if requested by Licensee, reasonably cooperate in the transfer of any Manufacturing Know-How related to the Manufacture of the License Product in the Field and existing Third Party manufacturing agreements to Licensee for use pursuant to the license granted in Section 2.1.

6.2 Transfer of Bulk License Product. Promptly following the Effective Date of this Agreement, Schering shall transfer to Licensee free of charge (except reasonable costs of transfer as set forth below), in a mutually agreed manner, quantities of Bulk Licensed Product and related documentation (eg, batch records, process and release testing results, protocols, stability data and location of stability specimens) that are reasonably sufficient for Licensee to complete the Proof of Concept Trial and as are further described in **Schedule 6.2**.

6.3 Quality.

(a) Licensee shall be solely responsible for the release of Bulk Licensed Product transferred by Schering to Licensee pursuant to Section 6.2 to any clinical trial sites.

(b) Licensee will, within three (3) Business Days of receipt, notify Schering in writing of any complaints related to the manufacture of the Bulk Licensed Product transferred by Schering to Licensee pursuant to section 6.2.

(c) Licensee will, within one (1) Business Day, notify Schering of any recalls or stock recovery of an Bulk Licensed Product due to the quality of the Bulk Licensed Product.

6.4 Transfer of Manufacturing Technology.

(a) Upon request by Licensee, Schering shall transfer or cause to be transferred to Licensee, or a Third Party manufacturer designated by Licensee reasonably acceptable to Schering, all Schering Know-How that is reasonably necessary to enable Licensee or such Third Party manufacturer (as appropriate) to replicate the process employed by or on behalf of Schering to Manufacture Licensed Compound and, if applicable, the Licensed Product, in the Field to the extent not previously transferred.

(b) Licensee and/or its Third Party manufacturer shall use any information transferred pursuant to Section 6.3(a) in accordance with the license granted in Section 2.1 and solely for the purpose of Manufacturing the Licensed Compound and Licensed Product under this Agreement and for no other purpose.

(c) At the request of Licensee, during the six (6) month period following Licensee's request under Section 6.3(a), Schering will make employees and consultants of it and its Affiliates available to Licensee or Licensee's Third Party manufacturer for consultation, for a reasonable duration of time and at mutually agreed locations, as reasonably required by the Licensee or its Third Party manufacturer to ensure an orderly transition of Schering's manufacturing technology and operations. The scope of Schering's efforts for such consultation shall be defined in a

written manufacturing transition plan to be agreed upon by the Parties promptly after Licensee's request under Section 6.3(a). Licensee shall reimburse Schering for any FTE Costs and for all related reasonable out-of-pocket expenses, including reasonable travel expenses. Schering shall invoice Licensee monthly for such support.

(d) Schering's obligations to provide assistance and support under this Section 6.2 shall not extend beyond six (6) months after Licensee's request under Section 6.3(a).

ARTICLE VII - PAYMENTS; ROYALTIES AND REPORTS

7.1 Equity. Licensee shall contemporaneously issue equity in Licensee to Schering in the amount of Five Hundred Thousand Dollars ($500,000) pursuant to Share Purchase Agreement and related agreements dated as of even date herewith.

7.2 Development Milestones.

(a) First Indication. Licensee shall make each of the following one-time, non-refundable, non-creditable milestone payments to Schering upon first occurrence of the corresponding milestone event with respect to the Development of Licensed Product for the First Indication in the Field.

Event	Payment
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]

(b) Additional Indications. Licensee shall make each of the following one-time, non-refundable, non-creditable milestone payments to Schering upon first occurrence of the corresponding milestone events with respect to the Development of a Licensed Product for up to [*] Additional Indications.

Event	Payment
[*]	[*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]

(c) Payment of Milestones. Licensee shall notify Schering in writing within [*] after the achievement of each such milestone event giving rise to a payment obligation under this Section and Licensee shall pay Schering the indicated amount no later than [*] after notification to Schering of achievement of the specified milestone. For clarity, each of the milestones under this Section shall be payable to Schering regardless of whether Licensee, its Affiliates, or sublicensees achieves them. Under no circumstances will Licensee owe more than an aggregate total of Twenty-Seven Million Dollars ($27,000,000) pursuant to this Section 7.2.

7.3 Royalties.

(a) Royalty Rates. Subject to the terms and conditions of this Agreement, Licensee shall pay to Schering during the Royalty Term royalties on worldwide annual Net Sales of Licensed Product (for all indications and without regard to formulation) on a country-by-country basis in an amount equal to the following:

Calendar Year Net Sales	Royalty Rate
First [*]	[*]
Portion above [*] and up to and including [*]	[*]
Portion above [*] and up to and including [*]	[*]
Portion above [*]	[*]

(b) Term of Royalty Obligation. Royalties on the Licensed Product shall commence upon the First Commercial Sale of a Licensed Product in a particular country in the Territory and will continue on a product-by-product, country-by-country basis until the later of (i) the expiration of the last to expire Valid Claim covering a Licensed Product in such country or (ii) the [*] anniversary of the date of the First Commercial Sale of the Licensed Product in such country ("Royalty Term"). For clarity, during the Royal Term, the royalty payments pursuant to this Section 7.3 shall be payable regardless of whether Licensee, its Affiliate, or its sublicensee is selling the Licensed Product.

7.4 Reports; Payment of Royalty; Payment Exchange Rate and Currency Conversions.

(a) Royalties Paid Quarterly. Within [*] following the end of each Calendar Quarter, following the First Commercial Sale of a Licensed Product, Licensee shall furnish to Schering a written report for the Calendar Quarter showing the Net Sales of Licensed Product sold by Licensee, its Affiliates and its sublicensees in the Territory during such Calendar Quarter and the royalties payable under this Agreement for such Calendar Quarter. Such written report shall include the gross sales of Licensed Product on a country-by-country basis, an itemized calculation of any deductions taken from such gross sales to arrive at Net Sales for the applicable Calendar Quarter and the calculation of the amount of royalty payment due on such Net Sales. Simultaneously with the submission of the written report, Licensee shall pay to Schering, for the account of Licensee or the applicable Affiliate or sublicensee, as the case may be, a sum equal to the aggregate royalty due for such Calendar Quarter calculated in accordance with this Agreement.

(b) Method of Payment. All payments to be made by Licensee to Schering under this Agreement shall be paid by bank wire transfer in immediately available funds to such bank account as is designated in writing by Schering from time to time. Royalty payments shall be made in United States dollars to the extent that free conversion to United States dollars is permitted. The rate of exchange to be used in any such conversion from the currency in the country where such Net Sales are made shall be the rate of exchange used by Licensee for reporting such sales for United States financial statement purposes. If, due to restrictions or prohibitions imposed by national or international authority, payments cannot be made as aforesaid, the Parties shall consult with a view to finding a prompt and acceptable solution, and Licensee will make such payments in any manner as Schering may lawfully direct; provided that Licensee shall not be obligated to incur any additional out-of-pocket expenses in connection with such payments. Notwithstanding the foregoing, if royalties in any country cannot be remitted to Schering for any reason within [*] after the end of the Calendar Quarter during which they are earned, then Licensee shall be obligated to deposit the royalties in a bank account in such country in the name of Schering.

7.5 Maintenance of Records; Audits.

(a) Record Keeping by Licensee. Licensee and its Affiliates shall keep complete and accurate records in sufficient detail to enable the royalties payable hereunder to be determined. Upon [*] prior written notice from Schering, Licensee shall permit an independent certified public accounting firm of nationally recognized standing selected by Schering and reasonably acceptable to Licensee, at Schering's expense, to have access during normal business hours to examine the pertinent books and records of Licensee as may be reasonably necessary to verify the accuracy of the royalty reports hereunder. The examination shall be limited to the pertinent books and records for any year ending not more than [*] prior to the date of such request. An examination under this Section 7.5(a) shall not occur more than [*] in any Calendar Year. Licensee may designate competitively sensitive information which such auditor may not disclose to Schering, provided, however, that such designation shall not encompass the auditor's conclusions. The accounting firm shall disclose to Schering only whether the royalty reports are correct or incorrect and the specific details concerning any discrepancies. No other information shall be provided to Schering. All such accounting firms shall sign a confidentiality agreement (in form and substance reasonably acceptable to Licensee) as to any of Licensee's or its Affiliate's or sublicensee's confidential information which such accounting firms are provided, or to which they have access, while conducting any audit pursuant to this Section 7.5(a).

(b) Underpayments/Overpayments. If such accounting firm correctly concludes that additional royalties were owed during such period, Licensee shall pay such additional royalties within [*] of the date Schering delivers to Licensee such accounting firm's written report so correctly concluding. If such underpayment exceeds [*] of the sums correctly due Schering then the fees charged by such accounting firm for the work associated with the underpayment audit shall be paid by Licensee. Any overpayments by Licensee will be credited against future royalty obligations or refunded to Licensee within [*] following request by Licensee for the same, at Licensee's option.

(c) Record Keeping by Sublicensees. Licensee shall include in each Sublicense Agreement entered into pursuant to this Agreement a provision requiring the sublicensee to make reports to Licensee and to keep and maintain records of sales made pursuant to such sublicense and provide copies of such records to Licensee upon reasonable request in order for Schering's independent accountant to review such records to the same extent required of Licensee under this Agreement.

(d) Confidentiality. Schering shall treat all financial information subject to review under this Section 7.5, or under any Sublicense Agreement, in accordance with the confidentiality provisions of Article IX of this Agreement, and shall cause its accounting firm to enter into an acceptable confidentiality agreement with Licensee obligating it to retain all such financial information in confidence pursuant to such confidentiality agreement.

(e) Late Payments. Any amount owed by Licensee to Schering under this Agreement that is not paid within the applicable time period set forth herein shall accrue interest at the lower of the rate of the one (1) month London Inter-Bank Offering Rate ("LIBOR") plus [*] as set by the British Bankers Association as of the due date, or the maximum extent allowable by applicable law.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

ARTICLE VIII – INTELLECTUAL PROPERTY

8.1 Ownership of Intellectual Property. The Parties acknowledge and agree that Schering is and shall remain the owner of Compound Patent Rights and Schering Know-How.

8.2 Ownership of Program IP. All rights title and interest in or to any and all Program IP shall be determined in accordance with the following terms and conditions:

(a) Schering shall own all Program IP that is conceived solely by one or more employees, agents or consultants of Schering, its Affiliates, or Schering's subcontractors.

(b) Licensee shall own all Program IP that is conceived solely by one or more employees, agents or consultants of Licensee, its Affiliates, its subcontractors or its sublicensees.

(c) Licensee and Schering shall jointly own all Program IP that is conceived by one or more employees, agents or consultants of Schering or its Affiliates, together with one or more employees, agents or consultants of Licensee, its Affiliates, its subcontractors or its sublicensees.

(d) Licensee hereby grants to Schering an exclusive, sublicensable, royalty free license, under all Program IP to which Schering does not have an interest (either solely or jointly) solely to the extent necessary to Develop, make, have made, use, import, export, Commercialize, sell, offer for sale, and market the Licensed Product outside the Field in the Territory.

(e) Schering hereby grants to Licensee a non-exclusive, sublicensable (subject to the obligations and restrictions in Section 2.5), royalty free license, under all Program IP to which Licensee does not have an interest (either solely or jointly) solely to the extent necessary to Develop, make, have made, use, import, export, Commercialize, sell, offer for sale, and market the Licensed Product in the Field in the Territory.

(f) In the event of a dispute regarding inventorship, the Parties shall establish a procedure to resolve such dispute, which may include engaging independent Third Party patent attorneys jointly selected by the Parties to resolve such dispute. The Parties acknowledge that the ownership rights set out in this Section 8.2 are subject to the terms and conditions of this Agreement (including the licenses granted by Schering to Licensee), and subject thereto, each Party shall be free to use and exploit (which shall include the right to grant licenses under) any jointly owned Program IP, without any duty of accounting to the other Party.

8.3 Prosecution and Maintenance of Patents. Schering shall be solely responsible for the prosecution and maintenance in the Territory, on its own or through outside counsel, of the Compound Patent Rights and Program Patents solely owned or Controlled by Schering ("Schering Prosecution Patents"). Licensee shall be solely responsible for the prosecution and maintenance in the Territory, on its own or through outside counsel, of the Program Patent Rights solely owned or Controlled by Licensee or jointly owned by Schering and Licensee ("Licensee Prosecution Patents"). In connection with the Schering Prosecution Patents and the Licensee Prosecution Patents, each Party shall keep the other Party reasonably advised of the prosecuting Party's patent prosecution and maintenance and upon the written reasonable request of the other Party, will provide advance copies of any substantive papers related to the prosecution and maintenance of such patent filings.

8.4 Option of Licensee to Prosecute and Maintain Patents. Schering shall give notice to Licensee of any desire to cease prosecution and/or maintenance of the Schering Prosecution Patents and, in such case, shall permit Licensee, at Licensee's sole discretion, to continue the prosecution or maintenance at its own expense. If Licensee elects to continue the prosecution or maintenance, Schering shall execute such documents and perform such acts, at Licensee's expense, as may be reasonably necessary to effect an assignment of such Schering Prosecution Patents to Licensee. Any such assignment shall be completed in a timely manner to allow Licensee to continue such prosecution or maintenance. Any patents or patent applications so assigned shall no longer be considered Compound Patent Rights or Program Patents, as applicable.

8.5 Enforcement. In the event that either Licensee or Schering becomes aware of any alleged or threatened infringement in a country in the Field in the Territory of any issued patent within the Schering Prosecution Patents, it will notify the other Party in writing to that effect. [*] shall have three (3) months from the date of said notice to obtain a discontinuance of such infringement or bring suit against the Third Party infringer if such infringement relates to the use of the Licensed Product in the Field. If [*] fails to proceed within the specified 3-month period of time, then [*] shall have the right to obtain a discontinuance of such infringement or bring suit against the Third Party infringer only in the event that: (i) [*] a discontinuance of such infringement or [*] suit against the Third Party infringer [*] or (ii) [*] a discontinuance of such infringement or [*] suit against the Third Party infringer [*] and, in such discontinuance or suit, if [*], [*] discontinuance or suit. In the event that [*] is able to exercise its "step-in" rights to enforce Schering Prosecution Patents under this Section 8.5, [*] shall reimburse [*] costs and expenses for cooperation following the exercise of [*] step-in rights and all costs of enforcement going forward (provided, however, that if [*] later joins the enforcement action, then [*] shall be obligated for [*] costs and expenses after joining). The Party not initiating an action hereunder shall be notified prior to commencement of the trial, suit or action brought by the other Party and may join any such suit or action. In the event a Party joins an action hereunder, it shall pay one-half of the costs of such suit or action. In the event that a Party has joined in the action and shared in the costs thereof as set forth above, no settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the consent of joining Party, which consent shall not be unreasonably withheld. In the event that a Party has not joined the suit or action, such Party will in any event reasonably cooperate with the acting Party in any such suit or action and shall have the right to consult with such acting Party and be represented by its own counsel at its own expense. Any recovery or damages derived from a suit which a Party has joined and shared costs shall be used first to reimburse each of the Parties for its documented out-of-pocket legal expenses relating to the suit, with any remaining amounts to be shared [*], and [*]. Any recovery or damages derived from a suit which a Party has not joined shall be [*]. Schering shall incur no liability to Licensee as a consequence of litigation or any unfavorable decision resulting therefrom, including any decision holding any of the Schering Prosecution Patents invalid or unenforceable. Licensee shall incur no liability to Schering as a consequence of litigation or any unfavorable decision resulting therefrom brought pursuant to this Section 8.5.

8.6 Infringement and Third Party Licenses.

(a) Course of Action. In the event that Licensee's, its Affiliates' or its sublicensees' making, having made, importing, exporting, using, manufacturing, having manufactured Licensed Compound or Licensed Product or distributing, marketing, promoting, offering for sale or selling Licensed Product infringes, will infringe or is alleged by a Third Party to infringe, a claim of a patent that specifically covers the Licensed Compound, Licensed Product or its Manufacture, the Party becoming aware of same shall promptly notify the other. The Parties shall thereafter attempt to agree upon a course of action which may include: (i) modification of the Licensed Product or Licensed Compound or its use and Manufacture so as to be non-infringing; or (ii) obtaining a license or assignment from said Third Party.

(b) Licensee Right to Negotiate. In the event the Parties cannot agree on modifying the Licensed Product or Licensed Compound pursuant to Section 8.6(a), Licensee shall have the first right, but not the obligation, to negotiate with said Third Party for a suitable license or assignment. In the event that such negotiation results in a definitive agreement and the claimed infringement is for the making, using or selling of the Licensed Compound, then any lump sum or royalty payment made thereunder shall be paid by Licensee and Licensee shall have the right to offset such amount in accordance with Section 2.6. If Licensee fails to enter into a license or assignment pursuant to this Section 8.6(b), then following written notice from Licensee of such failure, Schering shall have the right to negotiate with said Third Party for a suitable license or assignment.

8.7 Third Party Infringement Suit. In the event that a Third Party sues Licensee alleging that Licensee's, its Affiliates' or its sublicensees' making, having made, importing, exporting, using, manufacturing, having manufactured Licensed Compound or Licensed Product or distributing, marketing, promoting, offering for sale or selling Licensed Product infringes or will infringe a claim of a patent that specifically covers the Licensed Compound, Licensed Product or its manufacture, then Licensee may elect to defend such suit and, during the period in which such suit is pending, notwithstanding Licensee's obligation to indemnify Schering under Section 11.1 herein, Licensee shall have the right to apply up to [*] of the royalties due Schering on sales of the allegedly infringing Licensed Product against its reasonable out-of-pocket litigation expenses.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

8.8 Abandonment. Schering shall promptly give notice to Licensee of the grant lapse, revocation, surrender, invalidation or abandonment of any Schering Prosecution Patents licensed to Licensee.

8.9 Patent Term Extension. The Party obtaining first Regulatory Approval for the Licensed Product in the United States shall be entitled to seek patent term extension in connection with the Compound Patent Rights. In the event that Licensee obtains such first Regulatory Approval, Schering agrees to cooperate with Licensee in the event that Licensee seeks patent term extension for the Compound Patent Rights; provided that Licensee reimburses all Schering's costs and expenses in connection therewith, including Schering's internal costs.

ARTICLE IX - CONFIDENTIALITY AND PUBLICATION

9.1 Confidentiality.

(a) Nondisclosure Obligation. Each of Schering and Licensee shall use any Proprietary Information received by it from the other Party only in accordance with this Agreement and shall not disclose, except as expressly provided herein, to any Third Party any such Proprietary Information without the prior written consent of the other Party. The foregoing obligations shall survive the expiration or termination of this Agreement for a period of [*]. These obligations shall not apply to Proprietary Information that:

(i) is known by the receiving Party at the time of its receipt, and not through a prior disclosure by the disclosing Party, as documented by the receiving Party's competent written records;

(ii) is at the time of disclosure, or thereafter becomes, published or otherwise part of the public domain without breach of this Agreement by the receiving Party;

(iii) is subsequently lawfully disclosed to the receiving Party by a Third Party who has the right to make such disclosure, as documented by the receiving Party's competent written records;

(iv) is independently developed by the receiving Party or its Affiliates and without the aid, use or application of any of the disclosing Party's Proprietary Information, and such independent development can be documented by the receiving Party's competent written records;

(v) is disclosed to any institutional review board of any entity conducting clinical trials with Licensed Product or to any governmental or other regulatory agencies in order to obtain patents or to gain approval to conduct clinical trials or to market Licensed Product, provided that such disclosure may be made only to the extent reasonably necessary to obtain such patents or authorizations.

(b) Permitted Disclosures.

(i) Notwithstanding anything to the contrary herein, the receiving Party may disclose the Proprietary Information of the disclosing Party solely to the extent such disclosure is required by applicable law, regulation, rule, act or order of any Governmental Authority or agency to be disclosed, provided that notice is promptly delivered to the disclosing Party in order to provide an opportunity to seek a protective order or other similar order with respect to such Proprietary Information and thereafter the receiving Party discloses to the requesting entity only the minimum information required to be disclosed in order to comply with the request, whether or not a protective order or other similar order is obtained by the disclosing Party.

(ii) Each of the Parties agrees not to disclose the terms and conditions of this Agreement to any Third Party and shall not make any public announcement or issue any press release in relation thereto, or otherwise publicize the existence or contents of this Agreement without the prior written approval by the other Party of the form, content and timing of such announcement, press release or other public disclosure. The foregoing provisions of this Section 9.1(b)(ii) notwithstanding, each Party shall have the right to disclose information related to the existence and/or terms and conditions of this Agreement as follows: (i) to the extent necessary (as reasonably

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

determined by its legal counsel) to be disclosed in order to comply with the rules and regulations of the United States Securities and Exchange Commission (or another similar securities exchange authority in Territory); (ii) to existing or potential acquirers or merger candidates, potential sublicensees or collaborators (to the extent contemplated hereunder), or to Affiliates, each of whom prior to disclosure must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article 9; (iii) to investment bankers, existing or potential investors, venture capital firms or other financial institutions or investors for purposes of obtaining financing, if such recipients are bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article 9; or (iv) in response to a valid order of a court or other governmental body. In each such event, the Party so required to disclose shall notify the other Party in advance of any such disclosure, shall provide the other Party with a reasonable opportunity to review and comment on the form and content of any such disclosure, shall disclose only the minimum information required in order to comply with such disclosure requirements, and shall use commercially reasonable efforts to obtain confidential treatment (to the fullest extent available).

9.2 Return of Confidential Information. The receiving Party will return all documents, and copies thereof, including those in the possession of the receiving Party's Agents pursuant to Section 9.1(b), containing the disclosing Party's Proprietary Information at any time upon the written request of the disclosing Party. However, the receiving Party may retain one (1) copy of such documents in a secure location solely for the purposes of (a) determining its obligations hereunder, (b) complying with any applicable regulatory requirements, or (c) defending against any product liability claim.

9.3 Breach of Confidentiality. The Parties agree that the disclosure of the disclosing Party's Proprietary Information in violation of this Agreement may cause the disclosing Party irreparable harm and that any breach or threatened breach of this Agreement by the receiving Party entitles disclosing Party to seek injunctive relief, in addition to any other legal or equitable remedies available to it, in any court of competent jurisdiction.

9.4 No Publicity. A Party may not use the name of the other Party in any publicity or advertising and may not issue a press release or otherwise publicize or disclose any information related to the existence of this Agreement or the terms or conditions herein, except (a) on the advice of its counsel as required by law (e.g., any Securities and Exchange Commission filings and disclosures) and provided the Party who will be disclosing such information has consulted with the other Party to the extent feasible prior to such disclosure with respect to the substance of the disclosure; or (b) as consented to in advance by the other Party in writing. The Parties shall agree on a form of initial press release that may be used by either Party on an ongoing basis to describe this Agreement. Each Party shall use good faith efforts to provide the other Party with reasonable advance written notice of any press release or other public disclosure of the results of any of its work on Licensed Products during the Term, provided that a Party's failure to do so shall not constitute a material breach of this Agreement.

9.5 Publication. To the extent that any proposed publication or public presentation (including without limitation any abstracts or manuscripts for publication, slides and texts of oral or other public presentations, and texts of any transmission through any electronic media (e.g., any computer access system such as the Internet, World Wide Web etc.) collectively or individually a "Public Presentation") to be made by a Party or its Affiliates may contain Proprietary Information of the other Party, the Party intending to make such publication or presentation shall provide to such other Party an advance copy of any such proposed publication or presentation prior to its submission or dissemination to any Third Party. The Party receiving such proposed publication or presentation shall have a period of at least [*] to review and recommend any changes it reasonably believes are necessary to protect its Proprietary Information. The Party intending to make such publication or presentation shall remove any Proprietary Information of the other Party therefrom; other changes recommended by such other Party shall not be unreasonably refused. In addition, if such publication could in the reviewing Party's reasonable judgment be expected to have a material adverse effect on the commercial value of the reviewing Party's Proprietary Information (or in the case of a proposed publication by Schering, on the Licensed Product in the Field), then the reviewing Party shall have the right to delay or prevent such publication as proposed by providing written notice to that effect during such [*] period. In the case where such publication may disclose any Program IP, any such delay shall be sufficiently long to permit the timely preparation and filing of a patent application(s) (or application(s) for other appropriate forms of protection) on the Proprietary Information involved.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

ARTICLE X - REPRESENTATIONS AND WARRANTIES

10.1 Representations and Warranties of Each Party. Each of Schering and Licensee hereby represents, warrants and covenants to the other Party hereto as follows:

(a) it is a corporation duly organized and validly existing under the laws of the state or other jurisdiction of its incorporation;

(b) the execution, delivery and performance of this Agreement by such Party has been duly authorized by all requisite corporate action;

(c) it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder;

(d) the execution, delivery and performance by such Party of this Agreement and its compliance with the terms and provisions herein does not and will not conflict with or result in a breach of any of the terms and provisions of or constitute a default under (i) a loan agreement, guaranty, financing agreement, agreement affecting a product or other agreement or instrument binding or affecting it or its property; (ii) the provisions of its corporate charter or other operative documents or bylaws; or (iii) any order, writ, injunction or decree of any court or governmental authority entered against it or by which any of its property is bound;

(e) except for the governmental and Regulatory Approvals required to market the Licensed Product in the Territory, the execution, delivery and performance of this Agreement by such Party does not require the consent, approval or authorization of, or notice, declaration, filing or registration with, any governmental or Regulatory Authority and the execution, delivery or performance of this Agreement will not violate any law, rule or regulation applicable to such Party;

(f) this Agreement has been duly authorized, executed and delivered and constitutes such Party's legal, valid and binding obligation enforceable against it in accordance with its terms subject, as to enforcement, to bankruptcy, insolvency, reorganization and other laws of general applicability relating to or affecting creditors' rights and to the availability of particular remedies under general equity principles; and

(g) it shall comply with all applicable material laws and regulations relating to its activities under this Agreement.

10.2 Schering's Representations. Schering hereby represents, warrants and covenants to Licensee as follows:

(a) to the best of Schering's knowledge, as of the Effective Date the Compound Patent Rights and Schering Know-How in the Field are subsisting and are not invalid or unenforceable, in whole or in part;

(b) as of the Effective Date, it has the full right, power and authority to grant all of the right, title and interest in the license granted under Article II herein;

(c) as of the Effective Date, it has not assigned, transferred, conveyed or otherwise encumbered, and during the Term of this Agreement will not assign, transfer, convey or otherwise encumber, its right, title and interest in the Compound Patent Rights or Schering Know-How in the Field except in accordance with this Agreement;

(d) to the best of Schering's knowledge, as of the Effective Date, it is the sole and exclusive owner of the Compound Patent Rights and Schering Know-How in the Field, all of which is free and clear of any liens, charges and encumbrances, and no other person, corporate or other private entity, or governmental entity or subdivision thereof, has or shall have any claim of ownership with respect to the Compound Patent Rights and Schering Know-How in the Field, whatsoever;

(e) to the best of Schering's knowledge, as of the Effective Date, the Manufacture, use or Commercialization of Licensed Compound and Licensed Product in the Field do not infringe any valid and enforceable patent rights owned or possessed by any Third Party;

(f) as of the Effective Date there are no claims, judgments or settlements against or owed by Schering or pending or threatened claims or litigation against Schering relating to Compound Patent Rights and Schering Know-How in the Field;

(g) to the best of Schering's knowledge as of the Effective Date, there are no commitments under or activities ongoing under any agreements with any third parties for the Manufacture of Licensed Product for Development and Commercialization of Licensed Product; and

(h) as of the Effective Date, it is in compliance in all material respects with any agreements with Third Parties concerning the Compound Patent Rights and Schering Know-How in the Field and during the Term of this Agreement (i) it will use Commercially Reasonable Efforts not to diminish the rights under the Compound Patent Rights, Schering Know-How and Program Know-How owned or Controlled by Schering in the Field granted to Licensee hereunder, including without limitation, by not committing or permitting any actions or omissions which would cause the breach of any such agreements between itself and Third Parties which provide for intellectual property rights applicable to the Manufacture or use of Licensed Compound or the Development, distribution, marketing, promotion or sale of Licensed Product in the Field, and (ii) it will provide Licensee promptly with notice of any such alleged breach.

10.3 Licensee's Representations. Licensee hereby represents, warrants and covenants to Schering as follows:

(a) during the Term of this Agreement it will not use in any capacity, in connection with performing its obligations under this Agreement, any individual who has been debarred pursuant to the United States Food, Drug and Cosmetic Act;

(b) it has or will have the capacity and resources to Develop and Commercialize Licensed Product and to Manufacture Licensed Compound as such obligations come due under this Agreement.

10.4 No Inconsistent Agreements. Neither Party has in effect, and after the Effective Date neither Party shall enter into, any oral or written agreement or arrangement that would be inconsistent with its obligations under this Agreement.

10.5 Representation by Legal Counsel. Each Party hereto represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting of this Agreement. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption shall exist or be implied against the Party which drafted such terms and provisions.

10.6 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH IN THIS ARTICLE 10, THE LICENSED COMPOUND, LICENSED PRODUCT, COMPOUND PATENT RIGHTS AND SCHERING KNOW-HOW ARE PROVIDED "AS IS" AND WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR ANY PARTICULAR PURPOSE OR ANY WARRANTY THAT THE USE OF THE MATERIALS WILL NOT INFRINGE OR VIOLATE ANY PATENT OR OTHER PROPRIETARY RIGHTS OF ANY THIRD PARTY.

10.7 No Warranty. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY HERETO MAKES ANY REPRESENTATION AND EXTENDS NO WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED. IN PARTICULAR, BUT WITHOUT LIMITATION, SCHERING MAKES NO REPRESENTATION AND EXTENDS NO WARRANTY CONCERNING WHETHER THE DESIGNATED COMPOUND OR A DESIGNATED PRODUCT IS FIT FOR ANY PARTICULAR PURPOSE OR SAFE FOR HUMAN CONSUMPTION.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

ARTICLE XI - INDEMNIFICATION AND LIMITATION ON LIABILITY

11.1 Indemnification by Licensee. Licensee shall indemnify, defend and hold harmless Schering and its Affiliates, and each of its and their respective employees, officers, directors and agents (each, a "Schering Indemnified Party") from and against any and all Third Party liability, loss, damage, cost, and expense (including reasonable attorneys' fees), subject to the limitations in Section 11.5 (collectively, a "Liability") which a Schering Indemnified Party may incur, suffer or be required to pay resulting from or arising out of (a) the Development, Manufacture, promotion, distribution, use, marketing, sale or other disposition of the Licensed Product in the Field by Licensee, its Affiliates or sublicensees, and (b) any material breach by Licensee of any of its representations, warranties and covenants contained in herein. Notwithstanding the foregoing, Licensee shall have no obligation under this Agreement to indemnify, defend or hold harmless any Schering Indemnified Party with respect to claims, demands, costs or judgments which result from the negligence or willful misconduct of Schering, its Affiliates, or any of their respective employees, officers, directors or agents, or Schering's breach of its obligations under this Agreement.

11.2 Indemnification by Schering. Schering shall indemnify, defend and hold harmless Licensee and its Affiliates, and each of its and their respective employees, officers, directors and agents (each, a "Licensee Indemnified Party") from and against any Third Party Liability which a Licensee Indemnified Party may incur, suffer or be required to pay resulting from or arising out of (i) the Development, Manufacture, promotion, distribution, use, marketing, sale or other disposition of the Licensed Product outside the Field by Schering, it Affiliates or sublicensees, and (ii) any material breach by Schering of any of its representations, warranties and covenants contained herein. Notwithstanding the foregoing, Schering shall have no obligation under this Agreement to indemnify, defend or hold harmless any Licensee Indemnified Party with respect to claims, demands, costs or judgments which result from the negligence or willful misconduct of Licensee, its Affiliates, or any of their respective employees, officers, directors or agents, or Licensee's breach of its obligations under this Agreement.

11.3 Conditions to Indemnification. The obligations of the indemnifying Party under Sections 11.1 and 11.2 are conditioned upon the delivery of written notice to the indemnifying Party of any potential Liability promptly after the indemnified Party becomes aware of such potential Liability. The indemnifying Party shall have the right to assume the defense of any suit or claim related to the Liability if it has assumed responsibility for the suit or claim in writing; however, if in the reasonable judgment of the indemnified Party, such suit or claim involves an issue or matter which could have a materially adverse effect on the business operations or assets of the indemnified Party, the indemnified Party may retain control of the defense or settlement thereof by providing written notice of such effect to the indemnifying Party, but in no event shall such action or notice be construed as a waiver of any indemnification rights that the indemnified Party may have at law or in equity. If the indemnifying Party defends the suit or claim, the indemnified Party may participate in (but not control) the defense thereof at its sole cost and expense. The foregoing notwithstanding, the Parties acknowledge and agree that failure of the indemnified Party to promptly notify the indemnifying Party of a potential Liability shall not constitute a waiver of, or result in the loss of, such Party's right to indemnification under Section 11.1 or 11.2, as appropriate, except to the extent that the indemnifying Party's rights, and/or its ability to defend against such Liability, are materially prejudiced by such failure to notify.

11.4 Settlements. Neither Party may settle a claim or action related to a Liability without the consent of the other Party, which consent shall not be unreasonably withheld, if such settlement would impose any monetary obligation on the other Party or require the other Party to submit to an injunction or otherwise limit the other Party's rights under this Agreement. Any payment made by a Party to settle any such claim or action shall be at its own cost and expense.

11.5 Limitation of Liability. With respect to any claim by one Party against the other arising out of the performance or failure of performance of the other Party under this Agreement, the Parties expressly agree that the liability of such Party to the other Party for such breach shall be limited under this Agreement or otherwise at law or equity to direct damages only and in no event shall a Party be liable for punitive, exemplary or consequential damages, except to the extent the liability of such Party relates to its indemnification obligations of the other Party pursuant to this Article XI or a breach of the obligations of confidentiality and non-use set forth in Article IX.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

11.6 Insurance. Each Party acknowledges and agrees that during the Term of this Agreement it shall maintain adequate insurance and/or a self-insurance program for liability insurance, including products liability and contractual liability insurance, to cover such Party's obligations under this Agreement. In the case of Licensee, it will maintain a minimum of [*] of coverage for such insurance. Each Party shall provide the other Party with evidence of such insurance and/or self-insurance program, upon request.

ARTICLE XII - TERM AND TERMINATION

12.1 **HSR Act.** To the extent required by the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended ("HSR Act"), each Party will (i) file or cause to be filed, as promptly as practicable after the date hereof, with the United States Federal Trade Commission ("FTC") and the United States Department of Justice ("DOJ"), all reports and other documents required to be filed by such Party under the HSR Act concerning the transactions contemplated hereby and (ii) promptly comply with or cause to be complied with any requests by the FTC or DOJ for additional information concerning such transactions, in each case so that the waiting period applicable to this Agreement and the transactions contemplated hereby under the HSR Act will expire as soon as practicable after the date hereof. Each Party agrees to request, and to cooperate with the other Party in requesting, early termination of any applicable waiting period under the HSR Act. Each Party shall be responsible for its own costs, expenses, and filing fees in connection with the filings. This Agreement is effective on the earlier of: (i) the date after which the waiting period pursuant to the HSR Act has expired, (ii) the date on which the transaction contemplated in this Agreement has been approved by the FTC and DOJ, and (iii) if the Parties agree that no filing is required under the HSR Act, the date first written above ("Effective Date").

12.2 Term and Expiration. This Agreement shall be effective as of the Effective Date and unless terminated earlier by mutual written agreement of the Parties or pursuant to Sections 12.3 or 12.4 below, the Term of this Agreement shall continue in effect on a country-by-country and product-by-product basis until the expiration of Licensee's obligation to pay royalties under Article VII herein (the "Term"). Upon expiration of this Agreement in its entirety, Licensee's license pursuant to Section 2.1 shall become a fully paid-up, non-exclusive, perpetual license.

12.3 Termination by Licensee.

(a) Licensee's Right to Terminate. Notwithstanding anything contained herein to the contrary, Licensee shall have the unilateral right to terminate this Agreement in its entirety with or without cause, at any time by giving [*] advance written notice to Schering. In the event of such termination, the rights and obligations hereunder shall terminate; provided, however, that any payment obligations due and owing as of the termination date shall continue. For clarity, milestones achieved prior to the date of notice shall continue to be payable, but no additional milestone payments shall apply for activities conducted during the [*] notice period.

(b) Effect of Termination. Notwithstanding anything contained herein to the contrary, following any termination of this Agreement in its entirety under Section 12.3(a), all rights and licenses granted to Licensee hereunder shall revert back to Schering pursuant to Section 12.6.

12.4 Termination for Cause.

(a) Termination for Cause. This Agreement may be terminated, in its entirety by written notice by either Party at any time during the Term of this Agreement:

(i) if the other Party is in breach of its material obligations hereunder (except with respect to a breach by Licensee of its obligations under Section 5.2, for which termination pursuant to Section 12.4(b) shall be Schering's sole and exclusive remedy) and has not cured such breach within [*] after receipt of written notice requesting cure of the breach, or in the event that the breach cannot be reasonably cured within such [*] period, has not initiated actions reasonably expected to cure such breach within [*] after receipt of such notice; or

(ii) upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings by or against the other Party, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party, or in the event a receiver or custodian is appointed for such Party's business, or if a substantial portion of such Party's business is subject to attachment or similar process; provided, however, that in the case of any involuntary bankruptcy proceeding, such right to terminate shall only become effective if the proceeding is not dismissed within [*] after the filing thereof.

(b) Termination for Breach of Section 5.2. Subject to the terms and conditions of this Section 12.4(b), Schering shall have the right, and such right shall be its sole and exclusive remedy and Licensee's sole and exclusive liability, to terminate this Agreement in the event Licensee and its Affiliates and sublicensees have ceased employing Commercially Reasonable Efforts to Develop and Commercialize Licensed Products in the Field for a period of [*] or more. In order to exercise such termination right, Schering shall first provide written notice to Licensee stating Schering's reasons for concluding that Licensee and its Affiliates and sublicensees have ceased employing Commercially Reasonable Efforts to Develop and Commercialize Licensed Product in the Field for the aforementioned period. If Licensee disagrees with the conclusion that Licensee and its Affiliates and sublicensees have ceased employing Commercially Reasonable Efforts to Develop and Commercialize Licensed Product in the Field for the aforementioned period, Licensee shall have a period of [*] after such written notice to provide Schering with evidence that Licensee or any of its Affiliates or sublicensees has not ceased employing Commercially Reasonable Efforts to Develop and Commercialize Licensed Product in the Field for the aforementioned period. If Licensee has not provided Schering with such evidence within such [*] period, this Agreement shall terminate at the end of such [*] period upon written notice from Schering. Notwithstanding the foregoing, if Schering gives Licensee a notice pursuant to the second sentence of this Section 12.4(b), and Licensee provides notice during the [*] period set forth above that Licensee disputes the conclusion that Licensee and its Affiliates and sublicensees have ceased employing Commercially Reasonable Efforts to Develop and Commercialize Licensed Product in the Field for the aforementioned period, then this Agreement shall not terminate unless and until an arbitrator issues a final award pursuant to Article 13 upholding the basis for termination under this Section 12.4(b).

(c) Effect of Termination for Cause on License.

(i) Termination by Licensee for Cause. In the event this Agreement is properly terminated by Licensee under Section 12.4(a), Licensee's license pursuant to Section 2.1 shall become a fully paid-up, perpetual license and the payments to be made to Schering by Licensee hereunder shall be reduced by [*]. Notwithstanding the preceding sentence, Licensee shall be responsible for the full amount of all payments due and owed to Schering prior to any written notice of termination.

(ii) Termination by Schering for Cause. In the event this Agreement is terminated by Schering under Section 12.4(a), the rights and license granted to Licensee under Section 2.1 of this Agreement shall terminate and all rights to the Licensed Compound and Licensed Product shall revert to Schering pursuant to Section 12.6.

12.5 Effect of Termination Generally. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination, and the provisions of Sections 10.6, 10.7, 12.3(b), 12.4(c), 12.5 and 12.6 and Articles IX, XIII and XIV shall survive the expiration or termination of this Agreement. Any expiration or early termination of this Agreement shall be without prejudice to the rights of either Party against the other that has accrued and is owed under this Agreement prior to termination, including the obligation to pay royalties for Licensed Product sold prior to such termination.

12.6 Licensed Product Reversion. Upon termination of this Agreement in its entirety by Schering for any reason or by Licensee pursuant to Section 12.3, the following provisions shall apply:

(a) Effective upon such termination, without further action by either Party, [*] license from Licensee under any Program IP that is owned or Controlled by Licensee that is necessary or useful for the use, Development, Manufacture, or Commercialization of the Licensed Product in the Field.

(b) Licensee shall reasonably cooperate with Schering in order to enable Schering to assume responsibility for the Development, Manufacture and/or Commercialization of all Licensed Products then being Developed, Manufactured or Commercialized by Licensee. Such cooperation and assistance shall be provided in a timely manner and shall include without limitation:

(i) Licensee shall transfer to Schering (or its nominee) all INDs, Regulatory Approvals, drug approval applications for Regulatory Approvals, and all supporting documentation for such filings and applications (to the extent assignable and not cancelled), made or obtained by Licensee or its Affiliates or any of its sublicensees to the extent relating to Licensed Product then being Commercialized or in Development.

(ii) Licensee shall assign to Schering all of its rights in any trademarks and shall transfer to Schering all of its rights in any domain names containing trademarks, in each case to the extent owned or Controlled by Licensee and to the extent that such trademarks have actually been or are planned to be utilized by Licensee in connection with the Commercialization of Licensed Product in the Field. Any assignment or transfer to Schering pursuant to this Section 12.6(b)(ii) shall be at no cost to Schering.

(iii) Licensee shall transfer to Schering (or its nominee), to the extent not previously provided, a copy of all Know-How owned or Controlled by Licensee relating to any Licensed Product then being Commercialized in the Field or in clinical Development by Licensee in the Field and reasonably necessary or useful for its continued Development, Manufacture and/or Commercialization in the Field, including without limitation all information contained in Licensee's regulatory and/or safety databases, all in the format then currently maintained by Licensee.

(iv) Upon the request of Schering, Licensee shall use reasonable and Commercially Reasonable Efforts to assign to Schering any Sublicense Agreements previously granted by Licensee related to the Development of Licensed Product in the Field.

(v) Upon the request of Schering, Licensee, its Affiliates and its sublicensees shall complete any clinical studies related to Licensed Product in the Field that (x) are being conducted under Licensee's IND for Licensed Product and are ongoing as of the date this Agreement is terminated, and (y) for which it is not practicable to transfer responsibility for conducting such studies to Schering; provided, however, that Schering agrees to reimburse Licensee for all Development costs incurred by Licensee after termination in completing such studies.

(vi) Upon the request of Schering, Licensee shall transfer to Schering, at a price to be agreed in good faith, which shall not be more than [*] of Licensee's fully allocated manufacturing cost for the Licensed Product, all quantities of Licensed Product in the possession of Licensee or its Affiliates (including, without limitation, clinical trial supplies and Licensed Product intended for commercial sale).

(vii) At Schering's request, Licensee shall promptly provide to Schering copies of all clinical trial, contract manufacturing, or service agreements entered into by Licensee or its Affiliates with respect to the Development or Manufacture of Licensed Product in the Field. At Schering's request, Licensee shall promptly assign (or cause to be assigned), such agreements to Schering, to the extent such assignment is permitted under such agreement or, in the case that such agreements involve products other than the Licensed Product, to the extent that the portion of the agreement involving solely the Development or Manufacture of Licensed Product in the Field can be assigned. In the event that such an assignment is not permitted under a particular clinical trial, contract manufacturing, or service agreement, then Licensee shall reasonably cooperate (at Schering's request) to assist Schering in obtaining the benefits of such agreement.

The Parties shall use commercially reasonable efforts to complete the transition of the Development, Manufacture and Commercialization of the Licensed Product from Licensee to Schering pursuant to this Section 12.6 as soon as is reasonably possible.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

ARTICLE XIII – DISPUTE RESOLUTION

13.1 Informal Discussions. Except as otherwise provided herein, in the event of any controversy or claim arising out of or relating to this Agreement, or the rights or obligations of the Parties hereunder, or the relationship between the Parties with respect to the Licensed Compound or Licensed Product, the Parties shall first try to settle their differences amicably between themselves. Either Party may initiate such informal dispute resolution by sending written notice of the dispute to the other Party, and within [*] after such notice appropriate representatives of the Parties shall meet for attempted resolution by good faith negotiations. If such representatives are unable to resolve promptly such disputed matter within the said [*], either Party may refer the matter by written notice to the other to the Chief Executive Officer of Schering, or his designee, and the Chief Executive Officer of Licensee, or his designee, for discussion and resolution. If such individuals or their designees are unable to resolve such dispute within [*] of such written notice, either Party may initiate arbitration proceedings in accordance with the provisions of this Article XIII.

3.2 Arbitration. All disputes arising out of or relating to this Agreement, or the rights or obligations of the Parties hereunder, or relating in any way to the relationship between the Parties with respect to the Licensed Compound or Licensed Product, other than disputes relating to patent rights which shall be submitted to a court of competent jurisdiction (unless mutually agreed by the Parties), shall be finally and exclusively settled by arbitration by a panel of three (3) arbitrators.

(a) The arbitration proceeding shall be conducted under the Commercial Arbitration Rules of the American Arbitration Association ("AAA") with such proceedings to be held in Newark, New Jersey, United States should a dispute be brought to arbitration by Licensee or in San Francisco, California should a dispute be brought to arbitration by Schering. In all cases, the arbitration proceedings shall be conducted in the English language, and all documents that are submitted in the proceeding shall be in the English language. Judgment upon the award rendered by arbitration may be issued and enforced by any court having competent jurisdiction.

(b) If a Party intends to begin an arbitration to resolve a dispute, such Party shall provide written notice to the other Party, informing the other Party of such intention and any statement of claim required under the applicable arbitration rules (as determined in accordance with Section 13.2(a)). Within [*] after its receipt of such notice, the other Party shall, by written notice to the Party initiating arbitration, add any additional issues to be resolved which would be considered mandatory counterclaims under New York law. For clarity, the resolution of any disputes regarding such counterclaims shall be conducted in the same proceedings as the initial claims.

(c) Within [*] following the receipt of the notice of arbitration, the Party referring the matter to arbitration shall appoint an arbitrator and promptly notify the other Party of such appointment. The other Party shall, upon receiving such notice, appoint a second arbitrator within [*], and the two (2) arbitrators shall, within [*] of the appointment of the second arbitrator, agree on the appointment of a third arbitrator who will act with them and be the chairperson of the arbitration panel. In the event that either Party shall fail to appoint an arbitrator within [*] after the commencement of the arbitration proceeding, the arbitrator shall be appointed by the AAA. In the event of the failure of the two (2) arbitrators to agree within [*] after the commencement of the arbitration proceeding to appoint the chairperson, the chairperson shall also be appointed by the AAA.

(i) All of the arbitrators shall have significant legal or business experience in pharmaceutical licensing matters. The arbitrators shall not be employees, directors or shareholders of either Party or any of their Affiliates.

(ii) Each Party shall have the right to be represented by counsel throughout the arbitration proceedings.

(iii) To the extent possible, the arbitration hearings and award will be maintained in confidence.

(iv) In any arbitration pursuant to this Agreement, the award or decision shall be rendered by a majority of the members of the panel provided for herein, with each member having one (1) vote. The arbitrators shall render a written decision with their resolution of the dispute, which decision shall set forth in reasonable detail the facts of the dispute, and the reasons for their decision. The decision of the arbitrators shall be final and non-appealable and binding on the Parties.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

13.3 Injunctive Relief. By agreeing to arbitration, the Parties do not intend to deprive any competent court of such court's jurisdiction to issue a pre-arbitral injunction, pre-arbitral attachment or other order in aid of the arbitration proceedings and the enforcement of any award or judgment. Without prejudice to such provisional remedies in aid of arbitration as may be available under the jurisdiction of a national court, the court of arbitration shall have full authority to grant provisional remedies and to award damages for failure of any Party to respect the court of arbitration's order to that effect.

13.4 Expenses of Arbitration and Expert Determination. Each Party shall bear its own attorneys' fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the arbitrators; *provided, however*, that the arbitrators shall be authorized to determine whether a Party is the prevailing Party, and if so, to award to that prevailing Party reimbursement for its reasonable attorneys' fees, costs and disbursements (including, for example, expert witness fees and expenses, photocopy charges and travel expenses). Absent the filing of an application to correct or vacate the arbitration award as permitted by applicable law, each Party shall fully perform and satisfy the arbitration award within [*] of the service of the award.

ARTICLE XIV - MISCELLANEOUS

14.1 Assignment/Change of Control.

(a) Assignment. Neither this Agreement nor any or all of the rights and obligations of a Party hereunder may be assigned, delegated, sold, transferred, sublicensed (except as otherwise provided herein) or otherwise disposed of, by operation of law or otherwise, to any Third Party without the prior written consent of the other Party, and any attempted assignment, delegation, sale, transfer, prohibited sublicense or other disposition, by operation of law or otherwise, of this Agreement or of any rights or obligations hereunder contrary to this Section 14.1 shall be a material breach of this Agreement by the attempting Party, and shall be void and without force or effect; provided, however, that either Party may, without such consent of such Party, assign the Agreement and its rights and obligations hereunder to an Affiliate or in connection with the transfer or sale of all or substantially all of its assets related to the division or the subject business, or in the event of its merger or consolidation or change in control or similar transaction. This Agreement shall be binding upon, and inure to the benefit of, each Party, its Affiliates, and its permitted successors and assigns. Each Party shall be responsible for the compliance by its Affiliates with the terms and conditions of this Agreement.

(b) Change of Control of Licensee. In the event that any Change of Control (as defined below) causes Licensee's rights and obligations hereunder to pass to any Third Party, such Third Party shall, within [*] after the effective date of such Change of Control, notify Schering of its intentions with regard to the Development and Commercialization of the Licensed Product under this Agreement. If the Third Party succeeding to Licensee's rights and obligations under this Agreement decides it will not continue the Development and/or Commercialization of the Licensed Product, then Schering shall have the right to terminate this Agreement upon [*] written notice to Licensee without any opportunity to cure and the effects of such termination shall be as set forth in Section 12.6. If the Third Party succeeding to Licensee's rights and obligations under this Agreement decides to continue the Development and Commercialization of the Licensed Product, then all of the rights and obligations of Licensee under this Agreement shall inure to such Third Party; provided, that for the immediate [*] period following such Change of Control, such Third Party shall follow the same Development Plan and budget as was in effect prior to such Change of Control; and provided, further that within such [*] period the Third Party successor shall submit to Schering a new Development Plan for the next succeeding [*] period, which shall not, without the prior written approval of Schering, which approval shall not be unreasonably withheld, materially differ from the Development Plan in effect prior to such Change of Control.

(c) Definition of Change of Control. As used in this Section 14.1 the term "Change of Control" means (i) any merger, reorganization, consolidation or combination in which Licensee is not the surviving corporation, or (ii) any "person" (within the meaning of Sections 13(d) and 14 (d)(2) of the Securities Exchange Act of 1934), excluding Licensee and its Affiliates, is or becomes the beneficial owner, directly or indirectly, of securities of Licensee representing 50% or more of either (A) the then-outstanding shares of common stock of Licensee or its parent

corporation, or (B) the combined voting power of Licensee's then-outstanding voting securities; or (C) if individuals who as of the Effective Date constitute the Board of Directors of Licensee or its parent corporation (the "Incumbent Board") cease for any reason to constitute at least a majority of such Board of Directors; provided, however, that any individual becoming a director subsequent to the Effective Date whose election, or nomination for election by Licensee's stockholders, was approved by a vote of at least a majority of the directors then comprising the Incumbent Board shall be considered as though such individual were a member of the Incumbent Board, but excluding, for this purpose, any such individual whose initial assumption of office occurs as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents by or on behalf of a person other than the Incumbent Board; or (D) approval by the stockholders of Licensee of a complete liquidation or the complete dissolution of Licensee.

14.2 Governing Law. This Agreement shall be governed, interpreted and construed in accordance with the laws of the State of New York, without giving effect to its conflict of law principles. Subject to the terms of this Agreement, all disputes under this Agreement shall be governed by binding arbitration pursuant to the mechanism set forth in Article XIII herein.

14.3 Waiver. Any delay or failure in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, nor operate to bar the exercise or enforcement thereof at any time or times thereafter, excepting only as to an express written and signed waiver as to a particular matter for a particular period of time.

14.4 Independent Relationship. Nothing herein contained shall be deemed to create an employment, agency, joint venture or partnership relationship between the Parties hereto or any of their agents or employees, or any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party. Neither Party shall have any power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever.

14.5 Export Control. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States of America which may be imposed upon or related to Schering or Licensee from time to time by the government of the United States of America. Furthermore, Licensee agrees that it will not export, directly or indirectly, any technical information acquired from Schering under this Agreement or any products using such technical information to any country for which the United States government or any agency thereof at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the Department of Commerce or other agency of the United States government when required by an applicable statute or regulation.

14.6 Entire Agreement; Amendment. This Agreement, including the Exhibits and Schedules hereto and thereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto and supersedes and terminates all prior agreements and understandings between the Parties with regard to the subject matter of this Agreement in the Territory. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change, waiver or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party. As of the Effective Date, this Agreement supersedes and terminates that certain Secrecy Agreement between the Parties effective as of November 20, 2008.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

14.7 Notices. Any notice required or permitted to be given or sent under this Agreement shall be hand delivered or sent by express delivery service or certified or registered mail, postage prepaid, or by facsimile transmission (with written confirmation copy by registered first-class mail) to the Parties at the addresses and facsimile numbers indicated below.

If to Schering, to:

Schering Corporation
c/o Merck & Co., Inc.
One Merck Drive
Attention: Chief Licensing Officer
P.O. Box 100, WS2A-30
Whitehouse Station, NJ 08889-0100
Facsimile: (908)735-1214

with a copy to:

Schering Corporation
c/o Merck & Co., inc.
One Merck Drive
P.O. Box 100
Whitehouse Station, NJ 08889-0100
Attn: Vice President and Associate General Counsel,
Business Development & Licensing
Fax No.: 908-735-1345

If to Licensee, to:

Eiger BioPharmaceuticals, Inc.
3350 W Bayshore Road, Suite 120
Palo Alto, CA 94303
Attn: Chief Executive Officer
Fax No.: 650-320-9901

with a copy to:

Cooley, LLP
3000 El Camino Real
Five Palo Alto Square
Palo Alto, CA 94306
Attn: Glen Y. Sato, Esq.
Fax No.: 650-849-7400

Any such notice shall be deemed to have been received on the earlier of the date actually received or the date five (5) days after the same was posted or sent. Either Party may change its address or its facsimile number by giving the other Party written notice, delivered in accordance with this Section 14.7.

14.8 Force Majeure. Failure of any Party to perform its obligations under this Agreement (except the obligation to make payments when properly due) shall not subject such Party to any liability or place them in breach of any term or condition of this Agreement to the other Party if such failure is due to any cause beyond the reasonable control of such non-performing Party ("Force Majeure"), unless conclusive evidence to the contrary is provided. Causes of non-performance constituting Force Majeure shall include, without limitation, acts of God, fire, explosion, flood, drought, earthquake, war, riot, sabotage, embargo, strikes or other labor trouble, failure in whole or in part of suppliers to deliver on schedule materials, equipment or machinery, interruption of or delay in

transportation, a national health emergency or compliance with any order or regulation of any government entity acting with color of right. The Party affected shall promptly notify the other Party of the condition constituting Force Majeure as defined herein and shall exert reasonable efforts to eliminate, cure and overcome any such causes and to resume performance of its obligations with all possible speed; provided that nothing herein shall obligate a Party to settle on terms unsatisfactory to such Party any strike, lockout or other labor difficulty, any investigation or other proceeding by any public authority or any litigation by any Third Party. If a condition constituting Force Majeure as defined herein exists for more than ninety (90) consecutive days, the Parties shall meet to negotiate a mutually satisfactory resolution to the problem, if practicable. If the Parties cannot in good faith reach a satisfactory resolution to the problem within sixty (60) days of meeting, the matter shall be handled pursuant to the dispute resolution provisions of Article XIII herein.

14.9 Severability. If any provision of this Agreement is declared illegal, invalid or unenforceable by a court having competent jurisdiction, it is mutually agreed that this Agreement shall continue in accordance with its terms except for the part declared invalid or unenforceable by order of such court, provided, however, that in the event that the terms and conditions of this Agreement are materially altered, the Parties will, in good faith, renegotiate the terms and conditions of this Agreement to reasonably substitute such invalid or unenforceable provisions in light of the intent of this Agreement.

14.10 Counterpart. This Agreement shall become binding when any one or more counterparts of it, individually or taken together, shall bear the signatures of each of the Parties hereto. This Agreement may be executed in any number of counterparts, each of which shall be an original as against either Party whose signature appears thereon, but all of which taken together shall constitute but one and the same instrument.

14.11 Captions. The captions of this Agreement are solely for the convenience of reference and shall not affect its interpretation.

14.12 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

IN WITNESS WHEREOF, this Agreement has been executed by the duly authorized representatives of the Parties.

SCHERING CORPORATION

By: /s/ David Nicholson
Title: SVP Licensing & Knowledge Management

EIGER BIOPHARMACEUTICALS, INC.

By: /s/ David Cory
Title: CEO

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SCHEDULE 1.11

COMPOUND PATENT RIGHTS

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Case Number	Status	Appln No.	Appln Date	Patent Number	Grant Date	Exp Date
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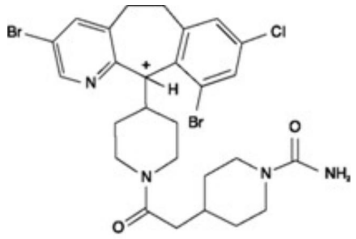
[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

SCHEDULE 1.29

LICENSED COMPOUND



Sarasar/Lonafarnib (SCH 66366)

(4(2[4-[(11R)-3,10-dibromo-8-chloro-6,11-dihydro-5H-benzo[5,6]-cyclohepta [1,2b]pyridin-11yl)-piperidino]-2-oxoethyl]-1-piperidinecarboxamide).

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

SCHEDULE 3.2(a)

PROOF OF CONCEPT PROTOCOL

[*]

Patients will undergo pre-study screening, which may include the following assessments:

- [*]

[*].

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

SCHEDULE 3.2(b)

INITIAL DEVELOPMENT PLAN

The initial plan for development of the Licensed Compound in the Field includes the following studies.

[*]

Goal: [*]

Dosages assessed: [*]

Primary outcome: [*]

Primary endpoint: [*]

Secondary outcomes:

[*]

Projected number of patients: [*]

Study location: [*]

Number of sites: [*]

Projected study initiation: [*]

Projected study termination: [*]

[*] Study

[*]

Goal: [*]

Dosages assessed: [*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Primary outcome:	[*]
Primary endpoint:	[*]
Secondary outcomes:	
[*]	
Projected number of patients:	[*]
Study location:	[*]
Number of sites:	[*]
Projected study initiation:	[*]
Projected study termination:	[*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

[*] Study

[*]

Goal:	[*].
Dosage assessed:	[*]
Primary outcome:	[*]
Primary endpoint:	[*]
Secondary outcomes:	
[*]	
Projected number of patients:	[*]
Study location:	[*]
Number of sites:	[*]
Projected study initiation:	[*]
Projected study termination:	[*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

SCHEDULE 6.2

BULK LICENSE PRODUCT TO BE TRANSFERRED

The Bulk Licensed Product to be transferred from Schering to Licensee is [*] of Licensed Product in the form of [*].

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

EXHIBIT 10.12

EXECUTION VERSION
Confidential

LICENSE AGREEMENT

between

EIGER BIOPHARMACEUTICALS, INC.

and

BRISTOL-MYERS SQUIBB COMPANY

LICENSE AGREEMENT

THIS LICENSE AGREEMENT (this "Agreement") is made and entered into as of the date last signed by a party below (the "Effective Date"), by and between **Bristol-Myers Squibb Company**, a Delaware corporation headquartered at 345 Park Avenue, New York, New York 10154 ("BMS"), and **Eiger BioPharmaceuticals, Inc.,** a Delaware corporation, with offices at 350 Cambridge Ave, Suite 350, Palo Alto, CA 94306 ("Eiger"). BMS and Eiger are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

RECITALS

WHEREAS, BMS and its Affiliates Control (as defined below) certain patent rights and know-how rights with respect to the Licensed Compounds (as defined below); and

WHEREAS, Eiger desires to obtain from BMS the licenses set forth herein, and BMS desires to grant such licenses to Eiger, all on the terms and conditions set forth in this Agreement;

NOW, THEREFORE in consideration of the foregoing and the mutual agreements set forth below, the Parties agree as follows:

ARTICLE 1

DEFINITIONS

The terms in this Agreement with initial letters capitalized, whether used in the singular or the plural, shall have the meaning set forth below or, if not listed below, the meaning designated in places throughout this Agreement.

1.1 "Act" means the United States Food, Drug and Cosmetic Act, as amended.

1.2 "Affiliate" of a Person means any other Person which (directly or indirectly) is controlled by, controls or is under common control with such Person. For the purposes of this definition, the term "control" (including, with correlative meanings, the terms "controlled by" and "under common control with") as used with respect to a Person, shall mean the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise, and "control" shall be presumed to exist if either of the following conditions is met: (i) in the case of a corporate entity, direct or indirect ownership of voting securities entitled to cast at least fifty percent (50%) of the votes in the election of directors or (ii) in the case of a non-corporate entity, direct or indirect ownership of at least fifty percent (50%) of the equity interests with the power to direct the management and policies of such entity.

1.3 "Approval" means, with respect to any Licensed Product in any regulatory jurisdiction, approval from the applicable Regulatory Authority sufficient for the manufacture, distribution, use, marketing, and sale of the Licensed Product in such jurisdiction in accordance with applicable Laws; provided, however

that for purposes of the U.S., Approval means BLA Approval and for purposes of the EU, Approval means MAA Approval.

1.4 "BLA" means a biologics license application for a new biologics drug filed with the FDA required for marketing approval for the applicable Licensed Product in the U.S.

1.5 "BLA Approval" means the final approval of a BLA for a given indication by the FDA for the applicable Licensed Product in the U.S.; provided, that, for milestone payment purposes, BLA Approval shall in any event be deemed achieved upon First Commercial Sale in the U.S. for such indication.

1.6 "BLA Filing" means the acceptance by the FDA of the filing of a BLA for the applicable Licensed Product.

1.7 "BMS Know-How" means Know-How that, as of the Effective Date, is Controlled by BMS and directly relates to and is reasonably necessary for, Eiger's Development and Commercialization of the Licensed Compounds and/or Licensed Products in the Field or is used by BMS to manufacture the Licensed Compounds as manufactured by BMS as of the Effective Date.

1.8 "BMS Patent Rights" means (a) the patents and patent applications listed in Appendix 1, (b) all divisionals, continuations, continuations-in-part thereof (excluding claims in continuations-in-part that necessarily rely on new matter invented by BMS after the Effective Date) or any other patent application claiming priority directly or indirectly to (i) any of the patents or patent applications in subsection (a), or (ii) any patent or patent application from which the patents or patent applications in (a) claim direct or indirect priority, (c) all patents issuing on any of the foregoing in (a) and (b), (d) all foreign counterparts of any of the foregoing in (a) through(c), including any patent applications filed under the Patent Cooperation Treaty ("PCT Applications"), and (e) all registrations, reissues, re-examinations, supplemental protection certificates, or extensions of any of the foregoing in (a) through (d). BMS Patent Rights in clause (a) above shall also include any claims in any patents or patent applications existing as of the Effective Date that are Controlled by BMS and cover the composition of matter of any intermediate or starting material reasonably necessary in or reasonably useful for the manufacture of any Licensed Compound as manufactured by BMS as of the Effective Date. BMS Patent Rights do not include any claims covering the composition of matter, manufacture or method of use of only a compound other than (i) a Licensed Compound or (ii) an intermediate or starting material reasonably necessary in or reasonably useful for the manufacture of any Licensed Compound as manufactured by BMS as of the Effective Date.

1.9 "Business Day" or "business day" means a day other than Saturday, Sunday or any day on which commercial banks located in New York, New York are authorized or obligated by Law to close.

1.10 "Calendar Quarter" means the respective periods of three consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.11 "Calendar Year" means each one-year period commencing on January 1 and ending on December 31.

1.12 "Clinical Trial" means any human clinical study of a pharmaceutical product.

1.13 "Combination Product" means a Licensed Product that includes at least one additional active ingredient other than the Licensed Compound. Drug delivery vehicles, adjuvants, and excipients shall not

be deemed to be "active ingredients", except in the case where such delivery vehicle, adjuvant, or excipient is recognized by the FDA as an active ingredient in accordance with 21 CFR 210.3(b)(7).

1.14 "Commercialization" or "Commercialize" means activities directed to commercially manufacturing, obtaining pricing and reimbursement approvals including regulatory activities relating to same, marketing, promoting, distributing, importing or selling a Licensed Product.

1.15 "Commercially Reasonable Efforts" means,

(a) with respect to the efforts to be expended by Eiger with respect to any objective, activity or decision to be undertaken under this Agreement, those efforts that a company within the bio-pharmaceutical industry of comparable size and resources [*] would reasonably use to accomplish such objective, activity or decision, and specifically means the carrying out of Development and Commercialization activities using efforts that a company within the bio-pharmaceutical industry of comparable size and resources [*] would reasonably devote to a product at a similar stage in its development or product life and of similar market potential, profit potential, based on conditions then prevailing and taking into account efficacy, safety, intellectual property protection, approved labeling, the competitiveness of alternative products sold by Third Parties in the marketplace, the patent and other proprietary position of the product, and the likelihood of regulatory approval given the regulatory structure involved. Commercially Reasonable Efforts shall be determined on a Major Markets Countries-by-Major Markets Countries basis for the Licensed Product, and it is anticipated that the level of effort will change over time, reflecting changes in the status of the Licensed Product and the Major Market(s) Country(ies) involved. Without limiting the foregoing, Commercially Reasonable Efforts require that Eiger: (i) promptly assign responsibility for such Development and Commercialization activities to specific individuals who are held accountable for progress and monitor such progress on an on-going basis, (ii) set and consistently seek to achieve specific and meaningful objectives and timelines for carrying out such Development and Commercialization activities, and (iii) consistently make and implement decisions and allocate resources designed to advance progress with respect to such objectives and timelines.

(b) with respect to the efforts to be expended by BMS with respect to any objective, activity or decision to be undertaken under this Agreement, those efforts consistent with the commercially reasonable practices normally devoted by BMS.

1.16 "Competitive Compound" means [*].

1.17 "Confidential Information" means all trade secrets, processes, formulae, data, Know-How, improvements, inventions, chemical or biological materials, techniques, marketing plans, strategies, customer lists, or other information (including all information and materials of a Party's customers and any other Third Party and their consultants) that has been disclosed by a Party to the other Party under this Agreement or that certain Confidential Disclose Agreement between the Parties, dated May 13, 2015 (the "CDA"), regardless of whether any of the foregoing are marked "confidential" or "proprietary" or communicated to the other by the disclosing Party in oral, written, graphic, or electronic form. "Confidential Information" of BMS shall include the BMS Know-How.

1.18 "Controlled" or "Controls", when used in reference to intellectual property right or other intangible rights, shall mean the legal authority or right of a Party (or any of its Affiliates) to grant a license or sublicense of intellectual property rights to the other Party or any Third Party, or to otherwise

disclose confidential, proprietary or trade secret information to such other Party or to any Third Party, without breaching the terms of any agreement with any Third Party.

1.19 "Development" means non-clinical and clinical drug development activities reasonably related to the development and submission of information to a Regulatory Authority, including toxicology, pharmacology and other discovery and pre-clinical efforts, test method development and stability testing, process development, formulation development, development manufacturing, delivery system development, quality assurance and quality control development, statistical analysis, clinical studies (including pre- and post-Approval studies but specifically excluding regulatory activities directed to obtaining pricing and reimbursement approvals), and post-marketing commitments/requirements. When used as a verb, "Develop" means to engage in Development.

1.20 "Development Plan" means, with respect to a Licensed Product, a plan and related timing estimates prepared by Eiger for the then current calendar year and the two (2) following years (or through first BLA or MAA filing if later) setting forth a summary of the Development activities to be conducted for such Licensed Product in all Major Market Countries, including the indications expected to be targeted, a good faith estimate of reasonable timelines for completing key Development activities and filing of key regulatory submissions (including estimated timelines for commencement of each stage of clinical Development), and including, where known, the primary endpoints and any comparator or agents to be used in combination with a Licensed Compound/Licensed Product for any such studies and any go/no-go decision criteria for any such studies. The initial Development Plan as of the Effective Date is attached hereto as Appendix 2. A copy of the study protocol for a given study will be provided to BMS if available and if requested by BMS.

1.21 "Distributor" means, with respect to a country, any Third Party that is used by pharmaceutical manufacturers generally in such country on a non-exclusive basis (and without any grant or license by Eiger of any intellectual property rights) to sell and distribute finished, packaged pharmaceutical products to pharmacies, managed care organizations, governmental agencies (*e.g.*, federal, state and local), and other group purchasing organizations (*e.g.*, pharmaceutical benefits managers) and the like in such country; provided, that Eiger shall be permitted to grant or license such intellectual property rights to the Third Party solely to the extent reasonably necessary to comply with applicable law or to enable such distributor to sell and distribute (but not to market or promote) a Licensed Product. For clarity, a Distributor of a Licensed Product in a country shall not include any person or entity that has been granted a right, whether by license or otherwise and whether express or implied (including by subcontract or agency), by a Party or its Affiliates to research, Develop or manufacture (but a Distributor may have the right to repackage or relabel finished product specifically for sale or distribution in such country) any such Licensed Product or that otherwise assumes any regulatory or other responsibilities with respect to obtaining or maintaining regulatory approvals for such Licensed Product in such country.

1.22 "Dollar" or "$" means the lawful currency of the United States.

1.23 "EMA" means the European Medicines Agency, or any successor agency thereto.

1.24 "EU" means the European Union, as its membership may be altered from time to time, and any successor thereto.

1.25 "FDA" means the U.S. Food and Drug Administration, or any successor agency thereto.

1.26 "Field" means all therapeutic and diagnostic uses in humans and animals, including the prevention, treatment or control of any disease, disorder or condition.

1.27 "First Commercial Sale" means, with respect to any Licensed Product in a country in the Territory, the first sale for use or consumption by the general public of such Licensed Product in such country after Approval of such Licensed Product has been granted, or such marketing and sale is otherwise permitted, by the Regulatory Authority of such country.

1.28 "GAAP" means United States generally accepted accounting principles, consistently applied.

1.29 "Governmental Authority" means any multi-national, national, federal, state, local, municipal, provincial, county, or other political subdivision, agency or other body, domestic or foreign or other government authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, court, tribunal or other entity).

1.30 "IND" means an Investigational New Drug Application, as defined in the Act, filed with the FDA or its foreign counterparts, including as applicable clinical trial applications ("CTAs"), clinical trial exemptions ("CTXs") and investigational medicinal product dossiers.

1.31 "Initiation" means, when used with respect to a Clinical Trial, the dosing of the first patient with the first dose in such Clinical Trial.

1.32 "Know-How" means tangible and intangible information, techniques, technology, practices, inventions (whether patentable or not), methods, knowledge, trade secrets, data and results (including all biological, chemical, pharmacological, toxicological, clinical, analytical and quality control data and methods (including any applicable reference standards), manufacturing assay and related data, manufacturing and formulation processes, data and results relating to drug substance, drug product, starting materials, and radiolabeled compounds, know-how and trade secrets).

1.33 "Knowledge" means, with respect to BMS, the actual knowledge of the individuals listed on Appendix 9 hereto, based on such individuals' good faith understanding of the facts and information in their possession or control without any duty to conduct any additional investigation within such individual's scope of responsibility with respect to such facts and information.

1.34 "Laws" means all applicable laws, statutes, rules, regulations and other pronouncements having the effect of law of any Governmental Authority that may be in effect from time to time, including for clarity any applicable rules, regulations and other requirements of any Regulatory Authority that may be in effect from time to time.

1.35 "Licensed Compound" means (i) the proprietary BMS molecule known as PEG-interferon Lambda-1a having chemical structure set forth in Appendix 3, [*], as well as (ii) [*], (iii) [*], and (iv) [*].

1.36 "Licensed Product" means any pharmaceutical product containing a Licensed Compound (alone or with other active ingredients Controlled by Eiger), in all forms, presentations, formulations and dosage forms. For clarity, "other active ingredients" does not include any other active ingredients or molecules that are proprietary to, or Controlled by, BMS and its Affiliates and would require a license from BMS with respect to the composition, method of use or manufacture of such other molecule, unless

separately licensed from BMS or its Affiliates (with BMS and its Affiliates having no obligation, express or implied, to do so).

1.37 "MAA" means a marketing authorization application filed for Approval in the EU of the applicable Licensed Product.

1.38 "MAA Approval" means Approval by the EMA of a MAA filed with the EMA for the applicable Licensed Product under the centralized European procedure. If the centralized EMA filing procedure is not used, MAA Approval shall be achieved upon the first Approval for the applicable Licensed Product in three of the following countries: France, Germany, Italy, Spain and the United Kingdom. For clarity, MAA Approval shall include any pricing and reimbursement approvals required prior to sale of such Licensed Product in the European Union, or in connection with Approvals achieved in three of the foregoing five European Union member states; provided, that MAA Approval shall in any event be deemed achieved upon First Commercial Sale in any country in the European Union.

1.39 "MAA Filing" means the validation by the EMA of a centralized filing of an MAA for the applicable Licensed Product.

1.40 "Major Market Countries" means the following countries: [*]. "Major Market Country" means any one of these countries.

1.41 "Net Sales" means, with respect to any Licensed Product, the gross amount invoiced in arm's-length transactions by a Party, an Affiliate of such Party, or any permitted Sublicensee (or such Sublicensee's Affiliates) (all of the foregoing persons and entities, for purposes of this definition and Sections 8.4, 8.6, and 8.7), shall be considered a "Related Party") for sales of such Licensed Product to a Third Party, less the sum of the following (to the extent not reimbursed by any Third Party):

(a) discounts (including cash discounts and quantity discounts), cash and non-cash coupons, retroactive price reductions, charge-back payments and rebates granted to managed care organizations or to federal, state and local governments, their agencies, and purchasers and reimbursers or to customers;

(b) credits or allowances actually granted upon claims, damaged goods, rejections or returns (including inventory management fees) of such Licensed Product, including Licensed Product returned in connection with recalls or withdrawals;

(c) amounts written off by reason of uncollectible debts;

(d) freight, postage, shipping, transportation and insurance charges for the delivery of the Licensed Product; and

(e) taxes or duties levied on, absorbed or otherwise imposed on sale of the Licensed Product, including value-added taxes, healthcare taxes or other governmental charges otherwise imposed upon the billed amount (to the extent not paid by the Third Party), as adjusted for rebates and refunds, in each case as accounted for by the party recording such Net Sales.

No deduction shall be made for any item of cost incurred by any Related Party in Developing or Commercializing Licensed Products except as permitted pursuant to clauses (a) to (d) of the foregoing sentence; provided that, Licensed Products transferred to Third Parties in connection with clinical and non-clinical research and trials, Licensed Product samples, compassionate sales or use, or an indigent

program or for similar bona fide business purposes in accordance with applicable local laws and regulations in which a Related Party agrees to forego a normal profit margin for good faith business shall give rise to Net Sales only to the extent that any Related Party invoices or receives amounts therefor exceeding the cost of goods.

Such amounts shall be determined consistent with a Related Party's customary practices and in accordance with GAAP.

It is understood that any accruals for individual items reflected in Net Sales are periodically [*] trued up and adjusted by each Related Party consistent with its customary practices and in accordance with GAAP.

Sale or transfer of Licensed Products between any of the Related Parties shall not result in any Net Sales, with Net Sales to be based only on any subsequent sales or dispositions to a non-Related Party. To the extent that any Related Party receives consideration other than or in addition to cash upon the sale or disposition of a Licensed Product to a non-Related Party, Net Sales shall be calculated based on the average price charged for such Licensed Product, as

applicable, during the preceding royalty period, or in the absence of such sales, based on the fair market value of the Licensed Products, as determined by the Parties in good faith. For clarity, (i) Net Sales shall not include amounts [*] in consideration of [*], provided that such consideration [*], (ii) sales to [*], or [*] shall be considered sales to [*], (iii) Net Sales by a Related Party to a non-Related Party consignee are not recognized as Net Sales by such Related Party until the non-Related Party consignee sells the Licensed Product and (iv) [*].

In the case of any Combination Product sold in the Territory, Net Sales for such Combination Product shall be calculated by multiplying actual Net Sales of such Combination Product by the fraction A/(A+B) where A is the invoice price of the Licensed Product that contains only Licensed Compound as its active ingredient if sold separately, and B is the total invoice price of the other active ingredient or ingredients in the Combination Product, if sold separately. If, on a country-by-country basis, the other active ingredient or ingredients in the Combination Product are not sold separately in said country, Net Sales for the purpose of determining royalties of the Combination Product shall be calculated by multiplying actual Net Sales of the Combination Product by the fraction C/D, where C is the invoice price of the Licensed Product that contains only Licensed Compound as its active ingredient if sold separately, and D is the invoice price of the Combination Product. If neither the Licensed Product that contains only Licensed Compound as its active ingredient nor the other active ingredient(s) are sold separately in a given country, the Parties shall determine Net Sales in accordance with the formulas provided above in this paragraph based on [*], or, if neither the Licensed Product that contains only Licensed Compound as its active ingredient nor the other active ingredient(s) are sold in any other countries, the Parties shall negotiate in good faith a reasonable adjustment to Net Sales in such country [*]. Notwithstanding the foregoing, for purposes of determining royalties and milestones on Net Sales under this Agreement, the portion of Net Sales of the Combination Product allocated to the Licensed Product shall [*].

Should Eiger, its Affiliates or Sublicensees enter into a Third Party agreement for the purchase of a Licensed Product that provides discounts or rebates on such Licensed Product that are conditioned on pricing terms or conditions for purchase of another product or products owned or Controlled by Eiger, its Affiliates or Sublicensees, as the case may be, then the discount or rebate on such Licensed Product under such agreement shall be determined, for purposes of determining Net Sales under this Agreement for a given accounting period, based on [*].

1.42 "Patent Rights" means (a) patents and patent applications, (b) all divisionals, continuations, continuations-in-part thereof or any other patent application claiming priority directly or indirectly to (i) any of the patents or patent applications in subsection (a), or (ii) any patent or patent application from which the patents or patent applications in (a) claim direct or indirect priority, (c) all patents issuing on any of the foregoing in (a)-(b), (d) all foreign counterparts of any of the foregoing in (a)-(c), including PCT Applications, and (e) all registrations, reissues, re-examinations, supplemental protection certificates, or extensions of any of the foregoing in (a)-(d).

1.43 "Person" means any individual, firm, corporation, partnership, limited liability Eiger, trust, business trust, joint venture, governmental authority, association or other entity.

1.44 "Phase II Clinical Trial" means a Clinical Trial of a Licensed Product on a sufficient number of subjects that is designed to explore a variety of doses, dose response, and duration of effect, and to generate initial evidence of clinical safety and activity in a target patient population, as described in 21 C.F.R. 312.21(b), or a similar clinical study prescribed by a Regulatory Authority outside the U.S.

1.45 "Phase IIa Clinical Trial" means a Phase II clinical trial of a compound or product, the principal purpose of which is a preliminary determination of safety and pharmacodynamic effect or efficacy in the target population over a range of doses.

1.46 "Phase IIb Clinical Trial" means a Phase II clinical trial of a compound or product, the principal purpose of which is a further determination of efficacy and safety, in the target population, at the intended clinical dose or doses or range of doses, on a sufficient number of subjects and for a sufficient period of time to confirm the optimal manner of use of such compound or product (dose and dose regimen) prior to initiation of the Phase III Clinical Trials.

1.47 "Phase III Clinical Trial" means a Clinical Trial of a Licensed Product on a sufficient number of subjects that is designed to establish that a pharmaceutical product is safe and efficacious for its intended use, and to determine warnings, precautions, and adverse reactions that are associated with such pharmaceutical product in the dosage range and dose duration to be prescribed, which trial is intended to support Approval of a Licensed Product, as described in 21 C.F.R. 312.21(c), or a similar clinical study prescribed by a Regulatory Authority outside the U.S.

1.48 "PMDA" means the Japanese Pharmaceutical and Medical Device Agency or its successor, or Ministry of Health, Labour and Welfare.

1.49 "PMDA Filing" means the acceptance by the PMDA of the filing of an MAA for the applicable Licensed Product in Japan.

1.50 "Regulatory Authority" means any national or supranational governmental authority, including the FDA, PMDA or EMA, that has responsibility in countries in the Territory over the Development and/or Commercialization of the Licensed Compounds and/or Licensed Products.

1.51 "Sublicense Revenues" means all consideration Eiger receives from a Sublicensee pursuant to any Sublicense or from a Third Party assignee pursuant to an assignment of this Agreement that is not a permitted assignment pursuant to Section 15.4.2, including any upfront payment, milestone payments and royalty payments (excluding that portion of any milestone or royalty payment amounts received from a Sublicensee or assignee that are paid by Eiger as milestone and royalty payments to BMS under Article 8 hereof); collaboration fee; and premiums on equity investments in Eiger in connection with the grant of

the Sublicense (with the premium to be reasonably allocated to the value of this Agreement as compared to Eiger's other assets) [*]; and in any event excluding, for clarity, any amounts received by Eiger: (a) as bona

fide, fair market value, actual reimbursement for research, Development or Commercialization activities performed or paid for by Eiger after the grant of a Sublicense, and only to the extent they are documented and are reasonably detailed [*]; (b) for reimbursement of Eiger's fully-burdened cost to manufacture and supply Licensed Products or Licensed Compounds; or (c) in the form of bona fide loans made by Sublicensee or assignee to Eiger. For clarity, Sublicense Revenues from milestones and royalties include the amounts received by Eiger in excess of the amounts paid to BMS under Article 8 for substantially the same milestone or royalties. By way of illustration, and not limitation, if Eiger receives a [*] milestone payment from a Sublicensee in the amount of [*], then (assuming Eiger pays the [*] milestone due to BMS [*]) the Sublicense Revenue amount shall be [*] with respect to such payment. For further clarity, a Change of Control of Eiger shall not be deemed a Sublicense. "Change of Control" shall mean any transaction of series of transactions, whether by merger, sale of substantially all of the assets, or sale or transfer of more than fifty percent (50%) of the outstanding stock of Eiger in which the members of the Board of Directors immediately preceding the closing of the Change of Control transaction no longer constitute a majority of the Board of Directors of the surviving entity following the closing of such transaction.

1.52 "Sublicense" means a grant of rights by Eiger to a Sublicensee under any of the rights licensed to Eiger by BMS under Section 2.1 with respect to the Development, manufacture, or Commercialization of any Licensed Product or Licensed Compound, and includes any reverse co-promotion agreements.

1.53 "Sublicense Agreement" means a written, definitive agreement for a Sublicense.

1.54 "Sublicensee" means any Third Party to whom rights are granted under any of the rights licensed to Eiger by BMS under Section 2.1 with respect to any Licensed Product or Licensed Compound, including through any license, sublicense, co-development, co-discovery, co-promotion, distribution, joint venture, Development and Commercialization collaboration or similar transaction between Eiger (or an Affiliate of Eiger) and a Third Party. For clarity, a Distributor or an Eiger contractor permitted pursuant to Section 3.7 is not considered a Sublicensee.

1.55 "Territory" means worldwide.

1.56 "Third Party" means any Person other than Eiger and BMS, and any Affiliates of Eiger and BMS.

1.57 "United States" or "U.S." means the United States of America including Puerto Rico and any U.S. territories and possessions.

1.58 "Valid Claim" means a claim of (i) an issued and unexpired patent, which claim has not been held invalid or unenforceable by a court or other government agency of competent jurisdiction from which no appeal can be or has been taken and has not been held or admitted to be invalid or unenforceable through re-examination or disclaimer, opposition procedure, nullity suit or otherwise, or (ii) a pending patent application that has not been finally abandoned, finally rejected or expired; *provided, however*, that if a claim of a pending patent application shall not

have issued within [*] after the earliest filing date from which such claim takes priority, such claim shall not constitute a Valid Claim for the purposes of this Agreement unless and until a patent issues with such claim.

Additional Definitions. In addition to those terms defined above, definitions for each of the following terms are found in the body of this Agreement as indicated below:

Defined Term	Section
BMS	Preamble
BMS Reversion Products	13.4.1
Business Combination	13.2.4
CDA	1.17
CTA	1.30
CTX	1.30
Eiger	Preamble
Effective Date	Preamble
Force Majeure	15.3
Indemnification Claim	12.3
Indemnitee	12.3
Indemnitor	12.3
Indication	8.2.1(v)
Inventory Disposal Period	13.4.5
Joint Invention	10.1
Joint Patent Rights	10.1
Know-How Transfer Period	3.1
Liability Cap	9.5
Losses and Claims	12.1
"Party" or "Parties"	Preamble
PCT Application	1.5
Pharmacovigilance Agreement	3.5
Related Party	1.41
Royalty Term	8.4.2
Skipped Milestone	8.2.1(iii)
[*]	8.2.1(i)
Surviving Sublicensee	2.2.1(g)
TA Period	3.2
Third Party Compensation	8.4.4
Title 11	13.10
Transferred Materials	4.1
Triggering Event	5.6.2

ARTICLE 2

LICENSE GRANT

2.1 BMS Patent Rights and BMS Know-How.

2.1.1 Subject to all the terms and conditions set forth in this Agreement, BMS hereby grants to Eiger a non-transferable (except in accordance with Section 15.4), exclusive license, with the right to sublicense in accordance with Section 2.2, under the BMS Patent Rights and BMS Know-How solely to the extent necessary to research, discover, Develop, make, have made, use, sell, offer to sell, export and import Licensed Compounds and/or Licensed Products in the Field in the Territory. For clarification, nothing in this Section 2.1 or this Agreement shall be interpreted as a grant of rights to make, have made, sell, use, co-formulate or use in combination a Licensed Compound with any molecule that is not a Licensed Compound and is proprietary to BMS or its Affiliate or would require a license from BMS with respect to the composition, method of use or manufacture of such other molecule (unless separately licensed from BMS or its Affiliates with BMS and its Affiliates being under no obligation, express or implied, to do so).

2.1.2 Subject to all the terms and conditions set forth in this Agreement, BMS hereby grants to Eiger a non-transferable (except in accordance with Section 15.4), non-exclusive license, without the right to sublicense except to Eiger Affiliates and non-profit institutions solely for the purpose identified in Section 5.7), under patent rights and know-how Controlled by BMS or its Affiliates covering the manufacture, composition of matter or method of use of the reagents and research tools set forth on Appendix 10 hereto, solely to the extent necessary to research, discover, Develop, make, have made, use, sell, offer to sell, export and import Licensed Compounds and/or Licensed Products in the Field in the Territory.

2.2 Sublicenses. Eiger shall have the right to grant Sublicenses with respect to the rights licensed to Eiger under Section 2.1: [*], *provided* that, in each case (x) and (y), such Sublicenses are granted solely in accordance with this Section 2.2:

2.2.1 Eiger shall have the right to enter into a Sublicense Agreement [*], provided that:

(a) such Sublicense Agreement shall refer to this Agreement and shall be subordinate to and consistent with the terms and conditions of this Agreement, and, shall not limit Eiger's ability to fully perform all of its obligations under this Agreement (except to the extent assumed by Sublicensee but as to which Eiger remains responsible to BMS for the performance thereof by the Sublicensee) or BMS' rights under this Agreement;

(b) in such Sublicense Agreement, the Sublicensee shall agree in writing to fully perform the terms and conditions of this Agreement applicable to the Sublicensee;

(c) promptly after the execution of such Sublicense Agreement, Eiger shall provide a copy of such Sublicense Agreement to BMS, which copy may be redacted to remove confidential terms that are not necessary for BMS to confirm the Sublicense Agreement's compliance with, or calculations of Sublicense Revenues under, the terms and conditions of this Agreement;

(d) Eiger shall remain primarily responsible and liable for performance of all of its obligations under this Agreement (even where sublicensed or assumed by a Sublicensee) and for compliance by its Sublicensees with applicable terms of this Agreement, including all payments due (including, without limitation, its payment obligations under Sections 11.1 and Articles 8 and 10 hereof) and the making of reports under this Agreement on account of its Sublicensees' activities under the Sublicense Agreement, and shall use Commercially Reasonable Efforts to monitor such Sublicensee's compliance with and to enforce the terms of such Sublicense Agreement;

(e) the Sublicensee shall assume and agree in writing to be bound by and comply with the applicable terms and conditions of this Agreement in the same manner as Eiger, including, without limiting the generality of the foregoing, the Sublicensee shall [*];

(f) such Sublicensees shall [*], except with prior written consent of Eiger and BMS in each of their sole discretion and in any event in accordance with and subject to all of the terms and conditions of this Section 2.2 and all of the other terms and conditions of this Agreement;

(g) any Sublicense rights granted by Eiger in a Sublicense Agreement (to the extent such Sublicense rights are granted to Eiger in this Agreement) shall terminate effective upon the termination under Article 13 of the license from BMS to Eiger with respect to such sublicensed rights, provided that such Sublicense rights shall not terminate if, as of the effective date of such termination under Article 13, the Sublicensee is not in material breach of its obligations to Eiger under its Sublicense Agreement, the Sublicensee was previously granted an exclusive Sublicense to Develop and Commercialize the Licensed Products or Licensed Compounds, and, within sixty (60) days of such termination, the Sublicensee agrees in writing to be bound directly to BMS under a license agreement substantially similar to this Agreement with respect to the rights and obligations Sublicensed by Eiger to the Sublicensee under the Sublicense Agreement, substituting such Sublicensee (a "Surviving Sublicensee") for Eiger, and provided further that (A) such license agreement shall [*]; (B) the scope of the rights granted to and obligations assumed by the Surviving Sublicensee under such license agreement (with respect to licensed activities, Licensed Products and territory) shall [*]; (C) Eiger shall no longer be obligated under this Agreement to pay amounts set forth in this Agreement, to the

extent such amounts are payable based on the activities of such Surviving Sublicensee, its Affiliates and its sublicensees from and after the effective date of such termination; (D) such license agreement shall obligate the Surviving Sublicensee to [*] from and after the effective date of such termination, [*]; (E) the Sublicensee [*] as of the effective date of termination; and (F) except as expressly set forth in the license agreement or agreed by Eiger, such license agreement shall not [*];

(h) the provisions of this Section 2.2 shall also apply in the event of any subsequent amendment or modification of any such Sublicense Agreement; and

(i) BMS shall be made an express third party beneficiary of the Sublicensee's obligations under such Sublicense that relate to compliance with the applicable terms and conditions of this Agreement with the express right to enforce same directly against the Sublicensee or against Eiger as BMS may elect .

2.2.2 For clarity, where provisions of this Agreement provide that Eiger shall be "solely" responsible or the like with respect to a matter (for example, Sections 5.4, 5.5, or 7.1), it is understood that such responsibilities may be carried out or borne on Eiger's behalf by an Affiliate of Eiger or by a permitted Sublicensee or contractor of Eiger.

2.2.3 It shall be a material breach of this Agreement for Eiger to enter into any Sublicense hereunder not in compliance with this Section 2.2 without the prior written consent of BMS.

2.3 No Trademark License. No right or license, express or implied, is granted to Eiger to use any trademark, trade name, trade dress, domain name, logos, slogans, or service mark owned or Controlled by BMS or any of its Affiliates. Eiger, at its sole cost and expense, shall be responsible for the selection, registration and maintenance of all trademarks which it employs in connection with Licensed Products and its activities conducted pursuant to this Agreement, if any, and shall own and Control such trademarks.

2.4 No Implied Licenses. No license or other right is or shall be created or granted hereunder by implication, estoppel or otherwise. All such licenses and rights are or shall be granted only as expressly provided in this Agreement.

2.5 Retained Rights. All rights not expressly granted by a Party hereunder are reserved by such Party and may be used by such Party for any purpose. Without limiting the foregoing, [*]. Nothing in this Agreement shall prevent (i) Eiger and its Affiliates from using for any purpose any BMS Know-How that is in the public domain as of the Effective Date (or enters the public domain thereafter) and is not covered by a Valid Claim of a BMS patent right or (ii) BMS and its Affiliates from using for any purpose any BMS Know-How that is in the public domain as of the Effective Date (or enters the public domain thereafter) and, subject to terms of this Agreement, is not covered by a Valid Claim of a BMS Patent Right.

ARTICLE 3

TRANSFER OF KNOW-HOW, IND AND PGX DATABASE; TECHNICAL ASSISTANCE

3.1 Documentation.

3.1.1 BMS shall provide Eiger with electronic (or tangible embodiments, if electronic is not available) of the Know-How listed on Appendix 6 within the period of time following the Effective Date and in the format set forth on Appendix 6, including copies of originals of laboratory notebooks or pages thereof and, where required by Eiger to fulfill its duties under applicable Law, copies of manufacturing run and batch records required to be maintained by BMS under applicable Law; *provided* that, with respect to BMS Know-How contained in laboratory notebooks, BMS shall only be required to provide Eiger with copies of those laboratory notebook pages (electronic copies, if they exist) [*] that contain BMS Know-How relating to Licensed Compounds. Such documentation is Confidential Information of BMS licensed in accordance with this Agreement and shall not be used by Eiger for any purpose other than for the discovery, research, manufacture, Development or Commercialization (including any import, manufacture, use, offer for sale, or sale) of Licensed Compounds and/or Licensed Products in accordance with this Agreement. BMS shall be responsible for providing one (1) set of copies (electronic, where they exist) only and Eiger shall [*]. BMS shall have no obligation to reformat or otherwise alter or modify any materials, or to create materials in electronic form, in order to provide them to Eiger. Any and all materials and other BMS Know-How delivered to Eiger pursuant to this Section 3.1 are and shall remain the sole property of BMS.

Without limiting the foregoing, if, within [*] after the Effective Date, if Eiger reasonably determines that there is additional, specific BMS Know-How Controlled by BMS and its Affiliates that existed as of the Effective Date that is reasonably necessary for the continued Development or manufacture (but only those manufacturing and formulation processes, techniques and trade secrets used by BMS for making such Licensed Compounds as of the Effective Date) of any Licensed Compound or Licensed Product that has not been provided during the Know-How Transfer Period, then Eiger may request within such [*] that BMS transfer to Eiger such additional BMS Know-How and BMS will endeavor to locate and provide same, provided that BMS shall not be required to conduct an unreasonable search for any such additional BMS Know-How. BMS shall have no obligation to reformat or otherwise alter or modify any materials, or to create materials in electronic form, in order to provide them to Eiger.

3.1.2 Notwithstanding Sections 3.1.1 or 3.2, nothing herein shall require BMS to transfer, disclose or provide to Eiger (i) any reagents, assays or other tangible biological or chemical materials that are not listed on Appendix 4 and, (ii) any general information or know-how that should reasonably be known to a pharmaceutical company engaged in the research, development, manufacture or commercialization of interferon therapeutic agents to treat Hepatitis B or Hepatitis C.

3.1.3 Any data or information included in the INDs to be transferred under Section 3.3 does not need to be separately transferred pursuant to Section 3.1.1 or Section 3.2.

3.2 Technical Assistance. During the [*] period following the Effective Date (the "TA Period"), BMS shall reasonably cooperate with Eiger to provide transition and technical assistance to Eiger in order to understand and use the BMS Know-How provided to Eiger under Section 3.1 (for clarity, this support does not include integration of the data/information into Eiger systems/repositories). Such cooperation shall include providing Eiger with reasonable access by teleconference or in-person at BMS' facilities (subject to BMS' customary rules and restrictions with respect to site visits by non-BMS personnel) to BMS personnel who are appropriately qualified and experienced for such purpose, directly involved in the research and Development or manufacture of Licensed Compounds and Licensed Products. In no event shall BMS be obligated to provide Eiger with more than [*] FTE hours of technical assistance and consultation in connection with the BMS Know-How transferred under Section 3.1 to the extent the Know-How does not relate to manufacturing Know-How, and (y) [*] FTE hours technical assistance and consultation in connection with the BMS Know-How transferred under Section 3.1 to the extent it relates to manufacturing (including CMC) Know-How. [*]. If Eiger believes it needs additional assistance, it will discuss same with BMS, and, at BMS' sole discretion, BMS may provide additional assistance requested by Eiger, and [*]. Further: (i) such access shall be requested and coordinated through a single contact person to be designated by BMS, (ii) BMS makes no warranty, express or implied, that Eiger shall be able to successfully implement and use the BMS Know-How, and (iii) BMS shall not be in default hereunder for any inadvertent failure to disclose all pertinent information related to the BMS Know-How, provided that such information shall be supplied to Eiger promptly upon discovery of such failure to disclose or upon request of Eiger identifying with reasonable specificity the nature of the information to be disclosed. Eiger shall be responsible for ensuring that its personnel who receive such assistance are appropriately qualified and experienced for such purpose.

3.3 IND. BMS will assign and transfer within [*] after the Effective Date all of its rights, title and interests in and to the active IND [*] (but, for clarity, not any CTAs, CTXs or investigational medicinal product dossiers nor any inactive IND) for the Licensed Compounds. Eiger will cooperate in connection therewith and shall perform all duties under such IND from and after such assignment. Subject to the foregoing, the Parties will reasonably cooperate to ensure an orderly transition of duties under such IND and to fulfill applicable filing obligations with regulatory authorities. BMS will continue to conduct and close out any existing CTAs and CTXs in the ordinary course following the Effective Date.

3.4 Safety Database. BMS shall transfer to Eiger the safety database for the Licensed Compounds, in the form in which it is held by BMS, as soon as practicable and in any event within [*] after the Effective Date, and Eiger shall perform all responsibilities thereafter with respect to reporting of adverse events relating to the Licensed Compounds.

3.5 [*]

3.6 Third Party Agreements. BMS shall use Commercially Reasonable Efforts to promptly assign to Eiger any unexpired Third Party agreements solely and exclusively related to the research and non-clinical Development of the Licensed Compound (and not related as well to any other proprietary molecules of BMS that are not interferons) set forth on Appendix 11 and is assignable to Eiger without consent of such Third Party, provided, however, that if such Third Party agreement is not assignable to Eiger without the written consent of such Third Party, BMS shall use Commercially Reasonable Efforts to obtain a consent to such assignment (but which shall not, for clarity, require BMS to pay any termination fee or additional consideration to the other party to such agreement).

3.7 Eiger Contractors**.** For clarity, references to Eiger in Article 3 (except Section 3.8) and Article 4 shall include Third Party contractors engaged by Eiger to perform services for the benefit of Eiger (i.e., Third Parties who receive limited rights to perform services similar to other parties on a basis and on terms customarily understood for a vendor, such as a contract manufacturing organization) who have entered into appropriate agreements protecting the confidentiality and proprietary nature of the BMS Know-How, Licensed Compounds, technical data and information and other Transferred Materials (as defined below) in accordance with this Agreement, provided, that Eiger shall remain responsible and liable for the compliance by such individuals with the terms of this Agreement and shall use Commercially Reasonable Efforts to require such Third Parties to assign to Eiger any inventions and know-how relating to the License Compounds and Licensed Products that may be made or generated by them in the course of their services for Eiger.

3.8 USAN. Within [*] after the Effective Date, BMS and Eiger shall take all reasonably necessary actions (including the filing of any necessary forms) for the United States Adopted Names Council to remove BMS and include Eiger as the manufacturer of the Licensed Compounds and Licensed Products. Eiger shall be solely responsible for the payment all related fees.

ARTICLE 4

TRANSFER OF MATERIALS

4.1 Materials. BMS shall initiate the transfer to Eiger (i) within the time period after the Effective Date specified in Appendix 4, those Licensed Compounds identified in Appendix 4, ex-works (EXW) BMS designated site in the United States and/or Belgium, in the quantities set forth in Appendix 4, and (ii) within [*] after the Effective Date, those reagents and research tools set forth on Appendix 10 (any such materials that are actually transferred, the "Transferred Materials"). The Transferred Materials shall be transferred to Eiger at the location(s) designated by Eiger within [*] after the Effective Date. Title and risk of loss shall be transferred to and borne by Eiger upon delivery of the Transferred Materials by BMS to a common carrier for shipment to Eiger, and Eiger shall be responsible for any indirect taxes levied upon the transfer, including customs duties and import VAT if applicable. [*]. Other than the Transferred Materials, unless included within the scope of BMS Know-How and identified on Appendix 4 or Appendix 10 and subject to Section 3.2, BMS shall have no obligation to provide Eiger with any compounds or other materials, such as assays or biomaterials, under this Agreement. To the

extent set forth in Appendix 4, BMS represents and warrants that the Transferred Materials are manufactured in accordance with cGMP and any manufacturing specifications included within the IND relating to such Transferred Materials. Except as expressly set forth above, the Transferred Materials are provided **"AS IS" and BMS makes no representations or warranties, express or implied, as to the Transferred Materials, including any warranty as to merchantability or fitness for a particular use or purpose.** If requalification of any Licensed Compound included within the Transferred Material is required, it will be the responsibility of Eiger to perform such requalification at its expense and BMS will not be responsible for such requalification. Eiger agrees that: (a) Eiger shall be fully responsible for its and its Affiliates', Sublicensees' and contractors' use, storage, handling and disposition of the Transferred Materials, (b) under no circumstances shall BMS be liable or responsible for Eiger's or its Affiliates', Sublicensees' and contractors' use, storage, handling or disposition of the Transferred Materials (except for BMS' breach of the warranty set forth above), and (c) Eiger assumes sole responsibility for any claims, liabilities, damages and losses that might arise as a result of Eiger's and its Affiliates', Sublicensees' and contractors' use, storage, handling or disposition of any Transferred Material (except to the extent resulting from BMS' breach of the warranty set forth above). Eiger shall indemnify, defend and hold harmless BMS and its Affiliates, and their respective officers, directors, employees, agents, licensors, and their respective successors, heirs and assigns and representatives, from and against any and all third party damages, liabilities, losses, costs and expenses (including reasonable legal expenses, costs of litigation and reasonable attorney's fees) arising in connection with any claims, suits, proceedings, whether for money damages or equitable relief, of any kind, arising out of or relating to Eiger's, or any of its Affiliates', Sublicensees' or contractors' use, storage, handling or disposition of any Transferred Material (except for BMS' breach of the warranty set forth above). Transferred Materials may only be provided by Eiger to Affiliates of Eiger, Sublicensees and contractors of Eiger.

ARTICLE 5

DEVELOPMENT

5.1 Development. Eiger shall itself or through its Affiliates or Sublicensees use Commercially Reasonable Efforts to Develop Licensed Products for Approval in the Major Market Countries, including by (i) setting forth in the Development Plan a program of Development activities and reasonable estimated timelines therefor for each phase of pre-clinical and clinical Development for Licensed Compounds and Licensed Products (it being understood that such Development Plan may be revised as a result of input from Regulatory Authorities and data generated by Eiger as it Develops Licensed Products), and (ii) assigning appropriately qualified and experienced personnel to perform and monitor the progress of, or overseeing Third Parties who perform, such Development activities on an on-going basis. The initial Development Plan as of the Effective Date is attached hereto as Appendix 2. During the Term, Eiger shall promptly provide BMS no later than January 31 of each Calendar Year with a copy of the revised Development Plan (such annual updates to the Development Plan may be provided as part of the Development Report outlined in Section 5.2). Eiger shall notify BMS of any material change (including any material delay in Development or Commercialization of Licensed Product) to the Development Plan last provided to BMS within thirty (30) days after becoming aware of such material change and the reasons therefor.

5.2 Development Reports. Eiger shall provide BMS with written Development reports on or before January 31 of each Calendar Year during the term of Development activities summarizing (but without disclosing specific data or results) such activities in sufficient detail to enable BMS to determine Eiger's compliance with its diligence obligations in Section 5.1. Such reports shall include without limitation (a) the research and other Development activities accomplished by Eiger under the existing Development Plan through the end of the immediately preceding Calendar Year with respect to Licensed Compounds and Licensed Products, and (b) updates on Eiger's progress against the existing Development Plan; provided, however, that the first such report shall be due on or before January 31, 2017. If any such Development obligations have been sublicensed to a Sublicensee, Eiger shall require the Sublicensee to provide to BMS the same information as required of Eiger hereunder with respect to the progress of the Development of Licensed Compounds and Licensed Products by such Sublicensee. If requested by BMS, Eiger (and, if applicable, Sublicensee) personnel who prepared the report will meet with BMS (which may be by teleconference) to discuss and answer any reasonable questions or comments that BMS might have on the report and Eiger's (and, if applicable, each of its Sublicensee's) Development activities.

5.3 Records. Eiger shall maintain complete and accurate records of all work conducted in furtherance of the research, Development and Commercialization of the Licensed Compounds and/or Licensed Products and all results, data and developments made in furtherance thereof to the extent required under applicable Laws. Such records shall properly reflect all work done and results achieved in sufficient detail and in good scientific manner to the extent required under applicable Laws.

5.4 Development Responsibilities and Costs. As between the Parties, Eiger shall have sole responsibility for, and shall bear the cost of conducting, research and Development with respect to the Licensed Compounds and/or Licensed Products. Eiger shall research and Develop the Licensed Compounds and/or Licensed Products in compliance with all applicable Laws, including all legal and regulatory requirements pertaining to the design and conduct of clinical studies.

5.5 Regulatory Responsibilities and Costs. As between the Parties, Eiger shall have sole responsibility for, and shall bear the cost of preparing, all regulatory filings and related submissions with respect to the Licensed Compounds and/or Licensed Products. Except as set forth in Article 13, Eiger shall own all INDs, Approvals and submissions in connection therewith and all Approvals shall be obtained by and in the name of Eiger.

5.6 Competitive Compound.

5.6.1 For [*] after the Effective Date, neither Eiger nor its Affiliates (nor any Sublicensee of Eiger or any Affiliate of such Sublicensee) shall itself or through any Third Party, or in collaboration with any Third Party, engage, directly or indirectly in the clinical Development or Commercialization of a Competitive Compound.

5.6.2 Notwithstanding Section 5.6.1, if Eiger or any of its Affiliates, either through its own development efforts or by acquisition, or obtains ownership of or a license to, or is acquired by or otherwise merges with an entity (or an Affiliate of such entity) that owns or has a license to, a Competitive Compound, in all such cases that would result in a violation of Section 5.6.1 (any such event, a "Triggering Event"), then Eiger shall promptly notify BMS in writing and elect (as applicable) one of the following actions within [*] after such Triggering Event:

(a) divest itself of such Competitive Compound and notify BMS in writing of such divestiture, which divestiture may occur by an outright sale to a Third Party of all of Eiger's and its Affiliate's rights to such Competitive Compound or by an outlicense arrangement under which Eiger has no continuing active involvement in the development or commercialization of such Competitive Compound (for clarity, efforts in connection with (i) the receipt and audit of payments in respect of the Competitive Compound, (ii) the maintenance, defense and enforcement of any applicable licensed patents, and (iii) the receipt of information to ensure compliance with the applicable agreement (including efforts to enforce or terminate same, or seek damages, for breach) shall not constitute continuing active involvement). Eiger shall use Commercially Reasonable Efforts to complete such divestiture within [*] after the applicable Triggering Event. If Eiger is unable to complete the divesture within such [*] period, Eiger may continue to divest such Competitive Compound thereafter, *provided*, that Eiger or its Affiliate shall cease the Development and Commercialization of the Competitive Compound prior to the end of such [*] period and shall not restart the Development and Commercialization of the Competitive Compound thereafter (and if such Development or Commercialization is restarted, then BMS may immediately terminate this Agreement upon written notice to Eiger). For clarity, Eiger's (or its Affiliates') Development and Commercialization of the Competitive Compound in the ordinary course during such [*] period shall not be deemed a breach of Eiger's exclusivity obligations set forth herein; or

(b) Eiger shall notify BMS in writing whether Eiger desires to negotiate terms under which the Competitive Compound would be included as a Product within this Agreement. If the Parties can agree and execute a binding agreement, within [*] after notice from Eiger electing this option, on the terms (including compensation to BMS) for including the Competitive Compound as a Product within this Agreement and Eiger's Commercially Reasonable Efforts obligations under Sections 5.1 and 6.1, then Eiger shall not be deemed in breach of Section 5.6.1; provided, that BMS shall not be under any obligation, express or implied to negotiate or enter into any such agreement. If the Parties are unable to reach written agreement during the applicable time period, then, Eiger may elect to either divest such Competitive Compound under clause (a) or terminate this Agreement pursuant to Section 13.3.2 hereof.

5.7 Institution Requests. Eiger shall be responsible for receiving, evaluating, responding and, as applicable, fulfilling (at Eiger's discretion) requests from scientists at non-profit institutes for [*] and related reagents, including [*], for non-commercial research purposes.

ARTICLE 6

COMMERCIALIZATION

6.1 Eiger Obligations. Eiger shall use Commercially Reasonable Efforts to (i) obtain Approvals in each Major Market Country for at least one Licensed Product, (ii) effect the First Commercial Sale of each Licensed Product for which such Approvals are obtained into each Major Market Country as soon as reasonably practicable after receipt of such Approvals and (iii) Commercialize each such Licensed Product in each such Major Market Country following such First Commercial Sale therein with the goal of maximizing the Net Sales of such Licensed Product in such Major Market Country.

6.2 Reports. Following the First Commercial Sale of a Licensed Product in a country in the Territory, Eiger shall provide BMS with a written report within thirty (30) days of the filing of the Eiger Annual Report with the U.S. Securities and Exchange Commission (or if no such report is filed, then within 30 days after the end of a calendar year), summarizing significant Commercialization activities with respect to Licensed Products during the just ended Calendar Year in countries in which there has been a First Commercial Sale of a Licensed Product, [*]. If requested by BMS, Eiger personnel who prepared the report will meet with BMS, which may be by teleconference, to discuss and answer any questions or comments that BMS might have on the report and Eiger's Commercialization activities.

ARTICLE 7

MANUFACTURE AND SUPPLY

7.1 Manufacture and Supply. As between the Parties, Eiger shall be solely responsible at its expense for making or having made all of its requirements of the Licensed Compounds and/or Licensed Products needed for Development and Commercialization of same in the Territory, except for Transferred Materials.

ARTICLE 8

FINANCIAL TERMS

In partial consideration of the rights granted by BMS to Eiger pursuant to this Agreement, Eiger shall make the payments provided for in this Article 8.

8.1 Initial Payment. Eiger shall (x) pay to BMS a nonrefundable, noncreditable payment of Two Million Dollars ($2,000,000) in cash by wire transfer into an account designated in writing by BMS within [*] after the Effective Date and (y) enter into a Stock Purchase Agreement with BMS, issuing common stock to BMS valued at Three Million Dollars ($3,000,000) on the Effective Date, in the form attached as Appendix 7 concurrently with the execution of this Agreement.

8.2 Milestone Payments.

8.2.1 Development Milestones. Eiger shall pay to BMS the following milestone payments set forth in the table below within [*] after the first achievement of the specified milestone event by Eiger, its Affiliates, and Sublicensees for the first Licensed Product to achieve such milestone event in any Indication. Eiger shall provide written notice to BMS within [*] after the first achievement of the specified milestone event by Eiger, Affiliates, and Sublicensees. Each milestone payment shall not be refundable or returnable in any event.

Milestone	Amount of Milestone Payment (Dollars)
[*]	
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
Total Development Milestones for First Indication	[*]
	$ 61 million

For purposes of this Section:

(i) A [*] means that [*].

(ii) The set of milestone payments in the table above shall be payable by Eiger to BMS once per Indication upon the first achievement of each such milestone event for the first such Licensed Compound (whether the first such Licensed Compound is the lead Licensed Compound or any back-up Licensed Compound) to achieve the milestone event. Milestones payments for additional Indications that achieve the above milestones events for such additional Indication will be at [*] of the above milestone payment amounts for the first Indication.

(iii) If a particular milestone event is not achieved with respect to an Indication ("Skipped Milestone"), such Skipped Milestone will be deemed to have been achieved upon the occurrence of the next most successive milestone with respect to such Indication, and payment for such Skipped Milestone then shall be due.

(iv) For purposes of this Section 8.2.1, "Indication" shall mean any separately defined, well-categorized class of human disease, syndrome or medical condition for which a separate marketing authorization application may be filed with a Regulatory Authority.

8.2.2 Sales-Based Milestones. Each of the following milestone payments shall be paid by Eiger to BMS for total annual sales of Licensed Product within [*] after the Net Sales of all Licensed Products in a given Calendar Year first reach the threshold amounts set forth in the table below:

Milestone – First Achievement of annual Net Sales of all Licensed Products in any Calendar Year of:	Amount of Milestone Payment (Dollars)
[*]	[*]
[*]	[*]
[*]	[*]
Total Sales-Based Milestones	$ 128.0 million

Each milestone payment shall not be refundable or returnable in any event, nor shall it be creditable against royalties or other payments.

8.3 Sublicense Revenue Sharing. In addition to the milestones and royalty payments set forth in Sections 8.2 and 8.4, Eiger shall pay to BMS the following percentage of all Sublicense Revenues Eiger receives in connection with any Sublicense or any assignment of rights to the BMS Patents, the Licensed Compounds and/or Licensed Products, depending on the stage of Development of the most advanced Licensed Compound or Licensed Product that is subject to the applicable Sublicense or such assignment. Eiger shall pay to BMS its share of Sublicense Revenues within [*] after receipt of payment by Eiger from the Sublicensee.

DEVELOPMENT STAGE OF LICENSED COMPOUND OR LICENSED PRODUCT AS OF THE DATE OF THE SUBLICENSE

	(A) PRIOR TO [*]	(B) IF AFTER (A) AND PRIOR TO [*]	(C) IF AFTER (B) AND PRIOR TO [*]	(D) [*]
PERCENT OF SUBLICENSE REVENUES PAYABLE TO BMS	**[*]**	**[*]**	**[*]**	**[*]**

8.4 Royalty Payments.

8.4.1 Subject to the terms of this Agreement Eiger shall pay to BMS tiered royalties based on the total annual worldwide Net Sales in the Territory of each Licensed Products (including all indications and formulations for such Licensed Product) by Eiger, its Affiliates and Sublicensees during the applicable Royalty Term for such Licensed Product. The royalty payable with respect to each particular Licensed Product shall be calculated by multiplying the applicable royalty rate below by the portion of total annual worldwide Net Sales in the applicable tier in a Calendar Year of the applicable Licensed Product by Eiger, its Affiliates and Sublicensees, as follows.

Portion of total annual worldwide Net Sales in a Calendar Year for such Licensed Product that falls within the following tiers	Royalty Rate
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]

By way of example, in a given Calendar Year, if the total annual worldwide Net Sales for a Licensed Product is [*], the following royalty payment would be payable under this Section 8.4 (subject to the reductions set forth below): [*]. For clarity, all dosages, dosage forms, SKUs, methods of delivery and presentations of a Licensed Product containing the same Licensed Compound shall be considered as one Licensed Product for purposes of this Section 8.4.1.

8.4.2 Royalty Term. Royalties shall be payable on a product-by-product and country-by-country basis on Net Sales of Licensed Products from the First Commercial Sale of a particular Licensed Product in a country until the later of (i) [*] after the First Commercial Sale of such Licensed Product in such country, (ii) the expiration of the last to expire Valid Claim in BMS Patent Right that would be infringed by the manufacture, use, sale, importation or offer for sale in such country of a given Licensed Product (including by reasons of extensions thereof under applicable Laws, including patent term extensions, or supplemental protection certificates or their equivalents in any country), or (iii) the expiration of any regulatory or marketing exclusivity for such Licensed Product in such country, including but not limited to any pediatric exclusivity and data exclusivity (the "Royalty Term"); *provided* that, if (ii) no longer applies, the royalty payable by Eiger to BMS with respect to such Licensed Product shall be determined by a royalty rate equal to [*] of the royalty rate set forth in Section 8.4.1.

8.4.3 Royalty Conditions. The royalties under Section 8.4.1 shall be subject to the following conditions:

(a) only one royalty shall be due with respect to the same unit of Licensed Product;

(b) no royalties shall be due upon the sale or other transfer among any Related Party, but in such cases the royalty shall be due and calculated upon the Related Party's Net Sales of Licensed Product to the first non-Related Party; and

(c) no royalties shall accrue on the disposition of Licensed Product in reasonable quantities by any Related Party as part of an expanded access program or as *bona fide* samples or as donations to non-profit institutions or government agencies for non-commercial purposes or for the performance of clinical trials, *provided*, in each case, that such Related Party does not receive any payment for such Licensed Product exceeding the cost of goods.

8.4.4 Royalty Reduction. If (i) Eiger, in its reasonable judgment, determines that it is required to obtain a license from any Third Party in order to avoid infringement of such Third Party's Patent Rights as a result of the Development or Commercialization (but excluding manufacturing) of any Licensed Product, (ii) such Patent Rights cover or claim the composition or method of use of a Licensed Product, and (iii) Eiger is required to pay to such Third Party a royalty, milestone payments or other monetary compensation in consideration for the grant or maintenance of such license ("Third Party Compensation"), then for the period during which Eiger owes royalties to BMS hereunder, the amounts that would otherwise have been payable as royalties to BMS under this Agreement shall be reduced by [*] of all Third Party Compensation payable by or on behalf of Eiger to such Third Party. Notwithstanding the foregoing, (x) in no event shall the royalty reductions described in this Section 8.4.4 act to reduce the royalties payable by Eiger to less than [*] of the amounts payable by Eiger for a given Calendar Quarter pursuant to Section 8.4.1, and (y) if [*], then the royalty reduction set forth in this

Section 8.4.4 [*]. For further clarity, Eiger may carry over and apply any such royalty reductions, which are incurred or accrued in a Calendar Quarter and are not deducted in such Calendar Quarter, to any subsequent Calendar Quarter(s) in which royalties are due, subject to the same limitations set forth above and provided that if carryover cannot be so applied to future royalties, such carryover amounts shall lapse and shall not be subject any refund or other repayment from BMS.

8.4.5 Forecast. Eiger shall provide on or before September 30 of each Calendar Year a non-binding good faith forecast of sales, royalties and milestones for the entire current and next Calendar Year.

8.4.6 Effect of Patent Challenge. In the event Eiger (or any of its Affiliates or Sublicensees) challenges or knowingly assists (other than in response to a subpoena or court order), including without limitation by providing information, documents, advice, and/or funding, a challenge to the validity, scope, patentability or enforceability of any of the BMS Patent Rights, and such challenge is unsuccessful either because (i) Eiger files a suit or initiates another legal proceeding to challenging the validity or enforceability of any such BMS Patent Right and then withdraws or terminates the suit or proceeding, (ii) any challenged claim that would be infringed but for the license has been upheld, even in amended form, as determined by a court of competent jurisdiction or other legal tribunal, or (iii) Eiger, in connection with such challenge, fails to produce reasonably credible evidence demonstrating the invalidity or unenforceability of all applicable patent claims in the BMS Patent Rights in such country; then the royalty rates set forth in Section 8.4.1 above shall be increased by [*] of the percentages set forth above [*], [*]; provided however that if such challenge is by a Sublicensee, the foregoing shall not apply if Eiger promptly terminates such Sublicensee's Sublicense after become aware of such challenge (which in any event must be prior to any decision rendered with respect to such challenge).

8.5 Manner of Payment. All payments to be made by Eiger under this Agreement shall be made in U.S. Dollars by wire transfer of immediately available funds to such bank account as shall be designated by BMS. Late payments shall bear interest at the rate provided in Section 8.10.

8.6 Sales Reports and Royalty Payments. After the First Commercial Sale of a Licensed Product and during the term of this Agreement, Eiger shall furnish to BMS a written report, within [*] after the end of each Calendar Quarter (or portion thereof, if this Agreement terminates during a Calendar Quarter), showing the amount of royalty due for such Calendar Quarter (or portion thereof). Royalty payments for each Calendar Quarter shall be due at the same time as such written report for the Calendar Quarter. With each quarterly payment, Eiger shall deliver to BMS a full and accurate accounting to include at least the following information:

8.6.1 the total gross sales for each Licensed Product (by country) by Eiger and its applicable Related Parties, if any, and the calculation of Net Sales from such gross sales;

8.6.2 the deductions by category of permitted deductions set forth in the Net Sales definition;

8.6.3 the total Net Sales for each Licensed Product (by country) by Eiger and its applicable Related Parties, if any, and the calculation of Net Sales from such gross sales;

8.6.4 the calculation of royalties payable in Dollars which shall have accrued hereunder in respect of such Net Sales;

8.6.5 withholding taxes, if any, required by applicable Law to be deducted in respect of such royalties; and

8.6.6 the exchange rates used in determining the amount of Dollars payable hereunder.

If no royalty or payment is due for any royalty period hereunder, Eiger shall so report.

8.7 Sales Record Audit.

8.7.1 Eiger shall keep, and shall cause each of its applicable Related Parties, if any, to keep, complete, true and accurate books of accounts and records in accordance with GAAP, including gross sales in accordance with GAAP and any deductions thereto in accordance with this Agreement's Net Sales definition in connection with the calculation of Net Sales, sufficient to determine and establish the amounts payable incurred under this Agreement, and compliance with the other terms and conditions of this Agreement.

8.7.2 Such books of accounting of Eiger and its Affiliates shall be kept at their principal place of business and, with all necessary supporting data and records, shall during all reasonable times for the [*] next following the end of the Calendar Year to which each shall pertain, be open for inspection not more than once per Calendar Year at reasonable times by an independent certified public accountant selected by BMS and as to which Eiger has no reasonable objection, at BMS' expense, for the purpose of verifying royalty statements and payments for compliance with this Agreement for any period within the preceding [*].

8.7.3 Eiger shall include in its Sublicense Agreements with any Sublicensees, a right for Eiger to inspect or have such an accountant inspect, not more than once during any Calendar Year, the books of accounting and such supporting data and records of such Sublicensees for the purpose of verifying royalty statements and payments for compliance with this Agreement for any period within the preceding [*].

8.7.4 Results of any inspection under Section 8.7.2 or 8.7.3 shall be made available to both Eiger and BMS, and shall be deemed Eiger's Confidential Information under this Agreement; provided that the independent, certified public accountant shall disclose to BMS only the amounts that the independent auditor believes to be due and

payable hereunder to BMS, details concerning any discrepancy from the amount paid (including the reasons therefor) and the amount due, and shall disclose no other information revealed in such audit.

8.7.5 Such accountant must have agreed in writing to maintain all information learned in confidence, except as necessary to disclose to BMS such compliance or noncompliance by Eiger, its Affiliates or Sublicensees (who must agree in the Sublicense Agreement that such audit report may be disclosed to BMS). The results of each inspection, if any, shall be binding on both Parties. BMS shall pay for such inspections, except that in the event there is any upward adjustment in aggregate royalties payable for any Calendar Year shown by such inspection of more than [*] of the amount paid, Eiger shall pay for such inspection. Any underpayments shall be paid by Eiger within [*] after notification of the results of such inspection. Any overpayments shall be fully creditable against amounts payable in subsequent payment periods.

8.8 Currency Exchange. Eiger's then current standard exchange rate methodology will be employed for the translation of foreign currency sales into Dollars, provided such methodology is used by Eiger in the translation of its foreign currency operating results, is consistent with GAAP, and is audited by Eiger's independent certified public accountants in connection with the audit of the consolidated financial statements of Eiger, and is used for Eiger's external reporting of foreign currency operating results.

8.9 Taxes.

8.9.1 Each Party will pay any and all taxes levied on account of all payments it receives under this Agreement.

8.9.2 If laws or regulations require that taxes be withheld with respect to any royalty payments by Eiger to BMS under this Agreement, Eiger will: (a) deduct those taxes from the remittable payment, (b) pay the taxes to the proper taxing authority, and (c) send evidence of the obligation together with proof of tax payment to BMS on a reasonable and timely basis following that tax payment. Each Party agrees to cooperate with the other Party in claiming refunds or exemptions from such deductions or withholdings under any relevant agreement or treaty which is in effect. The Parties shall discuss applicable mechanisms for minimizing such taxes to the extent possible in compliance with applicable Laws. BMS will pay any and all taxes levied on account of all payments it receives under this Agreement; provided, that notwithstanding the foregoing, in the event that [*].

8.9.3 The Parties shall cooperate in accordance with applicable Laws to minimize indirect taxes (such as value added tax, sales tax, consumption tax and other similar taxes) in connection with this Agreement

8.10 Interest Due. Without limiting any other rights or remedies available to BMS, Eiger shall pay BMS interest on any payments that are not paid on or before the date such payments are due under this Agreement at a rate of [*] or the maximum applicable legal rate, if less, calculated on the total number of days payment is delinquent.

ARTICLE 9

REPRESENTATIONS AND WARRANTIES; DISCLAIMER; LIMITATION OF LIABILITY

9.1 Mutual Representations and Warranties. Each Party represents and warrants to the other Party that, as of the Effective Date: (i) it is duly organized, validly existing and in good standing under the Laws of the jurisdiction of its incorporation and has all requisite corporate power and authority to enter into this Agreement and to perform its obligations under this Agreement, (ii) execution of this Agreement and the performance by such Party of its obligations hereunder have been duly authorized, (iii) this Agreement has been duly executed and delivered on behalf of such Party, and is legally binding and enforceable on each Party in accordance with its terms, (iv) the performance of this Agreement by it does not create a breach or default under any other agreement to which it is a Party, (v) the execution, delivery and performance of this Agreement by such Party does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound, nor violate any Law or regulation of any court, governmental body or administrative or other agency having jurisdiction over such Party, (vi) no government authorization, consent, approval, license, exemption of or filing or registration with any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, under any Laws currently in effect, is or will be necessary for, or in connection with, the transaction contemplated by this Agreement or any other agreement or instrument executed in connection herewith, or for the performance by it of its obligations under this Agreement and such other agreements, and (vii) neither such Party, nor any of its employees, officers, subcontractors, or consultants who have rendered services relating to the Licensed Compounds: (a) has ever been debarred or is subject to debarment or convicted of a crime for which an entity or person could be debarred by the FDA under 21 U.S.C. Section 335a or (b) has ever been under indictment for a crime for which a person or entity could be so debarred.

9.2 Representations, Warranties, and Covenants of BMS. Except as set forth on Appendix 8:

9.2.1 BMS represents and warrants to Eiger that, as of the Effective Date:

(a) there is no pending litigation, or litigation that has been threatened in writing, which alleges, or any written communication alleging, that BMS' activities with respect to the research, Development or manufacture of the Licensed Compounds prior to the Effective Date have infringed or misappropriated, or would infringe or misappropriate, any of the intellectual property rights of any Third Party, and to BMS' Knowledge, the research, Development or manufacture of the Licensed Compounds prior to the Effective Date did not infringe or misappropriate any Third Party rights.

(b) no Third Party has challenged in writing the ownership, scope, duration, validity, enforceability, priority or right to use any BMS Patent Rights (including, by way of example, through the institution of or written threat of institution of interference, *inter partes* review, reexamination, protest, opposition, nullity or similar invalidity proceeding before the United States Patent and Trademark Office or any foreign patent authority or court) or BMS Know-How,

(c) there is no actual, pending, or, to BMS's Knowledge, alleged or threatened in writing, adverse interferences or governmental investigations or suits involving the Licensed Compounds;

(d) no BMS Patents or BMS Know-How has been licensed to BMS from any Third Party that BMS does not Control and which is material to the Development of the Licensed Compound as contemplated by the Development Plan;

(e) to BMS' Knowledge, it has complied with all applicable Laws in the Development of the Licensed Compounds prior to the Effective Date;

(f) except for the patent and patent applications that have been abandoned prior to the Effective Date, all fees required to be paid by BMS in any jurisdiction in order to maintain the Patent Rights licensed to Eiger hereunder have, to BMS' Knowledge, been timely paid as of the Effective Date and, to BMS' Knowledge, the claims included in any issued patents included in such Patent Rights are in full force and effect as of the Effective Date;

(g) BMS has full unencumbered title to the Transferred Material and sufficient right under the BMS Patent Rights and BMS Know-How to grant the licenses to Eiger as purported to be granted hereunder, and has not previously assigned, transferred, conveyed, or granted any license or other rights to its right, title and interest in the BMS Patent Rights or the BMS Know-How, in any way that would materially conflict with or materially limit the scope of any of the rights or licenses granted to Eiger hereunder;

(h) BMS solely owns all the rights, title and interest in the BMS Patent Rights and the BMS Patent Rights are free of any lien or security interest;

(i) except as set forth in Appendix 1, BMS and its Affiliates do not own or control any other Patent Rights that are necessary or, to BMS's Knowledge and reasonable belief as of the Effective Date, reasonably useful to carry out the Development (including manufacture) of Licensed Compounds and/or Licensed Products as contemplated by the Development Plan attached as Appendix 2 hereto; and

(j) subject to Section 3.1.2, to BMS' Knowledge, the documents, data and information that are included in the BMS Know-How transferred to Eiger pursuant to Section 3.1 comprise all of the Know-How Controlled by BMS that is reasonably necessary for the manufacture of BMS molecule known as PEG-interferon Lambda-1a as the same is manufactured as of the Effective Date, and

9.2.2 BMS covenants that it shall not license, sell, assign or otherwise transfer to any person (including any Affiliate of BMS) any BMS Patent Rights or any BMS Know-How, or assign or otherwise transfer any of its rights or obligations thereunder to any person (including any Affiliate of BMS) (or offer or agree to do any of the foregoing) in any manner that would have a material adverse impact on the rights granted to Eiger under this Agreement, except to the extent permitted by, and in compliance with, Section 15.4. In addition, BMS hereby covenants and agrees that after the Effective Date BMS shall use commercially reasonable efforts to not incur or permit to exist (and to cause each of its Affiliates not to incur or permit to exist), with respect to any BMS Patent Rights or any BMS Know-How, any lien, encumbrance, or security interest (including in connection with any indebtedness) in any manner that would have a material adverse impact on the rights granted to Eiger under this Agreement, except to the extent permitted by, and in compliance with, Section 15.4.

9.3 Representations and Warranties of Eiger. Eiger represents, warrants and covenants that:

9.3.1 it shall not engage in any activities that use the BMS Patent Rights and/or BMS Know-How in a manner that is outside the scope of the license rights granted to it hereunder,

9.3.2 all of its activities related to its use of the BMS Patent Rights and BMS Know-How, and the research, Development and Commercialization of the Licensed Compounds and/or Licensed Products, pursuant to this Agreement shall comply with all applicable Law,

9.3.3 prior to filing the first drug application (i.e., a BLA or its foreign equivalent) for a Licensed Product, Eiger shall have all licenses that are necessary in order for the manufacture, use or sale of such Licensed Product not to infringe the intellectual property of any Third Party known to Eiger as of such date, but excluding licenses applicable to any Third Party issued patents for which Eiger shall have obtained a well-reasoned, written opinion of an outside patent attorney that Eiger's activities under the scope of this Agreement are not reasonably likely to infringe any Valid Claim of such Third Party issued patent, and

9.3.4 it will make available funds necessary to consummate the transaction contemplated by this Agreement and to Develop and Commercialize the Licensed Compounds and Licensed Products in accordance with the terms of this Agreement.

9.4 DISCLAIMER. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO ANY LICENSED COMPOUNDS, LICENSED PRODUCTS, TRANSFERRED MATERIALS, THE BMS PATENT RIGHTS OR BMS KNOW-HOW OR ANY RIGHT OR LICENSE GRANTED BY BMS HEREUNDER, AND NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS A REPRESENTATION OR WARRANTY BY BMS THAT ANY PATENT OR OTHER PROPRIETARY RIGHTS INCLUDED IN THE BMS PATENT RIGHTS ARE VALID OR ENFORCEABLE OR THAT USE OF THE BMS PATENT RIGHTS, BMS KNOW-HOW AND TRANSFERRED MATERIALS CONTEMPLATED HEREUNDER DOES NOT INFRINGE ANY PATENT RIGHTS OR OTHER INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY.

9.5 Limitation of Liability. NOTWITHSTANDING ANYTHING IN THIS AGREEMENT OR OTHERWISE, NEITHER PARTY SHALL BE LIABLE TO THE OTHER WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT, WHETHER UNDER ANY CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY, FOR ANY INCIDENTAL, INDIRECT, SPECIAL, EXEMPLARY, PUNITIVE, MULTIPLE, OR CONSEQUENTIAL DAMAGES (INCLUDING, WITHOUT LIMITATION, LOST PROFITS, LOSS OF USE, DAMAGE TO GOODWILL, OR LOSS OF BUSINESS), AND IN ANY CASE, BMS SHALL NOT BE LIABLE FOR ANY DAMAGES OF ANY KIND (INCLUDING DIRECT DAMAGES) IN AN AMOUNT GREATER THAN THE AMOUNTS PAID BY EIGER TO BMS UNDER SECTIONS 8.1 AND 8.2 OF THIS AGREEMENT; *PROVIDED, HOWEVER*, THAT THE FOREGOING SHALL NOT APPLY TO ANY BREACH BY A PARTY OF ARTICLE 11 HEREOF, TO A BREACH BY EIGER OF SECTION 5.6, WILLFUL MISCONDUCT BY A PARTY, OR FOR AMOUNTS SOUGHT BY THIRD PARTIES IN CLAIMS THAT ARE SUBJECT TO THE PARTIES' RESPECTIVE INDEMNITY OBLIGATIONS UNDER ARTICLE 12. FOR THE AVOIDANCE OF DOUBT, ANY DAMAGES IN THE NATURE OF LOST ROYALTIES TO BMS SHALL BE CONSIDERED DIRECT DAMAGES.

ARTICLE 10

PATENT MAINTENANCE; INFRINGEMENT; PATENT EXTENSIONS

10.1 Inventions. Inventorship of inventions conceived or reduced to practice in the course of Development activities under this Agreement shall be determined by application of United States patent Laws pertaining to inventorship. If such inventions are jointly invented in the course of Development activities by one or more employees or consultants or contractors of both Parties, such inventions shall be jointly owned ("Joint Invention"), and if one or more claims included in an issued patent or pending patent application which is filed in a patent office in the Territory claim such Joint Invention, such patent or patent application shall be jointly owned ("Joint Patent Rights"). If such an invention is solely invented by an employee or consultant of a Party, such invention shall be solely owned by such Party, and any patent filed claiming such solely owned invention shall also be solely owned by such Party. This Agreement shall be understood to be a joint research agreement in accordance with 35 U.S.C. § 102(c) to develop the Licensed Compounds and/or Licensed Products. Each Party shall enter into binding agreements obligating all employees and consultants performing activities under or contemplated by this Agreement, including activities related to the BMS Patent Rights, Licensed Compounds or Licensed Products, to assign his/her interest in any invention conceived or reduced to practice in the course of such activities to the Party for which such employee or consultant is providing its services. With respect to contractors, Eiger shall use good faith and reasonable efforts to secure an agreement from such contractor to assign or license (with the right to sublicense) to Eiger inventions (and patent rights covering such inventions) made by such contractor in performing such services for Eiger.

10.2 Filing, Prosecution and Maintenance of BMS Patent Rights. Eiger will have lead responsibility, using its in-house patent counsel or outside patent counsel selected by Eiger (such determination and outside patent counsel selection to be subject to BMS' approval, such approval not to be unreasonably withheld), for the preparation, prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance of the BMS Patent Rights. Eiger shall be responsible for the costs incurred with respect to the filing, prosecution and maintenance of the BMS Patent Rights. Eiger shall provide BMS with [*] updates of the filing, prosecution and maintenance status for each of the BMS Patent Rights, and shall promptly provide copies of any material official correspondence to or from patent offices. The Parties shall reasonably consult with each other and cooperate with respect to the preparation, prosecution and maintenance of the BMS Patent Rights, including by providing assistance as described in Section 3.2, and will confer regarding where to prosecute the BMS Patent Rights. Eiger shall not take any action during prosecution and maintenance of the BMS Patent Rights that would materially adversely affect them (including reduction in claims scope), without BMS' prior express written consent (which consent shall not be unreasonably withheld, delayed or conditioned and shall be considered to be given if Eiger notifies BMS of proposed claim amendments or cancellations and BMS fails to object within [*] of such notification). Eiger may file a notice with governmental patent offices of the exclusive license to the BMS Patent Rights granted to Eiger hereunder. Post-grant proceedings involving the BMS Patent Rights, including oppositions, cancellations, *inter partes* review, and the like, shall be conducted by Eiger at the expense of Eiger, and Eiger shall promptly notify BMS of the initiation of such proceeding (or vice versa) and Eiger shall give BMS the opportunity to participate, at the sole expense of BMS, and BMS shall also participate and appear as necessary under the applicable rules governing the proceeding. Any settlement or compromise of such post-grant proceeding shall be subject to the approval of BMS, which approval shall not be unreasonably withheld, delayed or conditioned.

10.3 Patent Abandonment.

10.3.1 The Parties will confer and must mutually agree before any of the BMS Patent Rights may be abandoned in any Major Market Country; provided that BMS shall not unreasonably withhold, delay or condition its consent to a request by Eiger to abandon a BMS Patent Right if such abandonment will not adversely affect the amount or duration of any royalty payable to BMS hereunder. Eiger shall provide BMS with notice of the allowance and expected issuance date of any patent within the BMS Patent Rights, or any of the deadline for filing a new patent application, and BMS shall provide Eiger with prompt notice as to whether BMS desires Eiger to file such new patent application.

10.3.2 Subject to Section 10.3.1, in the event that Eiger decides either (a) not to continue the prosecution or maintenance of a patent application or patent within the BMS Patent Rights in any country, or (b) not to file any new patent application requested to be filed by BMS, Eiger shall provide BMS with express written notice of this decision at least [*] prior to any pending lapse or abandonment thereof, or if a decision not to continue prosecution or maintenance is responsive to an official communication from governmental agency that is received by Eiger less than [*] prior to a deadline for taking action in response thereto, then the deadline for giving such notice to BMS shall be [*] of the time remaining for response after such communication is received by Eiger. In such event, provided that the Parties have not expressly agreed to abandon a patent or not file a patent application under Section 10.3.1, then Eiger shall provide BMS with an opportunity

to assume responsibility for all external costs reasonably associated with the filing and/or further prosecution and maintenance of such patent application and any patent issuing thereon (such filing to occur prior to the issuance of the patent to which the application claims priority or expiration of the applicable filing deadline, as set forth above). In the event that BMS assumes such responsibility for such filing, prosecution and maintenance costs, Eiger shall transfer the responsibility for such filing, prosecution and maintenance of such patent applications and patents to BMS and Eiger shall no longer have any right or license in and to such patent application and patents issuing therefrom under this Agreement.

10.4 Enforcement of BMS Patent Rights against Infringers.

10.4.1 Enforcement by Eiger. In the event that BMS or Eiger becomes aware of a suspected infringement of any BMS Patent Right in the Field, including actual or alleged infringement under 35 USC §271(e)(2) that is or would be infringing activity involving the using, making, importing, offering for sale or selling of articles that the Party reasonably believes infringes any of the Patent Rights conferred under this Agreement, such Party shall notify the other Party promptly, including all information available to such Party with respect to such alleged infringement, and following such notification, the Parties shall confer. Eiger shall have the first right, but shall not be obligated, to bring an infringement action for suspected infringement in the Field at its own expense, in its own name and entirely under its own direction and control, subject to the following: (a) BMS shall reasonably assist Eiger (at Eiger's expense) in any action or proceeding being prosecuted for suspected infringement in the Field if so requested, including by being named or joined as a plaintiff to such actions or proceedings if requested by Eiger or required by Law, (b) BMS shall have the right to participate and be represented in any such suit by its own counsel at its own expense, (c) no settlement of any such action or proceeding which restricts the scope, or adversely affects the enforceability, of a BMS Patent Right in the Field may be entered into by Eiger without the prior written consent of BMS, which consent shall not be unreasonably withheld, delayed or conditioned, and further, no settlement of any such action or proceeding which pertains to the infringement of the BMS Patent Rights by virtue of the Development or Commercialization of a Licensed Compound in the Field by a Third Party that is not a Sublicensee may

be entered into by Eiger without the prior written consent of BMS, which consent shall not be unreasonably withheld, delayed or conditioned.

10.4.2 Timing; Enforcement by BMS. Eiger will have a period of [*] after its receipt or delivery of notice and evidence pursuant to Section 10.4.1 or receipt of written notice from a Third Party that reasonably evidences such infringement of the BMS Patent Rights, to elect to so enforce such BMS Patent Rights in the applicable jurisdiction (or to settle or otherwise secure the abatement of such infringement in accordance with Section 10.4.1), provided however, that such period will be (i) more than [*] to the extent applicable Law prevents earlier enforcement of such BMS Patent Right (such as the enforcement process set forth in or under the Hatch-Waxman Act), and provided further that if such period is extended because applicable Law prevents earlier enforcement, Eiger shall have until the date that is [*] following the date upon which applicable Law first permits such proceeding, and (ii) less than [*] to the extent that a delay in bringing such proceeding against such alleged Third Party infringer would materially limit or compromise the remedies (including monetary relief, and stay of regulatory approval) available against such alleged Third Party infringer. In the event Eiger does not so elect (or settle or otherwise secure the abatement of such infringement) before the first to occur of (A) the expiration of the applicable period of time set forth in the preceding subsections (i) and (ii), or (B) [*] before the expiration of any time period under applicable Law, that would, if a proceeding was not filed within such time period, limit or compromise the remedies available from such proceeding, it will so notify BMS in writing and in the case where BMS then desires to commence a suit or take action to enforce the applicable BMS Patent Right in the applicable jurisdiction, BMS will thereafter have the right to commence such a suit or take such action to enforce the applicable BMS Patent Right, as applicable, at BMS' expense, provided that BMS shall first consult with Eiger concerning the reasons Eiger elected not to bring such action and shall consider those reasons in good faith in deciding whether to bring such action. Eiger shall reasonably assist BMS (at BMS' expense) in any action or proceeding being prosecuted if so requested, including by being named or joined as a plaintiff to such actions or proceedings if requested by BMS or required by Law. Eiger shall have the right to participate and be represented in any such suit by its own counsel at its own expense. No settlement of any such action or proceeding which restricts the scope, or adversely affects the enforceability, of a BMS Patent Right may be entered into by BMS without the prior written consent of Eiger, which consent shall not be unreasonably withheld, delayed or conditioned.

10.4.3 Withdrawal. If either Party brings an action or proceeding under this Section 10.4 and subsequently ceases to pursue or withdraws from such action or proceeding, it shall promptly notify the other Party and the other Party may substitute itself for the withdrawing Party under the terms of this Section 10.4.

10.4.4 Damages. In the event that either Party exercises the rights conferred in this Section 10.4 and recovers any damages or other sums in such action, suit or proceeding or in settlement thereof, such damages or other sums recovered shall first be applied to all reasonable out-of-pocket costs and expenses incurred by the Parties in connection therewith, including attorneys' fees. If such recovery is insufficient to cover all such costs and expenses of both Parties, it shall be [*]. If after such reimbursement any funds shall remain from such damages or other sums recovered, such funds shall be [*]; *provided, however*, that if [*], such remaining amount [*].

10.5 Infringement of Third Party Rights

10.5.1 The Parties will promptly notify each other of any allegation that any activity under this Agreement infringes or may infringe the intellectual property rights of any Third Party.

10.5.2 In any legal allegation related to the infringement of a Third Party intellectual property right, Eiger will have the first right to control, at its expense, the defense of such allegation. BMS will have the right, at its own expense and with its own choice of counsel, to be represented in the defense of the allegation.

10.5.3 The Parties will reasonably cooperate with each other in all respects with all matters related to the defense of any legal allegation under this section.

10.6 Patent Term Extensions. BMS and Eiger shall each reasonably cooperate with one another and shall use Commercially Reasonable Efforts in obtaining patent term extension (including any pediatric exclusivity extensions as may be available) or supplemental protection certificates or their equivalents in any country with respect to Patent Rights covering the Licensed Products. If elections with respect to obtaining such patent term extensions are to be made, Eiger shall have the right, at its discretion, to make the election to seek patent term extension or supplemental protection with respect to the Patent Right for which such extension or supplemental protection should be sought, *provided* that Eiger shall use Commercially Reasonable Efforts to make such election so as to maximize the period of marketing exclusivity for the Licensed Product. For such purpose, for all Approvals Eiger shall provide BMS with written notice within [*] following receipt of each Approval. Notification of the receipt of an Approval shall be in accordance with Section 15.2 except that the notification shall be sent to:

Bristol-Myers Squibb Company
P.O. Box 4000
Route 206 & Province Line Road
Princeton, New Jersey 08543-4000
Attention: Vice President and Chief Patent Counsel
Telephone: 609-252-4825
Facsimile: 609-252-7884

10.7 Data Exclusivity and Orange Book Listings. With respect to data exclusivity periods (including any available pediatric extensions) or periods under national implementations of Article 10.1 of Directive 2001/EC/83 (and all international equivalents), Eiger shall use Commercially Reasonable Efforts consistent with its obligations under applicable Law to seek, maintain and enforce all such data exclusivity periods available for the Licensed Products. With respect to patent listing filings in the FDA Orange Book (and foreign equivalents thereof) for issued patents for a Licensed Product, Eiger shall, consistent with its obligations under applicable Law, have the right to list in a timely manner and maintain all applicable BMS Patent Rights. At least [*] prior to an anticipated deadline for the filing of patent listing information for BMS Patent Rights, Eiger shall consult with BMS regarding the content of such filing, and shall consider BMS's comments in good faith, provided that Eiger shall have the final decision right with respect to such filing, including the Patent Rights to be listed in any FDA Orange Book or any equivalent. BMS shall provide, consistent with its obligations under applicable Law, reasonable cooperation to Eiger in filing and maintaining such Orange Book (and foreign equivalent) listings.

10.8 Notification of Patent Certification. Eiger shall notify and provide BMS with copies of any allegations of alleged patent invalidity, unenforceability or non-infringement of a BMS Patent Right by a Third Party filing a bioequivalent or biosimilar application or other similar patent certification or filing, and any foreign equivalent thereof. Such notification and copies shall be provided to BMS within [*] after Eiger receives such certification, and shall be sent to the address set forth in Section 10.6. In addition, upon request by BMS, Eiger shall provide reasonable assistance and cooperation (including

making available to BMS documents possessed by Eiger that are reasonably required by BMS and making available personnel for interviews and testimony), at BMS' cost, in any actions reasonably undertaken by BMS to contest any such patent allegation or certification.

10.9 No Conflict Actions. BMS shall not be required to take any action pursuant to Sections 10.4, 10.7 or 10.8 that BMS reasonably determines in its sole judgment and discretion conflicts with or violates any court or government order or decree that BMS is then subject to or otherwise may create legal liability on the part of BMS.

10.10 Assignment of BMS Patent Rights to a BMS Affiliate. Notwithstanding any provision in this Agreement to the contrary, BMS shall have the right to transfer or assign ownership of any BMS Patent Rights to a BMS Affiliate as long as any such transfer or assignment is made expressly subject to and assumption in writing of the rights, obligations and licenses granted to Eiger under this Agreement. BMS shall remain responsible for the compliance by such Affiliate with the terms of this Agreement.

ARTICLE 11

NONDISCLOSURE OF CONFIDENTIAL INFORMATION

11.1 Nondisclosure. Each Party agrees that, for so long as this Agreement is in effect and for a period of [*] thereafter, a Party receiving Confidential Information of the other Party (or that has received any such Confidential Information from the other Party prior to the Effective Date under the CDA) shall (i) maintain in confidence such Confidential Information using not less than the efforts such Party uses to maintain in confidence its own proprietary industrial information of similar kind and value, (ii) not disclose such Confidential Information to any Third Party without the prior written consent of the other Party, except for disclosures expressly permitted below, and (iii) not use such Confidential Information for any purpose except those permitted by this Agreement (which includes the performance of its obligations and the exercise of its rights under this Agreement, but it being understood that this clause (iii) shall not create or imply any rights or licenses not expressly granted under Article 2).

11.2 Exceptions. The obligations in Section 11.1 shall not apply with respect to any portion of the Confidential Information that the receiving Party can show by competent proof:

11.2.1 is publicly disclosed by the disclosing Party, either before or after it is disclosed to the receiving Party hereunder; or

11.2.2 was known to the receiving Party or any of its Affiliates, without any obligation to keep it confidential or any restriction on its use, prior to disclosure by the disclosing Party; or

11.2.3 is subsequently disclosed to the receiving Party or any of its Affiliates by a Third Party lawfully in possession thereof and is disclosed without any obligation to keep it confidential or any restriction on its use; or

11.2.4 is published by a Third Party or otherwise becomes publicly available or enters the public domain, either before or after it is disclosed to the receiving Party, other than through the receiving Party's breach of its confidentiality obligations set forth herein; or

11.2.5 has been independently developed by employees or contractors of the receiving Party or any of its Affiliates without the aid, application or use of Confidential Information of the disclosing Party.

11.3 Authorized Disclosure. The receiving Party may disclose Confidential Information belonging to the other Party to the extent (and only to the extent) such disclosure is reasonably necessary in the following instances:

11.3.1 filing or prosecuting patents as set forth in this Agreement;

11.3.2 Eiger's research, Development or Commercialization (including any import, manufacture, use, offer for sale, or sale) activities, including Eiger's regulatory filings, with respect to Licensed Compounds and/or Licensed Product, including any Approvals or applications therefor;

11.3.3 prosecuting or defending litigation in relation to the BMS Patent Rights, BMS Know How or this Agreement, including responding to a subpoena in a Third Party litigation;, provided it has used good faith and reasonable efforts to obtain a protective order for such Confidential Information;

11.3.4 subject to Section 11.4, complying with applicable Laws (including the rules and regulations of the Securities and Exchange Commission or any national securities exchange) and with judicial process, if in the reasonable opinion of the receiving Party's counsel, such disclosure is necessary for such compliance; *provided, however,* that except where impracticable, the receiving Party shall give the disclosing Party reasonable advance notice of such disclosure requirement (which shall include a copy of any applicable subpoena or order) and shall afford the disclosing Party a reasonable opportunity to oppose, limit or secure confidential treatment for such required disclosure, and in the event of any such required disclosure, the receiving Party shall disclose only that portion of the Confidential Information of the disclosing Party that the receiving Party is legally required to disclose;

11.3.5 disclosure, in connection with the performance of this Agreement and solely on a "need to know basis", to Affiliates, existing or potential collaborators (including existing or potential co-marketing and co-promotion contractors), research collaborators, employees, consultants, or agents, each of whom prior to disclosure must be bound by written obligations of confidentiality and non-use no less restrictive than the obligations set forth in this Article 11; *provided, however*, that the receiving Party shall remain responsible for any failure by any Person who receives Confidential Information pursuant to this Article 11 to treat such Confidential Information as required under this Article 11; and

11.3.6 made by such Party to existing or potential acquirers or merger candidates; investment bankers; public and private sources of funding; existing or potential investors, venture capital firms or other financial institutions or investors for purposes of evaluating or carrying out an acquisition, merger, or financing transaction, *provided* that such Party has used good faith and reasonable efforts to secure an agreement from any such Third Party to be bound by obligations of confidentiality and restrictions on use of Confidential Information that are no less restrictive than the obligations in this Agreement.

If and whenever any Confidential Information is disclosed in accordance with this Section 11.3, such disclosure shall not cause any such information to cease to be Confidential Information except to the extent that such disclosure results in a public disclosure of such information (otherwise than by breach of this Agreement). Where reasonably possible and subject to Section 11.4, the receiving Party shall notify the disclosing Party of the receiving Party's intent to make such disclosure pursuant to this Section 11.3 sufficiently prior to making such disclosure so as to allow the disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information.

11.4 Terms of this Agreement. The Parties acknowledge that the terms of this Agreement shall be treated as Confidential Information of both Parties. For the avoidance of doubt, this Section 11.4 shall in no way prevent a Party from disclosing the existence of this Agreement or any terms of this Agreement in order to seek legal advice whenever deemed appropriate by such Party or to enforce such Party's rights under this Agreement, whether through arbitral proceedings, court proceedings or otherwise, or to defend itself against allegations or claims relating to this Agreement, or to comply with Applicable Law (except as provided in Section 11.5 below) when advised in a written opinion of outside counsel that terms of the Agreement are required to be disclosed to comply with Applicable Law.

11.5 Securities Filings. Notwithstanding anything to the contrary in this Agreement, in the event either Party proposes to file with the Securities and Exchange Commission or the securities regulators of any state or other jurisdiction a registration statement or any other disclosure document which describes or refers to this Agreement under the Securities Act of 1933, as amended, the Securities Exchange Act, of 1934, as amended, any other applicable securities Law or the rules of any national securities exchange, the Party shall notify the other Party of such intention and shall use reasonable efforts to provide such other Party with a copy of relevant portions of the proposed filing not less than [*] prior to (but in no event later than [*] prior to) such filing (and any revisions to such portions of the proposed filing a reasonable time prior to the filing thereof), including any exhibits thereto relating to this Agreement, and shall use reasonable efforts to obtain confidential treatment of any information concerning this Agreement that such other Party requests be kept confidential, and shall only disclose Confidential Information which it is advised by counsel is legally required to be disclosed. No such notice shall be required under this Section 11.5 if the substance of the description of or reference to this Agreement contained in the proposed filing has been included in any previous filing made by the either Party hereunder or otherwise approved by the other Party.

11.6 Publication by Eiger. Eiger may publish or present data and/or results relating to a Licensed Compound or Licensed Product developed in the Field in scientific journals and/or at scientific conferences, provided that Eiger shall notify BMS at least [*] in advance of the intended submission for publication or presentation of any proposed abstract, manuscript or presentation which discloses Confidential Information of BMS or discloses a patentable invention by delivering a copy thereof to BMS. BMS shall have [*] from its receipt of any such abstract, manuscript or presentation in which to notify Eiger in writing of any specific, reasonable objections to the disclosure, based on concern regarding the specific disclosure of Confidential Information of BMS, and Eiger will delete any BMS Confidential Information, and consider any other such objections in good faith, including whether it is necessary or advisable to delete any other information from such proposed publication. Once any such abstract or manuscript is accepted for publication, Eiger shall provide BMS with a copy of the final version of the manuscript or abstract.

ARTICLE 12

INDEMNITY

12.1 Eiger Indemnity. Eiger shall indemnify, defend and hold harmless BMS and its Affiliates, and their respective officers, directors, employees, agents, licensors, and their respective successors, heirs and assigns and representatives, from and against any and all damages, liabilities, losses, costs and expenses (including reasonable legal expenses, costs of litigation and reasonable attorney's fees) arising in connection with any claims, suits, proceedings, whether for money damages or equitable relief, of any kind brought by any Third Party (collectively "Losses and Claims") and arising out of or relating to (a) a breach of this Agreement by Eiger or any of its Affiliates, Sublicensees, agents and contractors, (b) the research, Development, Commercialization (including promotion, advertising, offering for sale, sale or other disposition), transfer, importation or exportation, manufacture, labeling, handling or storage, or use of, or exposure to, any Licensed Compound or any Licensed Product by or for, or failure to comply with applicable Law by, Eiger or any of its Affiliates, Distributors, Sublicensees, agents and contractors, including claims and threatened claims based on product liability, bodily injury, risk of bodily injury, death or property damage, infringement or misappropriation of Third Party patents, copyrights, trademarks or other intellectual property rights, or the failure to comply with applicable Law related to the matters referred to in this subsection (a) with respect to any Licensed Compound or any Licensed Product, (c) the prosecution, maintenance, enforcement and defense of the BMS Patents by Eiger, its Affiliates, Sublicensees, representatives and agents; and/or (d) the gross negligence, recklessness or willful misconduct of Eiger or its Affiliates or its or their respective directors, officers, employees and agents, in connection with Eiger's performance of its obligations or exercise of its rights under this Agreement; *except* in any such case for Losses and Claims to the extent reasonably attributable to any breach of this Agreement by BMS (including its representations and warranties set forth in Section 4.1 and Article 9), or BMS having committed an act or acts of gross negligence, recklessness or willful misconduct, or to the extent BMS has an indemnification obligation to Eiger pursuant to Section 12.2.

12.2 BMS Indemnity. BMS shall indemnify, defend and hold harmless Eiger and its Affiliates, and their respective officers, directors, employees, agents, licensors, and their respective successors, heirs and assigns and representatives, from and against any and all Losses payable to a Third Party based on Claims brought by a Third Party arising out of or relating to (a) a breach of this Agreement by BMS, including the representations, warranties and covenants of BMS set forth in Section 4.1 and/or Article 9, (b) the gross negligence, recklessness or willful misconduct of BMS or its Affiliates or its or their respective directors, officers, employees and agents, in connection with BMS's performance of its obligations or exercise of its rights under this Agreement, (c) personal injury arising out of the conduct by BMS of clinical studies for the Licensed Compounds prior to the Effective Date, (d) payments for services rendered to BMS prior to the Effective Date related to the Licensed Compounds, (e) the conduct and close of any existing CTAs and CTXs for the Licensed Compound not assigned to Eiger under Section 3.3 after the Effective Date; and/or (f) any Development, use, manufacture, or Commercialization of BMS Reversion Products by BMS following the reversion thereof to BMS pursuant to Section 13.4 in the Territory, including any product liability claims and intellectual property infringement claims in the Territory or any personal injury, property damage or other damage in the Territory arising therefrom; *except* in any such case for Losses and Claims to the extent reasonably attributable to any breach of this Agreement by Eiger, its Affiliates or Sublicensees, failure of Eiger, its Affiliates or Sublicensees to comply with Applicable Law with respect to its Development or Commercialization of the Licensed Compounds or Licensed Products, or Eiger, its Affiliates or Sublicensees having committed an act or acts of gross negligence, recklessness or willful misconduct, or to the extent Eiger has an indemnification obligation to BMS pursuant to Section 12.1.

12.3 Indemnification Procedure. A claim to which indemnification applies under Section 12.1 shall be referred to herein as an "Indemnification Claim". If any Person or Persons (collectively, the "Indemnitee") intends to claim indemnification under this Article 12, the Indemnitee shall notify the Party subject to the indemnification obligation (the "Indemnitor") in writing promptly upon becoming aware of any claim that may be an Indemnification Claim (it being understood and agreed, however, that the failure by an Indemnitee to give such notice shall not relieve Indemnitor of its indemnification obligation under this Agreement except and only to the extent that the Indemnitor is actually prejudiced as a result of such failure to give notice). The Indemnitor shall have the right to assume and control the defense of the Indemnification Claim at its own expense with counsel selected by the Indemnitor and reasonably acceptable to the Indemnitee, *provided, however,* that an Indemnitee shall have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnitee, if representation of such Indemnitee by the counsel retained by the Indemnitor would be inappropriate due to actual or potential differing interests between such Indemnitee and any other party represented by such counsel in such proceedings. If the Indemnitor does not assume the defense of the Indemnification Claim as aforesaid, the Indemnitee may defend the Indemnification Claim but shall have no obligation to do so. The Indemnitee shall not settle or compromise the Indemnification Claim without the prior written consent of the Indemnitor, and the Indemnitor shall not settle or compromise the Indemnification Claim in any manner which would have an adverse effect on the Indemnitee's interests (including any rights under this Agreement or the scope or enforceability of the BMS Patents Rights or BMS Know-How), without the prior written consent of the Indemnitee, which consent, in each case, shall not be unreasonably withheld, delayed or conditioned if the settlement or compromise would impose no financial or other obligations or burdens on the Indemnitee. The Indemnitee shall reasonably cooperate with the Indemnitor at the Indemnitor's expense and shall make available to the Indemnitor all pertinent information under the control of the Indemnitee, which information shall be subject to Article 11.

12.4 Insurance. Eiger shall, beginning with the initiation of the first clinical trial for a Licensed Product, maintain at all times thereafter during the term of this Agreement, and until the later of (i) [*] after termination or expiration of this Agreement or (ii) the date that all statutes of limitation covering claims or suits that may be brought for personal injury based on the sale or use of a Licensed Product have expired in all states in the U.S., insurance relating to the Licensed Product from a recognized, creditworthy insurance company, on a claims-made basis, with endorsements for contractual liability and for clinical trial and product liability, that is comparable in type and amount to the insurance customarily maintained by Eiger with respect to similar prescription pharmaceutical products that are marketed, distributed and sold in the Territory. Within ten (10) days following the Effective Date, and within thirty (30) days following any material change or cancellation in coverage, Eiger shall furnish to BMS a certificate of insurance evidencing such coverage as of such date, and in the case of cancellation, provide a certificate evidencing that Eiger's replacement coverage meets the requirements in the first sentence of this Section 12.4. The foregoing insurance requirement shall not be construed to create a limit on Eiger's liability hereunder.

ARTICLE 13

TERM AND TERMINATION

13.1 Term. This Agreement shall commence as of the Effective Date and, unless sooner terminated in accordance with the terms hereof or by mutual written consent, shall expire on a country-by-country basis and Licensed Product-by-Licensed Product basis, upon the expiration of the Royalty Term with respect to a given Licensed Product in the applicable country.

13.2 Termination by BMS. BMS shall have the right to terminate this Agreement, at BMS' sole discretion, as follows:

13.2.1 Insolvency. To the extent permitted under applicable Laws, BMS shall have the right to terminate this Agreement in its entirety, at BMS' sole discretion, upon delivery of written notice to Eiger upon the filing by Eiger in any court or agency pursuant to any statute or regulation of the United States or any other jurisdiction a petition in bankruptcy or insolvency or for reorganization or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of Eiger or its assets, upon the proposal by Eiger of a written agreement of composition or extension of its debts, or if Eiger is served by a Third Party (and not by BMS) with an involuntary petition against it inany insolvency proceeding, upon the [*] after such service if such involuntary petition has not previously been stayed or dismissed, or upon the making by Eiger of an assignment for the benefit of its creditors.

13.2.2 Breach. BMS shall have the right to terminate this Agreement in its entirety, at BMS' sole discretion, (x) as provided in Section 5.6 or (y) upon delivery of written notice to Eiger in the event of any material breach by Eiger of this Agreement (except that this Section 13.2.2 shall not apply to any breach of Sections 5.1 or 6.1, which are covered under Section 13.2.3), provided that such breach has not been cured within [*] after written notice is given by BMS to Eiger; provided, however, that if such breach relates to the failure to make a payment when due, such breach must be cured within [*] after written notice thereof is given by BMS. Notwithstanding the foregoing, in the case of a bona fide dispute over whether or to what extent Eiger has breached this Agreement, this Section 13.2.2 shall not be triggered until such dispute is resolved in BMS' favor and Eiger fails to cure such breach within the applicable cure period (which shall be tolled until the resolution of the dispute); provided, that Eiger shall have timely paid any amounts that are not in dispute. Any such termination of this Agreement shall become effective at the end of the applicable cure period, unless Eiger has cured any such breach or default prior to the expiration of such cure period.

13.2.3 Termination for Failure to Develop or Commercialize. BMS shall have the right to terminate this Agreement in its entirety in the event that Eiger fails to fulfill its obligations to Develop Licensed Compounds and/or Licensed Products in accordance with Section 5.1, or to Commercialize Licensed Products in accordance with Section 6.1, *provided* that Eiger has not cured such breach within [*] following written notice by BMS which notice shall be labeled as a "notice of material breach for failure to use Commercially Reasonable Efforts," and identifies the Major Market Country(ies) in which such breach has occurred. If Eiger disputes the material breach of its obligations under Sections 5.1 and 6.1, this Section 13.2.3 shall not be triggered until such dispute is resolved in BMS' favor and Eiger fails to cure such breach within any portion of the applicable cure period then remaining (which shall be tolled until the resolution of the dispute. For clarity, if arbitration is triggered under Section 14.2 [*] after receipt of the notice from BMS, it shall have [*] after an arbitrator's decision in favor of BMS to cure the breach). Any such termination of this Agreement shall become effective at the end of the applicable remaining cure period, unless Eiger has cured any such breach or default prior to the expiration of such

remaining cure period. If there is a dispute as to whether Eiger has cured within the remaining cure period following the arbitrator's decision, such dispute [*], provided, that [*].

13.2.4 Termination for Patent Challenge.

(a) BMS shall have the right to terminate this Agreement in its entirety in the event Eiger (or any of its Affiliates) challenges or knowingly supports (other than as may be necessary or reasonably required to assert a cross-claim or a counter-claim, or in response to a subpoena or court or administrative law request or order), including by providing information, documents, and/or funding, a challenge to the validity, scope, enforceability or patentability of any of the BMS Patent Rights. BMS's right to terminate this Agreement under this Section 13.2.4 may be exercised at any time after Eiger (or any of its Affiliates) may have challenged or knowingly supports (other than in response to a subpoena or court order) a challenge to the validity, scope, enforceability or patentability of any of the BMS Patent Rights. For the avoidance of doubt, an action by Eiger or any Affiliate in accordance with Article 10 to amend claims within a pending patent application within the BMS Patent Rights during the course of Eiger's prosecution and maintenance of such pending patent application or in defense of a Third Party proceeding, or to make a negative determination of patentability of claims of a patent application of BMS or to abandon a patent application of BMS during the course of Eiger's Prosecution and Maintenance of such pending patent application, shall not, where undertaken in accordance with Article 9 hereof, constitute a challenge under this Section 13.2.4.

(b) If a Sublicensee of Eiger challenges the validity, scope or enforceability of or otherwise opposes any of the BMS Patent Rights under which such Sublicensee is sublicensed, then Eiger shall, at BMS' election and upon written notice from BMS, promptly terminate such Sublicense. Eiger shall include within each License Agreement with each Sublicensee a right on the part of Eiger to terminate such License Agreement in the event such Sublicensee challenges or knowingly supports a Third Party in challenging (other than in response to a subpoena or court order), in a judicial or administrative proceeding, including without limitation by providing information, documents, or funding, the validity, scope or enforceability of any of the BMS Patent Rights after grant of the patent and (ii) Eiger shall exercise such right to terminate the License Agreement with a Sublicensee should such Sublicensee challenge or knowingly support a Third Party in challenging (other than in response to a subpoena or court order) in a judicial or administrative proceeding the validity or enforceability of any of the BMS Patent Rights after grant of the patent. If Eiger fails to exercise such termination right against such Sublicensee or is unable to do so because it did not include such a provision in its Sublicense, BMS may terminate this Agreement.

13.3 Termination by Eiger. Eiger shall have the right to terminate this Agreement, at Eiger's sole discretion, as follows.

13.3.1 Following completion by Eiger of the [*] of the Licensed Product, upon [*] prior written notice in the case where [*], or upon [*] prior written notice in the case where [*].

13.3.2 Eiger may terminate this Agreement in the event of a material breach by BMS, provided that such breach has not been cured within [*] following written notice by Eiger. Any such termination of this Agreement shall become effective at the end of the applicable cure period, unless BMS has cured any such breach or default prior to the expiration of such cure period.

13.4 Effect of Termination. Upon termination of this Agreement in its entirety by BMS under Section 13.2 or by Eiger under Section 13.3.1:

13.4.1 All rights and licenses granted to Eiger in Article 2 shall terminate, all rights of Eiger under the BMS Patent Rights and BMS Know-How shall revert to BMS, and Eiger and its Affiliates shall cease all use of the BMS Patent Rights, the BMS Know-How and the Transferred Materials, and shall return to BMS all unused portions of the Transferred Materials, subject, in the case of [*], to [*]. Following the effective date of such termination, all Licensed Compounds and/or Licensed Products shall thereafter be deemed "BMS Reversion Products".

13.4.2 With respect to all regulatory filings (including all INDs, MAAs, MAs, CTAs, CTXs and BLAs) and Approvals and all other regulatory filings and documents necessary to further Develop and Commercialize the BMS Reversion Products, as they exist as of the date of such termination (and all of Eiger's right, title and interest therein and thereto), BMS shall determine in its sole discretion which of these shall be (i) assigned to BMS, and Eiger shall provide to BMS one (1) copy of the applicable documents and filings, all documents and filings contained in or referenced in any such filings, together with the raw and summarized data for any preclinical and clinical studies of the BMS Reversion Products as well as any final documentation to inactivate any open INDs as BMS may elect to inactivate, subject, in the case of [*], to [*], and [*], or (ii) withdrawn, closed out, or inactivated [*]. For clarity, BMS shall have the right to use the foregoing material information, materials and data developed by Eiger solely in connection with BMS' development, manufacture and commercialization of BMS Reversion Products. BMS shall have the right to obtain specific performance of Eiger's obligations referenced in this Section 13.4.2 and/or in the event of failure to obtain assignment, Eiger hereby consents and grants to BMS the right to access and reference (without any further action required on the part of Eiger, whose authorization to file this consent with any Regulatory Authority is hereby granted) any and all such regulatory filings for any regulatory or other use or purpose in the Territory. Without limiting the foregoing in this paragraph, to the extent applicable, Eiger's obligations under Article 10 shall continue with respect to all countries in the Territory for which there is a failure to obtain assignment of all regulatory filings and Approvals.

13.4.3 All amounts due or payable to BMS that were accrued prior to the effective date of termination shall remain due and payable; but (except as otherwise expressly provided herein) no additional amounts shall be payable based on events occurring after the effective date of termination; provided, that the foregoing shall not be deemed to limit either Party's indemnification obligations under this Agreement for acts or omissions incurring prior to the termination date that are the subject of such indemnification even if the indemnification amount cannot be accrued or determined as of the termination date.

13.4.4 Should Eiger have any inventory of any Licensed Compound included in the BMS Reversion Products suitable for use in clinical trials, Eiger shall [*].

13.4.5 Should Eiger have any inventory of any Licensed Product included in the BMS Reversion Products approved and allocated prior to termination, Eiger shall have [*] thereafter in which to dispose of such inventory (subject to the payment to BMS of any royalties due hereunder thereon) (the "Inventory Disposal Period"), provided however, that (i) such right shall terminate at such time that BMS purchases all remaining stocks of inventory of such BMS Reversion Product as described in this Section 13.4.6, below, and (ii) such Licensed Product shall [*] provided to such purchaser for the Licensed Product in the applicable country during the [*] period preceding such termination and, in addition, such sales shall [*] for the [*] period preceding such termination. Notwithstanding the foregoing, if BMS takes over responsibility for sale of the BMS Reversion Products in any country in the Territory prior to the end of the Inventory Disposal Period, BMS shall be required to purchase all

remaining stocks of saleable inventory that meets BMS specifications and return policies of such BMS Reversion Product at [*] for such BMS Reversion Product, [*].

13.4.6 Eiger shall provide to BMS the tangible embodiments of all Know-How owned or Controlled by Eiger and its Affiliates to the extent necessary for the Development and Commercialization of the BMS Reversion Products in existence as of the date of such termination, subject, in the case of [*], to [*], and [*], including Eiger's manufacturing processes, techniques and trade secrets for making such BMS Reversion Products and all Know-How specifically relating to any composition, formulation, method of use or manufacture of such BMS Reversion Products, and BMS shall [*]. Eiger shall reasonably cooperate with BMS to assist BMS with understanding and using the Know-How provided to BMS under this Section 13.4.7. Such cooperation shall include providing BMS with reasonable access by teleconference or in-person at Eiger's facilities (subject to Eiger's customary rules and restrictions with respect to site visits by non-Eiger personnel and subject, in the case of [*], to [*]).

13.4.7 To the extent that Eiger owns any trademark(s), USAN names, and/or domain names that are used in connection with a BMS Reversion Product that BMS believes would be necessary for the Commercialization of a BMS Reversion Product (as then currently marketed, but not including any marks that include, in whole or part, any corporate name or logo of Eiger), Eiger shall assign (or, if applicable, cause its Affiliate to assign) to BMS all of Eiger's (and such Affiliate's) right, title and interest in and to any such trademark, USAN name or internet domain name in each terminated country.

13.4.8 Eiger shall grant and hereby grants to BMS an exclusive, royalty-bearing [*], non-transferable (except as provided in Section 15.4) license, with the right to grant sublicenses, under (a)(i) any Patent Rights owned or Controlled by Eiger or its Affiliates as at the effective date of termination (other than Patent Rights Controlled by BMS and its Affiliates that were licensed to Eiger under this Agreement) and (ii) all Patent Rights owned or Controlled by Eiger or its Affiliates after the date of such termination claiming any invention conceived or reduced to practice by or on behalf of Eiger during the term of this Agreement and (b) any Trademarks and USAN names owned by Eiger that are used in connection with the Licensed Product, in each case (a)(i) and (ii) that are not Patent Rights licensed from BMS and only to the extent such Patent Rights cover the composition of matter, use, or manufacture of BMS Reversion Products (solely to the extent actually practiced in connection with the BMS Reversion Products as of such termination effective date) and that, in each case of (a) and (b), are necessary to develop, manufacture or commercialize BMS Reversion Products.

13.4.9 Eiger shall provide to BMS all data generated during the term of this Agreement necessary for the development and/or commercialization of the relevant BMS Reversion Products and [*], subject to [*], and [*].

13.4.10 Neither Party shall be relieved of any obligation that accrued prior to the effective date of such termination.

13.4.11 BMS shall not owe any other compensation to Eiger for the research, Development and Commercialization of any BMS Reversion Product in the event of any such termination of the Agreement by BMS, except as expressly set forth in Section 13.4.8.

13.4.12 Any costs and expenses incurred by Eiger in connection with the assignments and transfers made by Eiger under this Section 13.4 shall be [*] unless [*], in which case any such costs and expenses reasonably incurred by Eiger shall be [*].

13.4.13 It is understood and agreed that BMS shall be entitled to specific performance as a remedy to enforce the provisions of this Section 13.4, in addition to any other remedy to which it may be entitled by applicable Law.

13.4.14 If Eiger is using Third Parties to manufacture and supply Licensed Compound and Licensed Product to it at the time of termination, Eiger will, at BMS' request, reasonably cooperate with BMS to assign such Third Party agreements to BMS as BMS may request. If Eiger is manufacturing any portion of the Licensed Compound and/or Licensed Product for itself, and has the capability in place as of the date of such termination to commercially manufacture and supply to BMS all or part of BMS' requirements of the applicable BMS Reversion Products for use and sale in the Territory, if BMS so elects in its sole discretion, Eiger shall supply to BMS for a period not to exceed [*] (with the period of time being within the sole discretion of BMS) as much of BMS' requirements of such BMS Reversion Products as reasonably possible for use and sale in the Territory, [*] for such BMS Reversion Products. In the event that Eiger has, prior to the date of such termination, engaged a Third Party to manufacture and supply any BMS Reversion Products, Eiger shall use reasonable efforts, at BMS' sole cost and expense, to assist in the transfer of such supply arrangements to BMS, or if not assigned or assignable, then Eiger shall supply such BMS Reversion Products [*] associated with providing such BMS Reversion Products to BMS.

13.4.15 Nothing in this Section 13.4 shall be deemed to limit any remedy to which either Party may be entitled by applicable Law.

13.5 Effect of Termination by Eiger for Breach by BMS. Upon termination of this Agreement by Eiger pursuant to Section 13.3.2:

13.5.1 All rights and licenses granted to Eiger in Article 2 shall terminate, all rights of Eiger under the BMS Patent Rights and BMS Know-How shall revert to BMS, and Eiger and its Affiliates shall cease all use of the BMS Patent Rights, the BMS Know-How and the Transferred Materials, and shall return to BMS all unused portions of the Transferred Materials.

13.5.2 All amounts due or payable to BMS that were accrued, or that arise out of acts or events occurring, prior to the effective date of termination or expiration shall remain due and payable; but (except as otherwise expressly provided herein) no additional amounts shall be payable based on events occurring after the effective date of termination or expiration.

13.5.3 Should Eiger have any inventory of any Licensed Product approved and allocated prior to termination for sale in a terminated country, Eiger shall have [*] thereafter in which to dispose of such inventory (subject to the payment to BMS of any royalties due hereunder thereon).

13.5.4 Neither Party shall be relieved of any obligation that accrued prior to the effective date of such termination or expiration.

13.5.5 Nothing in this Section 13.5 shall be deemed to limit any remedy to which Eiger may be entitled by applicable Law.

13.6 Effect of Expiration of this Agreement. Upon expiration of this Agreement:

13.6.1 All amounts due or payable to BMS that were accrued, or that arise out of acts or events occurring, prior to the effective date of expiration shall remain due and payable; but (except as otherwise

expressly provided herein) no additional amounts shall be payable based on events occurring after the effective date of expiration.

13.6.2 BMS shall have the right to retain all amounts previously paid to BMS by Eiger.

13.6.3 Neither Party shall be relieved of any obligation that accrued prior to the effective date of expiration.

13.6.4 The license with respect to BMS Patent Rights and BMS Know-How granted under Section 2.1 shall remain in effect and shall be fully paid-up.

13.7 Scope of Termination. Termination of this Agreement shall be as to all countries in the Territory and all Licensed Compounds and all Licensed Products.

13.8 Survival. The following provisions shall survive termination or expiration of this Agreement, as well as any other provisions which by their nature are intended to survive termination: Article 1 (as applicable), Sections 8.7 (for three (3) years after the end of the Calendar Year in which this Agreement was terminated), Section 9.4, Section 9.5, Section 10.1, Section 10.4 (with respect to an action, suit or proceeding commenced prior to termination), Section 10.8, Article 11, Article 12, Section 13.4 (if terminated by BMS under Section 13.2 or by Eiger under Section 13.3.1, Section 13.5 (if terminated by Eiger pursuant to Section 13.3.2), Section 13.6, Section 13.7, this Section 13.8, Section 13.10, Article 14 and Article 15.

13.9 Bankruptcy. The Parties agree that in the event a Party becomes a debtor under Title 11 of the U.S. Code ("Title 11"), this Agreement shall be deemed to be, for purposes of Section 365(n) of Title 11, a license to rights to "intellectual property" as defined therein. Each Party as a licensee hereunder shall have the rights and elections as specified in Title 11. Any agreements supplemental hereto shall be deemed to be "agreements supplementary to" this Agreement for purposes of Section 365(n) of Title 11.

13.10 No Limitation of Remedies. Except as herein expressly provided, notwithstanding anything to the contrary in this Agreement, except as otherwise set forth in this Agreement, termination or expiration of this Agreement shall not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such termination or expiration nor prejudice either Party's right to obtain performance of any obligation. Each Party shall be free, pursuant to Article 14, to seek (without restriction as to the number of times it may seek) damages, costs and remedies that may be available under applicable Law or in equity and shall be entitled to offset the amount of any damages and costs obtained in a final determination under Article 14 of monetary damages or costs (as permitted by this Agreement) against the other Party against any amounts otherwise due to such other Party under this Agreement.

ARTICLE 14

DISPUTE RESOLUTION

14.1 Resolution by Senior Executives. Except as provided in Sections 8.7 and 14.3, in the event of any dispute between the Parties in connection with this Agreement, the construction hereof, or the rights, duties or liabilities of either Party hereunder, including any disagreement as to whether there has been a material breach of this Agreement pursuant to Sections 13.2.2, 13.2.3, or 13.3.2, the Parties shall first attempt in good faith to resolve such dispute by negotiation and consultation between themselves. In the event that such dispute is not resolved on an informal basis within [*], either Party may, by written notice to the other Party, refer the dispute to (i) [*] and (ii) [*] or, [*] for attempted resolution by good faith negotiation within [*] after such notice is received; provided, however, such executive officers of Eiger and BMS may each designate a senior manager to whom such dispute is delegated instead for such attempted resolution.

14.2 Arbitration.

14.2.1 Except as provided in Sections 8.7 and 14.3, if any dispute between the Parties relating to or arising out this Agreement cannot be resolved in accordance with Section 14.1, such dispute shall be resolved by binding arbitration administered by JAMS pursuant to JAMS' Comprehensive Arbitration Rules and Procedures then in effect (the **"JAMS Rules"**), and judgment on the arbitration award may be entered in any court having jurisdiction thereof.

14.2.2 The arbitration shall be conducted by a panel of three (3) persons experienced in the pharmaceutical business: within [*] after initiation of arbitration, each Party shall select one person to act as arbitrator and the two Party-selected arbitrators shall select a third arbitrator within [*] of their appointment. If the arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator, the third arbitrator shall be appointed by JAMS. The place of arbitration shall be in [*], and all proceedings and communications shall be in English.

14.2.3 The arbitrators shall apply the terms and conditions of this Agreement and shall not award damages in contradiction to Section 9.5. Each Party shall bear its own costs and expenses and attorneys' fees and an equal share of the arbitrators' fees and any administrative fees of arbitration regardless of the outcome of such arbitration.

14.2.4 Except to the extent necessary to confirm an award or as may be required by law, neither a Party nor an arbitrator may disclose the existence, content or results of an arbitration without the prior written consent of both Parties The arbitrators shall have no authority to award any relief on the basis of any dispute, controversy or claim that is barred by the applicable Delaware statute of limitations.

14.3 Injunctive Relief. Notwithstanding anything in this Article 14, each Party shall have the right to seek injunctive or other equitable relief from the arbitrator or a court of competent jurisdiction pursuant to Section 15.8 that may be necessary to avoid irreparable harm, maintain the status quo or preserve the subject matter of the dispute, including any breach or threatened breach of Article 11.

ARTICLE 15

MISCELLANEOUS

15.1 Severability. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement with respect to such provision may be realized.

15.2 Notices. Any notice required or permitted to be given by this Agreement shall be in writing and shall be delivered by hand or overnight courier with tracking capabilities or mailed postage prepaid by first class, registered or certified mail, return receipt requested and addressed as set forth below unless changed by notice so given:

If to Eiger:

Eiger BioPharmaceuticals, Inc.
350 Cambridge Ave, Suite 350
Palo Alto, CA 94306
Attention: Chief Executive Officer

With a copy to:
Cooley LLP
3175 Hanover St.
Palo Alto, CA 94304
Attention: Glen Sato
gsato @cooley.com

If to BMS:
Bristol-Myers Squibb Company
P.O. Box 4000
Route 206 & Province Line Road
Princeton, New Jersey 08543-4000
Attention: Vice President, Business Development

With a copy to:
Bristol-Myers Squibb Company
P.O. Box 4000
Route 206 & Province Line Road
Princeton, New Jersey 08543-4000
Attention: Vice President & Assistant General Counsel, Business Development and Licensing

Any such notice shall be deemed delivered on the date received. A Party may add, delete, or change the person or address to whom notices should be sent at any time upon written notice delivered to the Party's notices in accordance with this Section 15.2.

15.3 Force Majeure. Neither Party shall be liable for delay or failure in the performance of any of its obligations hereunder if such delay or failure is due to causes beyond its reasonable control, including

acts of God, fires, earthquakes, strikes and labor disputes, acts of war, terrorism, civil unrest or intervention of any governmental authority ("Force Majeure"); *provided, however*, that the affected Party promptly notifies the other Party and further provided that the affected Party shall use Commercially Reasonable Efforts to avoid or remove such causes of non-performance and to mitigate the effect of such occurrence, and shall continue performance with the utmost dispatch whenever such causes are removed. When such circumstances arise, the Parties shall negotiate in good faith any modifications of the terms of this Agreement that may be necessary or appropriate in order to arrive at an equitable solution.

15.4 Assignment.

15.4.1 BMS may, without Eiger's consent, (x) assign, delegate or transfer some or all of its rights and obligations hereunder to any Affiliate of BMS, and (y) assign or transfer, in connection with any transfer or assignment of all of the BMS Patent Rights and BMS Know-How, to any Third Party (including a successor in interest by reason of merger, consolidation or sale of substantially all of the assets of BMS to which this Agreement relates).

15.4.2 Eiger may assign or transfer all of its rights and obligations hereunder without BMS's consent to a successor in interest by reason of merger, consolidation or sale of substantially all of the assets of Eiger (and so long as such assignment or transfer includes, without limitation, all Approvals, all manufacturing assets relating to this Agreement, and all rights and obligations under this Agreement); *provided, however*, that such successor in interest shall have agreed no later than the closing of such assignment or transfer transaction to be bound by the terms of this Agreement in a writing provided to BMS.

15.4.3 Subject to the foregoing, this Agreement shall inure to the benefit of, and be binding on, the Parties' permitted successors and assigns. Any assignment or transfer in violation of the foregoing shall be null and void and wholly invalid, the assignee or transferee in any such assignment or transfer shall acquire no rights whatsoever, and the non-assigning non-transferring Party shall not recognize, nor shall it be required to recognize, such assignment or transfer.

15.4.4 In the event that BMS assigns, delegates or otherwise transfers this Agreement in whole or in part, to an Affiliate of BMS, BMS hereby agrees to be jointly and severally liable with any such Affiliates for the actions of such Affiliates and for any and all amounts that become due and payable hereunder to Eiger. In the event that Eiger assigns or otherwise transfers or assigns this Agreement to an Affiliate of Eiger, Eiger hereby agrees to be jointly and severally liable with any such Affiliates for the actions of such Affiliates and for any and all amounts that become due and payable hereunder to BMS.

15.4.5 Notwithstanding anything to the contrary in this Agreement, in the event of any such transfer or assignment to a Third Party (including a successor in interest by reason of merger, consolidation or sale of assets permitted), the intellectual property rights of the acquiring party (if other than one of the Parties) or the acquired party (if acquired by a Party or its Affiliates) shall not be included in the technology licensed to the other Party hereunder to the extent (x) held by such Third Party that is acquired or is acquiring such Party prior to such transaction, or (y) such technology is developed thereafter outside the scope of activities conducted with respect to the Licensed Compounds or Licensed Products.

15.5 Further Assurances. Each Party agrees to do and perform all such further acts and things and shall execute and deliver such other agreements, certificates, instruments and documents necessary or that

the other Party may deem advisable in order to carry out the intent and accomplish the purposes of this Agreement and to evidence, perfect or otherwise confirm its rights hereunder.

15.6 Waivers and Modifications. The failure of any Party to insist on the performance of any obligation hereunder shall not be deemed to be a waiver of such obligation. Waiver of any breach of any provision hereof shall not be deemed to be a waiver of any other breach of such provision or any other provision on such occasion or any succeeding occasion. No waiver, modification, release or amendment of any obligation under or provision of this Agreement shall be valid or effective unless in writing and signed by each of the Parties.

15.7 Choice of Law. This Agreement shall be governed by, enforced, and shall be construed in accordance with the laws of the [*] without regard to its conflicts of law provisions.

15.8 Jurisdiction. Subject to Article 14, each Party irrevocably submits to the exclusive jurisdiction and venue of the state and federal courts for the [*] for the purposes of any suit, action, dispute, or other proceeding arising out of this Agreement or out of any transaction contemplated hereby. Each Party irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding arising out of this Agreement or the transactions contemplated hereby in the state and federal courts for the [*], and hereby and thereby further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.

15.9 Publicity. Upon execution of this Agreement, Eiger may issue the press release announcing the existence of this Agreement in the form and substance as set forth in Appendix 5. Each Party agrees not to issue any other press release or other public statement disclosing other information relating to this Agreement or the transactions contemplated hereby without the prior written consent of the other Party, such consent not to be unreasonably withheld, delayed or conditioned, *provided*, *however*, that such consent shall not be required for any disclosure which is required by Law or the rules of a securities exchange, as reasonably advised by the disclosing Party's outside counsel, and *provided*, *further*, that Eiger may from time to time issue public statements relating to the ongoing Development and/or Commercialization of Licensed Compounds and/or Licensed Products (excluding disclosure of the financial terms of this Agreement) pursuant to this Agreement without the prior written consent of BMS. The Parties agree that any such required disclosure shall not contain confidential business or technical information and, if disclosure of confidential business or technical information is required by Law, the Parties shall use appropriate diligent efforts to minimize such disclosure and obtain confidential treatment for any such information which is disclosed to a governmental agency. Each Party agrees to provide to the other Party a copy of any public announcement regarding this Agreement or the subject matter thereof as soon as reasonably practicable under the circumstances prior to its scheduled release. Except under extraordinary circumstances, each Party shall provide the other with an advance copy of any such announcement at least [*] prior to its scheduled release. Each Party shall have the right to expeditiously review and recommend changes to any such announcement and, except as otherwise required by Law, the Party whose announcement has been reviewed shall remove any information the reviewing Party reasonably deems to be inappropriate for disclosure. The contents of any announcement or similar publicity which has been reviewed and approved by the reviewing Party can be re-released by either Party without a requirement for re-approval.

15.10 Relationship of the Parties. Each Party is an independent contractor under this Agreement. Nothing contained herein is intended or is to be construed so as to constitute BMS and Eiger as partners, agents or joint venturers. Neither Party shall have any express or implied right or authority to assume or

create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement or undertaking with any Third Party.

15.11 Headings. Headings and captions are for convenience only and are not be used in the interpretation of this Agreement.

15.12 Entire Agreement. This Agreement constitutes the entire agreement between the Parties as to the subject matter of this Agreement, and supersedes and merges all prior negotiations, representations, agreements and understandings regarding the same.

15.13 Counterparts; Electronic Delivery. This Agreement may be executed in counter-parts with the same effect as if both Parties had signed the same document. All such counterparts shall be deemed an original, shall be construed together and shall constitute one and the same instrument. Signatures to this Agreement transmitted by email in "portable document format" (".pdf"), or by any other electronic means intended to preserve the original graphic and pictorial appearance of this Agreement shall have the same effect as physical delivery of the paper document bearing original signature.

15.14 Performance by Affiliates. Each Party recognizes that the other Party may perform some or all of its obligations under this Agreement through Affiliates to the extent permitted under this Agreement; *provided, however*, that such other Party shall remain responsible for the performance by its Affiliates as if such obligations were performed by such other Party.

15.15 Exports. Eiger agrees not to export or re-export, directly or indirectly, any information, technical data, the direct product of such data, samples or equipment received or generated under this Agreement in violation of any applicable export control Laws.

15.16 Interpretation.

15.16.1 Each of the Parties acknowledges and agrees that this Agreement has been diligently reviewed by and negotiated by and between them, that in such negotiations each of them has been represented by competent counsel and that the final agreement contained herein, including the language whereby it has been expressed, represents the joint efforts of the Parties and their counsel. Accordingly, in interpreting this Agreement or any provision hereof, no presumption shall apply against any Party as being responsible for the wording or drafting of this Agreement or any such provision, and ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.

15.16.2 The definitions of the terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation". The word "will" shall be construed to have the same meaning and effect as the word "shall". The word "any" shall mean "any and all" unless otherwise clearly indicated by context.

15.16.3 Unless the context requires otherwise, (a) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (b) any reference to any Laws herein shall be construed as referring to such Laws as from time to time

enacted, repealed or amended, (c) any reference herein to any Person shall be construed to include the Person's successors and assigns, (d) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (e) all references herein to Articles, Sections or Appendices, unless otherwise specifically provided, shall be construed to refer to Articles, Sections and Appendices of this Agreement; and (f) the term "and/or" in a sentence shall be construed such that the phrase "X and/or Y" means "X or Y, or both X and Y".

15.16.4 This Agreement should be interpreted in its entirety and the fact that certain provisions of this Agreement may be cross-referenced in a Section shall not be deemed or construed to limit the application of other provisions of this Agreement to such Section and vice versa.

*** * ***

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Parties have caused this License Agreement to be executed by their respective duly authorized officers.

EIGER BIOPHARMACEUTICALS, INC.

By: /s/ David Cory
(Signature)
Name: David Cory
Title: President and CEO

Date: April 19, 2016

BRISTOL-MYERS SQUIBB COMPANY

By: /s/ Graham R. Brazier
(Signature)
Name: Graham R. Brazier
Title: Vice President, Business Development

Date: April 20, 2016

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Appendix 1

BMS Patent Rights

SEE ATTACHED

[*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Appendix 2

Initial Development Plan

[*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Appendix 3

Licensed Compound

[*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Appendix 4

Transferred Materials to be provided by BMS

[*]

Appendix 5

Press Release

Eiger BioPharmaceuticals Announces License of Worldwide Rights to Pegylated Interferon Lambda-1a from Bristol-Myers Squibb

Including Rights for All Indications and Associated Patents

PALO ALTO, CALIF, April 19, 2016 /PRNewswire/ — Eiger BioPharmaceuticals, Inc. (NASDAQ: EIGR) announced today that it has licensed Pegylated Interferon Lambda-1a ("Lambda"), a novel, well-characterized, first in class Type III interferon to be studied as an investigational therapy for hepatitis delta virus (HDV) infection, from Bristol-Myers Squibb. Lambda has been administered in clinical trials involving over 3,000 subjects. It has not been approved for any indication. Eiger plans to evaluate Lambda as a potential monotherapy and combination treatment for chronic HDV infection, the most aggressive and deadly form of human viral hepatitis.

"We are very excited to execute this license with Bristol-Myers Squibb. The addition of Lambda to our pipeline is a significant step toward building a leading HDV franchise," said David Cory, President and CEO of Eiger. "There is no approved therapy for HDV. Along with Lonafarnib, our Phase 2 candidate for the treatment of HDV, Eiger has established a strategic position with the addition of Lambda. Eiger will leverage existing relationships with clinical investigators and clinical sites for efficient exploration of Lambda alone or in combination with other agents toward an approved therapy for HDV."

"Most cells in the body express the receptor for interferon alpha, a Type I interferon. However, receptors for Lambda, a Type III interferon, are expressed on liver cells, a desirable location for treating viral hepatitis, but less so on some blood cells and non-liver cells. Lambda represents a promising and potentially better tolerated interferon therapy for HDV," said Eduardo Martins, MD, DPhil, Senior Vice President of Liver and Infectious Diseases at Eiger.

The exclusive worldwide license from Bristol-Myers Squibb involved an upfront payment and the issuance of Eiger Common Stock and includes development and regulatory milestones through first commercial sale in the US, EU, and Japan and milestone payments based on commercial sales achievement as well as tiered annual net sales royalties.

About Sarasar™ (lonafarnib)

Lonafarnib is a well-characterized, late-stage, orally active inhibitor of farnesyl transferase, an enzyme involved in modification of proteins through a process called prenylation. HDV uses this host cell process inside liver cells to complete a key step in its life cycle. Lonafarnib inhibits the prenylation step of HDV replication inside liver cells and blocks the virus life cycle at the stage of assembly. Since prenylation is carried out by a host enzyme, this compound may present a higher barrier to development of viral resistance mutations to therapy. Lonafarnib has been dosed in over 100 HDV-infected patients across international academic centers and is in Phase 2 development for HDV. Lonafarnib has been granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA), and Fast Track Designation by U.S. FDA. Lonafarnib is not approved for any indication, and is licensed from Merck Sharp & Dohme Corp. (known as MSD outside of the United States and Canada).

About Hepatitis Delta Virus (HDV)

Hepatitis Delta (or Hepatitis D) is caused by infection with HDV and is considered to be one of the most severe forms of viral hepatitis in humans. Hepatitis D occurs only as a co-infection in individuals harboring Hepatitis B Virus (HBV). Hepatitis D leads to more severe liver disease than HBV alone and is associated with accelerated liver fibrosis, liver cancer, and liver failure. Hepatitis D is a disease with a significant impact on global health, which may affect up to approximately 15-20 million people worldwide. The prevalence of HDV varies among different parts of the world. Globally, HDV infection is reported to be present in approximately 4.3% to 5.7% of chronic Hepatitis B carriers. 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.

About Eiger

Eiger is a clinical-stage biopharmaceutical company committed to bringing to market novel products for the treatment of rare diseases. The company has built a diverse portfolio of well-characterized product candidates with the potential to address diseases for which the unmet medical need is high, the biology for treatment is clear, and for which an effective therapy is urgently needed.

Note Regarding Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this press release regarding our strategy, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives, intentions, beliefs and expectations of management are forward-looking statements. These forward-looking statements may be accompanied by such words as “anticipate,” “believe,” “could,” “estimate,” “expect,” “forecast,” “intend,” “may,” “plan,” “potential,” “project,” “target,” “will” and other words and terms of similar meaning. Examples of such statements include, but are not limited to, whether or not pegylated interferon lambda-1a or lonafarnib may be further developed and approved, statements relating to the availability of cash for Eiger’s future operations, Eiger’s ability to develop its drug candidates for potential commercialization, the timing of the commencement and completion of Phase 2 trials and whether the Lamda product can be successfully developed or commercialized. Eiger may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in our forward-looking statements and one should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions, expectations and projections disclosed in the forward-looking statements. Various important factors could cause actual results or events to differ materially from the forward-looking statements that Eiger makes, including the risks that Eiger’s planned clinical trials may be prolonged or delayed requiring Eiger to incur additional costs; that Eiger’s planned clinical trials may not satisfy the requirements of the FDA or non-U.S. regulatory authorities; that Eiger’s product candidates may have undesirable side effects which may delay or prevent marketing approval; that, even if approved by the FDA or non-U.S. regulatory authorities, Eiger’s product candidates may not achieve broad market acceptance; and the risks described in the “Risk Factors” sections the Registration Statement on Form S-4 (file no. 333-208521) and of Eiger’s periodic reports filed with the SEC. Eiger does not assume any obligation to update any forward-looking statements, except as required by law.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

SOURCE Eiger Bio, Inc.
Investors: Jim Shaffer, Eiger Bio, Inc., 919-345-4256, jshaffer@eigerbio.com

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Appendix 6

Documentation to be provided

[*]

- 1 -

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Appendix 7

Form of Stock Purchase Agreement

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[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Appendix 8

Exceptions to Section 9.2

[*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Appendix 9

List of ‘Knowledge” Individuals of BMS

[*]

Appendix 10

Reagents and Research Tools

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[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Appendix 11

Third Party Agreements

[*]

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

Exhibit 10.17

EXECUTION VERSION

AMENDMENT #6 TO LICENSE AGREEMENT

This Amendment #6 to License Agreement ("Amendment #6") is entered into as of the date of last signature below ("Amendment #6 Effective Date") by and between Merck Sharp & Dohme Corp. (formerly known as Schering Corporation), a New Jersey corporation having a place of business at 2000 Galloping Hill Road, Kenilworth, NJ 07033 ("Merck") and Eiger BioPharmaceuticals, Inc., a Delaware corporation having a place of business at 350 Cambridge Avenue, Suite 350, Palo Alto, CA 94306 ("Licensee") (each of Merck and Licensee, a "Party", and together, the "Parties") to amend that certain License Agreement between the Parties dated September 3, 2010, as amended on January 18, 2011 and subsequently first amended June 11, 2013, as second amended November 20, 2014, as third amended March 6, 2015, as fourth amended June 9, 2015, and as fifth amended December 15, 2015 (collectively, the "Agreement").

IN CONSIDERATION OF the mutual promises and covenants contained herein, the parties agree as follows:

1. Definitions.

(a) The following definition is hereby added to Article I of the Agreement:

> "Progeria" shall mean Hutchinson-Gilford Progeria Syndrome.

(b) Section 1.18 of the Agreement is hereby deleted and replaced with the following:

> "Field" means (i) the use of the Licensed Compound or Licensed Product for all human antiviral applications, except for the treatment of Hepatitis C virus, Hepatitis B virus, or HIV infections, provided, however, that the Field specifically includes, without limitation, the treatment of Hepatitis D virus infections, including the treatment of patients co-infected with Hepatitis D virus and either or both of Hepatitis C virus and Hepatitis B virus; and (ii) the Progeria Field.

(c) The definition of the term "Progeria Field", as set forth in Amendment #5 to the Agreement, is hereby deleted and replaced with the following:

> "Progeria Field" shall mean the use of any Licensed Product (including the Licensed Progeria Product) for purposes related to the treatment of Progeria in humans.

(d) The definition of the term "Licensed Progeria Product" as set forth in Amendment #5 to the Agreement, is hereby deleted and replaced with the following:

> "Licensed Progeria Product" shall mean a Licensed Product in finished capsule form containing the Licensed Compound as the sole active pharmaceutical ingredient for use in the Progeria Field"

(e) The definition of the term "First Indication", as set forth in Section 1.20 of the Agreement, is hereby deleted and replaced throughout the Agreement with the following:

"First Antiviral Indication" means treatment of the Hepatitis D virus infections in humans.

2. Section 2.1 of the Agreement is hereby deleted in its entirety and replaced with the following:

(a) License Grant. Subject to the terms and conditions of this Agreement, including Merck's retained rights under Section 2.3, Merck hereby grants to Licensee an exclusive (even as to Merck), sub-licensable (subject to the obligations and restrictions in Section 2.5), royalty-bearing license under the Merck Know-How, Compound Patent Rights, and Merck's interest in any solely or jointly owned Program IP to Develop, make, have made, use, import, export, Commercialize, sell, offer for sale, and market the Licensed Compound and Licensed Product in the Field in the Territory.

(b) License Expansion. In the event Licensee would like to expand the license granted in this Section 2.1 beyond the Field, it shall provide Merck with a reasonably detailed development plan including evidence of existing resources and capabilities, and proposed terms relating thereto. Merck will consider any such proposed requests from Licensee in good faith.

3. Section 2.3 of the Agreement is hereby deleted in its entirety and replaced with the following:

Retained Rights; Covenants. Merck retains any and all other rights under the Compound Patent Rights and Merck Know-How that are outside the scope of the license granted under Section 2.1, including, for the avoidance of doubt, the right to Develop the Licensed Compound and Licensed Product outside the Field. Notwithstanding the foregoing, Merck shall not Commercialize the Licensed Compound or Licensed Product or grant any Third Party any license or right under any Compound Patent Rights and/or Merck Know-How rights to Commercialize the Licensed Compound or the Licensed Product for any use whether in or outside of the Field. Licensee shall not grant any Third Party any license or right under any Compound Patent Rights and/or Merck Know-How, other than as expressly permitted by this Agreement. Any breach of this Section 2.3 shall be deemed a material breach of the Agreement.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

4. Section 2.5(e) of the Agreement (as subsequently amended) is hereby deleted in its entirety and replaced with the following:

> (e)Licensee shall, in each agreement under which it grants a sublicense under the license set forth in Section 2.1 (each, a "Sublicense Agreement"), require the sublicensee to transfer to Merck, if Merck terminates this Agreement under Section 12.4, and to Licensee, if only such Sublicense Agreement terminates, (i) all regulatory filings and Regulatory Approvals held, possessed or Controlled by such sublicensee with respect to a Licensed Product and (ii) all patent rights and Know-How Controlled by such sublicensee with respect to a Licensed Product or its use, Manufacture, sale, or importation (which patent rights and Know-How shall be transferred either by assignment or by a freely sublicensable exclusive license). In the event that this Agreement terminates other than for breach by a sublicensee, Merck may, in its sole discretion, elect to enter in an agreement with each sublicensee on the same terms as the existing Sublicense Agreement. All Sublicense Agreements shall be consistent with the terms and conditions of this Agreement. Licensee shall (I) use reasonable efforts to procure the performance by any sublicensee of the terms of each applicable Sublicense Agreement and (II) be responsible to Merck for any material breach by a sublicensee of any terms and conditions of this Agreement or obligations of Licensee hereunder. Licensee hereby guarantees the performance of its sublicensees that are party to a Sublicense Agreement as permitted herein, and the grant of any such sublicense will not relieve Licensee of its obligations under this Agreement, except to the extent they are satisfactorily performed by such sublicensee. [*].

5. Section 3.2(b) is hereby deleted in its entirety and replaced with the following:

> Development Plan. Licensee shall provide Merck with a reasonably detailed report updating its Development activities and timelines with respect to the following Calendar Year in accordance with Section 3.2(c) (the "Development Plan"). [*]. At Merck's written request, the President of Merck's research division, or his designee, and the President of Licensee's research division or equivalent position, or his designee, shall meet to discuss such comments. Any revision of the clinical protocols shall be submitted to Merck promptly after their completion.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

6. Section 3.7 is hereby deleted in its entirety and replaced with the following:

> Commercialization of Licensed Product in the Field. Licensee hereby covenants that it shall not, nor shall it authorize any Affiliate, permitted sublicensee or Third Party contractor to Commercialize Licensed Product in the Territory for any use outside the Field. Merck hereby covenants that neither it nor its Affiliates shall Commercialize the Licensed Compound or Licensed Product or grant any Third Party any license or right under any Compound Patent Rights and/or Merck Know-How rights to Commercialize the Licensed Compound or the Licensed Product for any use whether in or outside of the Field. [*]. To the extent either Party can prove the other Party materially breached this Section 3.7(a), such material breach shall permit such non-breaching Party to terminate this Agreement for cause under Section 12.4.

7. Sections 4.1(d) and 4.1(e) are each hereby deleted in their entirety and replaced with the following:

> (d)Licensee shall be solely responsible for (i) interfacing, corresponding and meeting with the FDA and other Regulatory Authorities throughout the Territory with respect to Licensed Product in the Field, including the Progeria Field and (ii) obtaining and maintaining Regulatory Approvals in the Territory with respect to Licensed Products in the Field, including the Progeria Field. Merck shall be under no obligation to provide Licensee with Regulatory assistance in fulfilling the necessary regulatory activities to achieve Regulatory Approval in the Field, including the Progeria Field, in the Territory other than providing copies of any available data in Merck's possession during the Term required to be submitted for obtaining and maintaining Regulatory Approvals in the Territory with respect to the Licensed Products in the Field, including the Progeria Field. Assistance shall include copies of material correspondence with FDA or other Regulatory Authorities in the United States, the Major European Countries and Japan relating to Regulatory Approval of Licensed Product, and responding to all reasonable inquiries by the other Party with respect thereto. Each Party shall also provide the other Party in a timely manner with meeting minutes from any material meetings with Regulatory Authorities in the United States, the Major European Countries and Japan concerning the Regulatory Approval of Licensed Product in the Field, including the Progeria Field. For mutual convenience, Licensee shall direct any such material correspondence with Regulatory Authorities, or any requests for data from Merck, via the following e-mail address [*].

(e) Licensee shall provide Merck with a table report on an annual basis that contains the status of Regulatory Approvals for the Licensed Product in the Field in the Territory.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

8. The following is added as Section 4.4 to the Agreement:

> Regulatory Approvals; Progeria Field. Licensee agrees to use Commercially Reasonable Efforts to achieve Regulatory Approval for a Licensed Product in the Progeria Field in the Territory.

9. Section 6.1 of the Agreement is hereby deleted in its entirety and replaced with the following:

> Manufacturing Responsibility. Licensee will be solely responsible for the Manufacture of Licensed Compound and Licensed Product for Development and Commercialization of Licensed Product by Licensee, its Affiliates and its sublicensees in the Field in the Territory.

10. The following sentence is added to the end of Section 6.2 of the Agreement:

> Notwithstanding the foregoing, as of the Amendment #6 Effective Date, [*].

11. Section 6.3 of the Agreement is hereby deleted in its entirety.

12. Section 6.5 is hereby deleted in its entirety and replaced with the following:

> 6.5 Licensee acknowledges receipt of Licensed Product, Licensed Compound, and Starting Material, as described in Amendment #5 from Merck. Licensee shall have sole responsibility for its supply of Licensed Compound and Licensed Product for purposes of the Agreement. In the event that Licensee requests any additional Starting Material, and to the extent such Starting Material is available, Merck shall employ good faith efforts to transfer such available Starting Material to Licensee's designated CMO as soon as practicable at a cost of [*] plus a reasonable cost of shipping.

13. Section 6.6 is hereby deleted in its entirety and replaced with the following:

> 6.6(a) Manufacture and Transfer. During the Term and subject to all applicable provisions of the Agreement, Licensee will be responsible for the Manufacture and supply of PRF's requirements for Licensed Progeria Product in [*], and/or [*] capsules as may be separately agreed with PRF under the supply agreement referenced in Section 6.6(b) as reasonably requested with respect to delivery dates and quantities for use by PRF in the Progeria Field in the Territory, at no cost to PRF or Merck. Licensee will be responsible for the Manufacture and supply of Licensed Compound and/or Licensed Product for Merck's use pursuant to Section 2.3 as reasonably requested by Merck from time to time during the Term of the Agreement solely for Merck to exercise its right to Develop the Licensed Compound and Licensed Product outside the Field pursuant to

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Section 2.3; provided that Merck shall pay actual labelling and shipping and handling costs for delivery of Licensed Product to Merck for quantities delivered for such uses. For any requests exceeding [*] of Licensed Compound, Merck will compensate Eiger for the cost of such drug plus [*]. Licensee shall transfer to Merck such amounts of Licensed Compound and/or Licensed Product on such schedule as is mutually agreed based on reasonable requests by Merck for Merck's use pursuant to Section 2.3. Notwithstanding the foregoing, Licensee shall [*].

6.6(b) PRF Supply Agreement. Within ten (10) days of the Amendment #6 Effective Date, Licensee shall execute an agreement with PRF for the supply of Licensed Progeria Product needed by PRF, at no cost to PRF, to be used by PRF for (i) Development purposes in the Progeria Field and (ii) expanded access beyond clinical trials. [*].

6.6(c) Continuity of Supply to PRF. (A) Upon expiration or termination of this Agreement; and/or (B) [*]; or (C) at any time in the event that Licensee terminates (i) this Agreement pursuant to Article XII, (ii) Licensee's Development, Manufacture or Commercialization of Licensed Product under this Agreement, (iii) Licensee's supply agreement contemplated in Section 6.6(b); or (iv) Licensee's Sublicense Agreement(s) with its CMO(s) for the Manufacture of Licensed Product, Licensee hereby grants to Merck [*]. In the event that Merck does not [*], then Licensee shall use commercially reasonable efforts to [*]. Merck shall have the right, but not the obligation, at its sole discretion, to purchase any raw materials, in process materials and/or finished goods originally manufactured for Licensee in the amounts deemed desirable by Merck and at Licensee's cost of goods. Merck shall have no obligation to purchase remaining materials in inventory. [*].

14. The following shall be added as Section 7.2(d) to the Agreement:

No Progeria Milestone Payments. Licensee shall have no obligation to make any milestone payments to Merck in relation to any Licensed Product (including the Licensed Progeria Product) for use in the Progeria Field.

15. Section 7.3(b) to the Agreement is hereby deleted in its entirety and replaced with the following:

Term of Royalty Obligation. Royalties on the Licensed Product shall commence upon the First Commercial Sale of a Licensed Product in a particular country in the Territory and will continue, on a product-by-product and country-by-country basis, until the [*] of the date of First Commercial Sale of the Licensed Product for the First Antiviral Indication in such country ("Royalty Term"). For clarity, during the Royalty Term, the royalty payments pursuant to this Section 7.3 shall be payable regardless of whether it is Licensee, its Affiliate, or its sublicensee that is selling the Licensed Product.

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16. The following shall be added as Section 7.3(c) to the Agreement.

> Licensed Progeria Product Royalty Exemption. It is understood and agreed by the Parties that it is Merck's intent that it shall receive no royalties for sales of Licensed Progeria Product. Subject to Regulatory Approval for Licensed Progeria Product, Merck shall receive no royalties on the sale of any Licensed Progeria Product for the [*] sold per Calendar Year (the approximate quantity needed to treat the currently estimated worldwide prevalence of patients with Progeria per year). The Parties shall amend the Agreement to adjust this amount in the future if there is a change in prevalence rates of Progeria or changes in the approved dosing regimen for Licensed Progeria Product in the Progeria Field. In order for the Parties to effectuate the intent of this Section 7.3(c), Licensee's Net Sales reports for Licensed Product (including the Licensed Progeria Product) as required by Section 7.4(a) shall include [*] in such Calendar Quarter. For clarity, Additional Indication shall not include the treatment or amelioration of Progeria.

17. Section 13.3 is hereby deleted in its entirety and replaced with the following:

> Equitable Relief. By agreeing to arbitration, the Parties do not intend to deprive any competent court of such court's jurisdiction to issue a pre-arbitral injunction, pre-arbitral attachment or other order in aid of the arbitration proceedings and the enforcement of any award or judgment. Without prejudice to such provisional remedies in aid of arbitration as may be available under the jurisdiction of a national court, the court of arbitration shall have full authority to grant provisional remedies and to award damages for failure of any Party to respect the court of arbitration's order to that effect. With respect to any pre-arbitral preliminary injunction sought under this Section 13.3, both Parties agree to waive any requirement that the other (i) post a bond or other security as a condition for obtaining any such relief or (b) show irreparable harm, balancing of harms, consideration of the public interest, or inadequacy of monetary damages as a remedy.

18. Except as set forth herein, all capitalized terms not defined in this Amendment #6 shall have the meanings given to them in the Agreement.

19. In the event of any inconsistency between the terms of this Amendment and the terms of the Agreement, the terms of this Amendment shall govern.

20. Except as expressly amended hereby, all of the terms and conditions of the Agreement remain in full force and effect.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

IN WITNESS WHEREOF, the Parties have executed this Amendment #6 by their duly authorized representatives as of the Amendment #6 Effective Date.

Eiger BioPharmaceuticals, Inc.		**Merck Sharp & Dohme Corp.**	
By:	/s/ David Cory	By:	/s/ Bryan Rafalko
Title:	President, CEO	Title:	SVP, Director of Business Development and Licensing
Date:	5/15/18	Date:	5/15/18

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Exhibit 10.18

EXECUTION VERSION

COLLABORATION AND SUPPLY AGREEMENT

This **Collaboration and Supply Agreement** ("**Agreement**") is made and entered into as of May 15, 2018 (the "**Effective Date**") by and between Eiger BioPharmaceuticals, Inc., a Delaware corporation having a place of business at 350 Cambridge Avenue, Suite 350, Palo Alto, CA 94306 ("**Eiger**"), and The Progeria Research Foundation, Inc., a 501(c)(3) not-for-profit organization currently located at 200 Lake St., Peabody MA 01960 ("**PRF**"). Eiger and PRF are individually referred to as a "**Party**" and collectively referred to as the "**Parties.**"

Whereas, PRF is engaged in research, development, investigation and testing activities for the treatment of Progeria (as defined below) and diseases related to Progeria;

Whereas, Eiger is engaged in the business of the research, development and commercialization of pharmaceutical products;

Whereas, Eiger and Merck Sharp & Dohme Corp. (successor-in-interest of Schering Corporation), a New Jersey corporation having a place of business at 2000 Galloping Hill Road, Kenilworth, NJ 07033 ("**Merck**") are parties to that certain License Agreement, dated September 3, 2010, as amended (the "**Merck License Agreement**"), under which Eiger obtained a license from Merck to develop, make, use and commercialize lonafarnib for certain uses;

Whereas, Eiger and Merck have agreed that Eiger will license and supply lonafarnib to PRF and that Eiger and Merck will execute an amendment to the Merck License Agreement ("**Merck Amendment**") expanding the license from Merck to Eiger for exclusive (even as to Merck) license rights to lonafarnib in certain specified indications, including Progeria, and, as between Merck and Eiger during the term of the Merck License Agreement and Merck Amendment, making Eiger solely responsible for granting a sublicense to PRF with respect to lonafarnib in the Field (as defined below) and supplying lonafarnib to PRF, in each case, on terms and conditions agreed upon by PRF and Eiger; and

Whereas, the Parties desire to collaborate to explore the use and commercialization of lonafarnib in the treatment of Progeria;

Now therefore, in consideration of the mutual promises and agreement set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1.Definitions. The following terms shall have the following respective meanings when used in this Agreement:

(a)"**Additional Site**" shall have the meaning set forth in Section 9(e).

(b)"**Affiliate**" of a Party means any person or entity that at any time is controlling, controlled by, or under common control with such Party, where "control" (or any of its correlates) means beneficial ownership, directly or indirectly, of more than fifty percent (50%) of the equity or other interests entitled to vote for the election of directors or equivalent governing body of a person or entity.

(c)"**CoA**" shall have the meaning set forth in Section 9(c).

(d)"**Combination Drug**" means a co-formulated pharmaceutical product or product candidate containing the Licensed Compound and one or more active pharmaceutical ingredient(s) in a single vehicle. For the avoidance of doubt, a Combination Drug does not cover the simultaneous administration of the Licensed Compound and one or more active pharmaceutical ingredients using more than one (1) vehicle.

(e)"**Commercialize**" or "**Commercialization**" means all activities comprising or relating to the manufacture, promotion, marketing, advertising, sale, distribution, disposal and other exploitation of any Licensed Products, including any Research Activities and any activities necessary to maintain any regulatory approvals.

(f)"**Controlled**" means, with respect to any Intellectual Property, know-how or Data, a Party has the legal authority or right (whether by ownership, license or otherwise) to grant a license, sublicense, right of access or right to use (as applicable) with respect to such Intellectual Property, know-how or Data to the other Party on the terms and conditions set forth in this Agreement at the time of such grant, in each case without breaching the terms of any applicable agreement with a third party.

(g)"**Data**" means, in any form or format, all clinical and non-clinical data, natural history data, correspondence with all regulatory authorities, regulatory documents , orphan drug designation of lonafarnib for Progeria (pursuant to 21 CFR § 316.27) or other regulatory exclusivities owned or Controlled by a Party, including any data relating to any Licensed Product collected, compiled, reviewed or analyzed by Accenture PLC and any summaries, memoranda or analyses prepared by Accenture PLC with respect to any such data.

(h)"**Default**" shall have the meaning set forth in Section 9(h).

(i)"**Defense**" shall have the meaning set forth in Section 20(d).

(j)"**Eiger Indemnified Parties**" shall have the meaning set forth in Section 20(c).

(k)"**FDA**" means the U.S. Food and Drug Administration, an agency of the U.S. Department of Health and Human Services.

(l)"**Federal Arbitration Act**" shall have the meaning set forth in Section 27(b).

(m)"**Field**" means the treatment of Progeria.

(n)"**IND**" shall have the meaning set forth in Section 5(c).

(o)"**Indemnified Party**" shall have the meaning set forth in Section 20(d).

(p)"**Indemnifying Party**" shall have the meaning set forth in Section 20(d).

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(q)"**Initial Term**" shall have the meaning set forth in Section 21.

(r)"**Intellectual Property**" means all patents, copyrights, trademarks, trade secrets and all other intellectual property and industrial property under the laws of any jurisdiction and all rights in, to and under each of the foregoing, together with all applications for registration or issuances with respect to any of the foregoing and all registrations and issuances with respect to any of the foregoing.

(s)"**JSC**" shall have the meaning set forth in Section 4.

(t)"**Licensed API**" means (i) prior to the filing of the Progeria NDA, the active pharmaceutical ingredient of the Licensed Compound in the form as previously supplied to PRF by Eiger prior to the Effective Date or (ii) following the filing of the Progeria NDA, the form of the active pharmaceutical ingredient of the Licensed Compound used for the Licensed Progeria Product under the Progeria NDA.

(u)"**Licensed Compound**" means that certain compound known as of the Effective Date as lonafarnib with the chemical structure described in Exhibit A, including any prodrug, metabolite, salt, ester, solvate, hydrate or crystalline form thereof.

(v)"**Licensed Product**" means any (i) pharmaceutical product or product candidate that contains the Licensed Compound, either alone or in combination with one or more other active pharmaceutical ingredients (including all formulations, line extensions and modes of administration thereof) and (ii) Licensed API.

(w)"**Licensed Progeria Product**" means any Licensed Product in finished capsule form containing lonafarnib as the sole active pharmaceutical ingredient (i) as manufactured and supplied by or on behalf of Eiger to Boston Children's Hospital pursuant to the Boston Children's Hospital Investigator Sponsored Clinical Trial Research Agreement, dated October 4, 2016, as amended on October 28, 2016, by and between Eiger and Boston Children's Hospital or (ii) following the filing of the Progeria NDA, as submitted to the FDA under the Progeria NDA.

(x)"**Losses**" shall have the meaning set forth in Section 20(b).

(y)"**Merck License Agreement Termination Notice**" shall have the meaning set forth in Section 22(b).

(z)"**NDA**" means any new drug application (as defined in Title 21 of the United States Code of Federal Regulations, as amended from time to time) filed with the FDA seeking regulatory approval to market and sell any Licensed Product in the United States for a particular indication.

(aa)"**Non-Conforming Product**" shall have the meaning set forth in Section 12(a).

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(bb)"**Pre-existing Eiger IP**" shall have the meaning set forth in Section 15.

(cc)"**Pre-existing PRF IP**" shall have the meaning set forth in Section 15.

(dd)"**PRF IND**" shall have the meaning set forth in Section 5(c).

(ee)"**PRF Indemnified Parties**" shall have the meaning set forth in Section 20(b).

(ff)"**PRF Second Source**" shall have the meaning set forth in Section 9(g).

(gg)"**Progeria**" means Hutchinson-Gilford Progeria Syndrome and progeroid laminopathies.

(hh)"**Progeria NDA**" shall have the meaning set forth in Section 5(a).

(ii)"**Progeria PRV**" shall have the meaning set forth in Section 6(a).

(jj)"**PRV Sale**" shall have the meaning set forth in Section 6(a).

(kk)"**Publishing Party**" shall have the meaning set forth in Section 17(a).

(ll)"**Renewal Term**" shall have the meaning set forth in Section 21.

(mm)"**Research Activities**" means any research, development, investigation or testing activities (including any activities in connection with any pre-clinical research or clinical trials and any activities conducted under any PRF IND (as defined below)) using any Licensed Product conducted by, on behalf of, under the direction or supervision of, as instructed by, with funding from or in collaboration with PRF.

(nn)"**Right of Reference**" means any written and signed statement by a Party to the applicable regulatory authority that authorizes such regulatory authority to reference data and information submitted previously by such Party to such regulatory authority, as described in 21 CFR § 312.23(b), or the equivalent authorization in a jurisdiction other than the United States.

(oo)"**Term**" shall have the meaning set forth in Section 21.

2.License Grants; Certain Covenants.

(a) Subject to the terms and conditions of this Agreement, Eiger hereby grants to PRF a non-exclusive, world-wide, royalty-free, fully paid-up sub-licensable (i) license under and to all Intellectual Property, know-how and Data Controlled by Eiger or any of its Affiliates and (ii) sublicense under and to all Intellectual Property, know-how and Data licensed by Merck or any of its Affiliates to Eiger or any of its Affiliates, in each case (i) and (ii) solely to (A) conduct or perform, or have conducted or performed, any Research Activities using any Licensed Product in the Field and (B) prepare, file, own and maintain any Progeria IND.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(b) Subject to the terms and conditions of this Agreement, PRF hereby grants to Eiger a non-exclusive, world-wide, fully paid-up, sub-licensable license under and to all Intellectual Property, know-how and Data Controlled by PRF solely to prepare and file any NDA for the Licensed Product, including the Progeria NDA.

(c) Eiger shall not amend the Merck License Agreement to narrow or limit the scope of the Licensed Progeria Product or Eiger's rights with respect to the Licensed Progeria Product or any Intellectual Property, know-how or Data related thereto.

(d) After the Effective Date, Eiger shall not, without PRF's prior written consent, enter into any agreement or amend any agreement that would limit Eiger's ability to fulfill its obligations pursuant to this Agreement, provided that this Section 2(d) shall not be deemed to limit or restrict Eiger's ability, or require PRF's consent, to amend or terminate an existing manufacturing agreement, or enter into a new manufacturing agreement, for Licensed Progeria Product so long as (i) Eiger replaces any existing manufacturer with at least a comparable manufacturer and (ii) Eiger continues to fulfill its obligations pursuant to this Agreement.

(e)PRF shall not conduct or have conducted any clinical trial involving use in humans of the Licensed Progeria Product in the Field at any Additional Site if such Additional Site does not agree in a written agreement (to which Eiger is an express third party beneficiary) to indemnify the Eiger Indemnified Parties for any Losses resulting from any suit, action, claim, demand or proceeding of any kind or nature arising from any death of, or bodily injury to, any person enrolled in such clinical trial that is caused by the ingestion or use of the Licensed Progeria Product by such person in the conduct of such clinical trial (except to the extent arising from (i) Eiger's breach of any of its representations, warranties, covenants or agreements set forth in Section 18, (ii) any of Eiger's actions or failure to take action with respect to any Licensed Progeria Product in accordance with this Agreement or (iii) Eiger's negligence or willful misconduct).

3.No Implied License. Nothing herein shall be deemed to grant either Party or any third party acting on behalf of either Party any implied license or right under any Intellectual Property rights Controlled by the other Party except as expressly set forth in this Agreement.

4.Management of Collaboration. Within [*] after the execution of this Agreement, the Parties shall establish a Joint Steering Committee ("**JSC**") to oversee the preparation and filing of regulatory filings and collaboration activities of the Parties (including as further described in Section 4(c)) and to conduct or perform any other activities as the Parties may agree upon in writing.

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EXECUTION VERSION

(a) The JSC will be comprised of [*] appointed by Eiger and [*] appointed by PRF. All JSC decisions will be made by unanimous vote, with the JSC representatives of Eiger collectively having one vote and the JSC representatives of PRF collectively having one vote. If the JSC is unable to decide or resolve unanimously: (i) when to file the Progeria NDA with the FDA; or (ii) any other matter subsequent to a change of control of Eiger, then in each case (i) and (ii), the Parties agree to resolve such dispute in accordance with the dispute resolution procedures set forth in Section 27. For all other matters that are within the scope of the JSC's responsibility as agreed upon by the Parties in writing, that are properly presented to the JSC for action and that the JSC is unable to decide or resolve unanimously, Eiger shall have final decision making authority with respect to such matter. For purposes of this Section 4(a), "change of control" means any transaction or series of transactions as a result of which all or a majority of Eiger's outstanding voting stock or all or a majority of the business or assets of Eiger are sold or otherwise transferred or disposed of and are no longer directly or indirectly owned by the persons owning a majority of the voting stock of Eiger prior to the first such transaction.

(b) The JSC shall meet in accordance with a schedule established by mutual written agreement of the Parties, but no less frequently than [*] per calendar year, unless the Parties mutually agree in writing to a different frequency, with the location for such meetings to be determined by the JSC. The JSC shall remain in effect as long as necessary to support regulatory preparation and filing for approval of the Licensed Progeria Product in all territories.

(c) The responsibilities of the JSC shall include (i) reviewing and providing input on current and proposed future Research Activities; however, the Parties acknowledge and agree that the JSC does not have any right to approve or veto any such Research Activities, (ii) discussing overall regulatory requirements for obtaining regulatory approval of any Licensed Progeria Product in the Field, (iii) determining when to submit applications for regulatory approval of any Licensed Progeria Product in the Field, (iv) discussing whether to make the Licensed Progeria Product available in the Field as an investigational drug for treatment use pursuant to Section 8(b) in a particular jurisdiction outside the United States if Eiger believes in good faith that doing so will subject Eiger to an unreasonable risk of liability, (v) discussing whether to make the Licensed Progeria Product available in the Field as an investigational drug for treatment use pursuant to Section 8(b), (vi) reviewing and commenting on correspondence and submissions to regulatory authorities, (vii) coordinating safety monitoring activities between the Parties with respect to the Licensed Progeria Product and any Licensed API supplied by or for Eiger under this Agreement, (viii) facilitating the flow of information between the Parties, (ix) discussing whether to seek regulatory approval of the Licensed Progeria Product in the Field in any country outside of the United States and (ix) performing such other functions as may be appropriate to further the purposes of this Agreement and that are agreed upon by the Parties in writing.

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5.Regulatory.

(a) Promptly after the Effective Date and delivery to Eiger of Data and know-how Controlled by PRF in the Field, Eiger shall undertake a review of the regulatory and clinical Data and information provided by PRF and provide the JSC with its reasonable determination of the estimated time for filing of a NDA for a Licensed Progeria Product in [*] and [*] capsule formulations in the Field ("**Progeria NDA**") by Eiger. In the event that the JSC determines that such PRF Data and know-how and any other information Controlled or possessed by Eiger or any of its Affiliates supports the filing of the Progeria NDA by the first anniversary of the Effective Date, Eiger agrees to use commercially reasonable efforts to prepare and file the Progeria NDA [*]. Eiger agrees that if the JSC determines that filing the Progeria NDA [*] is impracticable, then Eiger will use commercially reasonable efforts to file the Progeria NDA as soon as practicable thereafter, as determined by the JSC. In any event, Eiger agrees to use commercially reasonable efforts to file the Progeria NDA [*] for the Licensed Product. The Parties agree that Eiger will submit a request to the FDA for a rare pediatric disease designation for the Licensed Progeria Product for the treatment of Progeria prior to submission of the Progeria NDA, and will use commercially reasonable efforts to submit such request (i) [*] it submits any request for expedited approval of the Progeria NDA under 21 USC § 356 or (ii) by the [*], whichever is earlier, unless the parties mutually agree upon an alternate submission date in writing after conferring with each other in good faith. Following the approval of the Progeria NDA, Eiger agrees to use commercially reasonable efforts to develop and register a [*] of the Licensed Progeria Product for use in the Field. The Parties further agree to use commercially reasonable efforts to prepare and file NDA equivalents outside of the United States for the Licensed Progeria Product for the treatment of Progeria as determined by the JSC.

(b) Eiger shall be the sole sponsor of the Progeria NDA or similar submission during the Term. During the Term, PRF shall, at Eiger's sole cost and expense, provide reasonable cooperation and assistance reasonably requested by Eiger with respect to obtaining and maintaining regulatory approvals for an NDA for any Licensed Progeria Product in the Field. Upon the reasonable written request of PRF, Eiger shall make available to PRF records of the Licensed Product reasonably necessary for PRF to fulfill its regulatory requirements with respect to its use of the Licensed Progeria Product in the Field.

(c)PRF shall have the right, but not the obligation, at its sole cost and expense, to own and maintain an Investigational New Drug ("**IND**") application under which Research Activities of PRF are conducted with respect to Licensed Product ("**PRF IND**"); provided that if PRF elects to exercise such right, then (i) Eiger shall be the exclusive (subject to Section 9(h)) provider of the Licensed Progeria Product under the PRF IND and shall supply the Licensed Progeria Product to PRF as set forth in Section 9; (ii) PRF shall grant Eiger a Right of Reference to Data included in or as part of the PRF IND; (iii) in connection with the PRF IND, Eiger shall grant PRF a Right of Reference to Data included in or as part of any IND or NDA submitted, sponsored or obtained by Eiger for any Licensed Product; and (iv) any material regulatory correspondence or material submission under a PRF IND shall be reviewed and discussed by the JSC prior to submission by PRF to the FDA. If PRF desires to pursue a study of a Combination Drug in the Field under the PRF IND, Eiger shall consider in good faith entering into a third party collaboration with another drug supplier to enable PRF to pursue such study with Licensed Product.

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(d) Eiger shall be solely responsible for any additional clinical or non-clinical studies necessary for obtaining and maintaining approval of the Progeria NDA. Eiger shall be solely responsible for the costs of such additional studies up to a cumulative total of [*]. The Parties will negotiate in good faith regarding the allocation of any costs in excess of this amount. Eiger agrees to maintain complete and accurate books and records relating to such additional studies. Eiger shall promptly notify PRF in writing when the costs of such additional studies total each of [*]. If the costs of such additional studies exceeds [*] and the Parties agree that PRF shall share the costs of any such additional studies in excess of such amount, PRF shall have the right to inspect such books and records (upon reasonable prior written notice to Eiger and during Eiger's normal business hours and no more than once per year), using an independent certified public accountant retained by PRF and reasonably acceptable to Eiger, for the sole purpose of verifying the costs of such additional studies. PRF shall bear the expense of any such inspection, except that if any such inspection reveals that the actual costs of such additional studies are less than [*] by [*] or more, then Eiger shall bear the expense of such investigation.

(e) The Parties shall reasonably cooperate in good faith with respect to the conduct of any inspections by any regulatory authority of a Party's site or facility (or, in the case of PRF, any clinical site conducting Research Activities with PRF as permitted under this Agreement) related to any Licensed Product. To the extent permitted by applicable law, Eiger shall be allowed to attend any such inspection relating to any Research Activities (other than any Research Activities using Licensed API and no other Licensed Product).

6.Priority Review Voucher.

(a) The Parties acknowledge that a Priority Review Voucher may be available and awarded to Eiger as the sponsor of the Progeria NDA ("**Progeria PRV**"). The Parties agree that, if awarded, Eiger will use commercially reasonable efforts to sell the Progeria PRV to a third party ("**PRV Sale**") on commercially reasonable terms within twelve (12) months of the issuance of such Progeria PRV. Eiger agrees not to retain the Progeria PRV for itself or any of its Affiliates. [*].

(b)PRF and Eiger shall share the proceeds of any PRV Sale [*]. For clarity, as used in this Section 6(b), "proceeds" means the gross amounts received by Eiger with respect to any PRV Sale, less applicable taxes on such amounts.

7.Commercialization Diligence; Patient Support Programs.

(a) Eiger shall use commercially reasonable efforts to Commercialize the Licensed Progeria Product in the Field in the United States within [*] of the Progeria NDA approval in the United States. In addition, Eiger shall use commercially reasonable efforts to obtain regulatory approval of and Commercialize the Licensed Progeria Product in the Field outside the United States.

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(b) Eiger shall (i) establish a patient support program prior to the first commercial sale of the Licensed Progeria Product in the United States and (ii) use commercially reasonable efforts to [*] in which Eiger seeks regulatory approval of the Licensed Progeria Product to treat Progeria, in each case (i) and (ii), to [*] after the Licensed Progeria Product is approved by the applicable regulatory authority to treat Progeria in each applicable country. For the avoidance of doubt, Eiger's obligations under this Section 7 to provide the Licensed Progeria Product [*] means that Eiger will [*].

(c) Prior to seeking regulatory approval in any particular country outside the United States, if Eiger in good faith believes that (i) it will not be commercially reasonable to establish any such program described in Section 7(b)(ii) in such country and (ii) following regulatory approval of the Licensed Progeria Product in such country, [*], then the JSC shall discuss whether to seek regulatory approval of the Licensed Progeria Product for the Field in such country as set forth in Section 4(c).

8.Expanded Access. Eiger shall use commercially reasonable efforts to make the Licensed Progeria Product available in the Field as an investigational drug for treatment use (a) in the United States in a manner consistent with all applicable laws, rules and regulations, as each such law, rule or regulation is then in effect and (b) outside the United States, in accordance with "named patient" programs in countries where they are available and delivery by or for Eiger is permitted under applicable law without unreasonable cost, expense or risk of liability, in each case (a) and (b), [*]; provided that, with respect to (a) and (b), the aggregate net cost to Eiger for making the Licensed Progeria Product available as an investigational drug for treatment use under this Section 8 shall not in the aggregate exceed [*]. For the avoidance of doubt, such [*] excludes the costs of manufacturing the Licensed Progeria Product. Eiger shall notify PRF promptly in writing if the aggregate costs of making the Licensed Progeria Product available in the Field as an investigational drug for treatment use pursuant to the foregoing clauses (a) and (b) will exceed such [*]. If Eiger in good faith believes that (i) it is not commercially reasonable to make the Licensed Progeria Product available in the Field as an investigational drug for treatment use pursuant to the foregoing clauses (a) or (b) or (ii) making the Licensed Progeria Product available in the Field as an investigational drug for treatment use pursuant to the foregoing clause (b) will subject Eiger to an unreasonable cost, expense or risk of liability, then the Parties shall discuss in good faith potential alternatives. For purposes of this Section 8, "commercially reasonable efforts" shall be deemed met if Eiger spends, excluding the costs of manufacturing the Licensed Progeria Product, [*] to make the Licensed Progeria Product available as an investigational drug for treatment use in accordance with the foregoing clauses (a) and (b).

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9.Supply of Licensed Progeria Product; Second Source.

(a) Eiger shall supply and deliver to PRF the Licensed Progeria Product requested by PRF for any Research Activities, by delivery dates reasonably agreed upon by the Parties, in the quantities and to the delivery locations as reasonably agreed upon by the Parties, at no cost or expense to PRF, provided that:

(i)each month, PRF shall provide Eiger in writing with a rolling non-binding estimate of its monthly requirement for the Licensed Progeria Product for Research Activities in each of the following [*], which PRF shall, if applicable, update such estimate before the beginning of each month;

(ii)the quantities set forth in the non-binding estimate are reasonably consistent with the quantities ordered and within a reasonable variance from the applicable forecast, provided that Eiger may request that the Parties mutually agree to specific minimum or maximum order variance limits to the extent quantities actually ordered deviate substantially from forecasted orders; and

(iii)PRF shall specify, on a best estimates basis, each estimated order and the related factors or contingencies for the delivery of the Licensed Progeria Product [*] before PRF's requested delivery date, unless otherwise mutually agreed upon by the Parties in writing, and the Parties shall regularly update and discuss the status and timing of delivery over the course of such period, provided that in any event any quantities originally estimated shall be within any maximum order variance set forth under Section 9(a)(ii).

(b) Eiger will package the Licensed Progeria Product in accordance with Eiger's IND application number [*] approved by the U.S. Food and Drug Administration on March 7, 2011 or Eiger's then-approved NDA for a Licensed Product.

(c) Eiger shall (i) retain a sample of each batch of the Licensed Progeria Product supplied under or pursuant to this Agreement and (ii) maintain and provide to PRF access to records of the Licensed Progeria Product in each shipment, including certificates of analysis that include the dates of manufacture (such certificates, "**CoAs**"). As reasonably requested by PRF, Eiger shall promptly provide PRF (A) a copy of such CoAs and (B) access to a copy of any such other records described in subclause (ii) of the foregoing sentence and any records of testing performed on such Licensed Progeria Product (as such testing records are required to be maintained by Eiger pursuant to any applicable law, statute, rule or regulation).

(d)PRF shall use the Licensed Progeria Product in the formulation supplied by Eiger and shall in no way modify, reverse-engineer, create derivatives of, reformulate or otherwise use a different form of such Licensed Progeria Product.

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(e) If PRF wishes to conduct (or have conducted) any Research Activities or clinical trials at a site other than Boston Children's Hospital ("**Additional Site**") for any Licensed Progeria Product in the Field, PRF shall notify Eiger and Eiger shall promptly and as soon as practicable enter into a material transfer agreement directly with such Additional Site to provide the Licensed Progeria Product for use in the Field. The JSC shall discuss in good faith plans and supply needs for the Licensed Progeria Product for any Additional Sites. Eiger acknowledges and agrees that PRF has the right to conduct, direct or sponsor any clinical trials at any Additional Sites using the Licensed Progeria Product, alone or in combination with other therapeutic or pharmaceutical agents, solely in the Field.

(f) Eiger shall (i) continue to supply the Licensed Progeria Product at no charge to Boston Children's Hospital pursuant to the Boston Children's Hospital Investigator Sponsored Clinical Trial Research Agreement, dated October 4, 2016, as amended on October 28, 2016, by and between Eiger and Boston Children's Hospital and (ii) supply any Additional Sites, in each case (i) and (ii), until [*] (or such longer period of time that PRF and Eiger may agree upon in writing) after regulatory approval of the Licensed Progeria Product in the Field in the territory in which Boston Children's Hospital or such Additional Site, as applicable, is located. If, however, any patient is enrolled in any PRF conducted, directed or sponsored clinical trial and receiving the Licensed Progeria Product from Eiger at the end of such [*], Eiger will continue to supply the Licensed Progeria Product at no charge to each such patient for the duration of the clinical trial. In the event that any Additional Site is located in a territory where a Licensed Progeria Product does not receive regulatory approval during the Term for commercial sale, Eiger will provide the Licensed Progeria Product [*] to such Additional Site for the Term.

(g) From time to time during the Term, PRF may identify a second source of supply for the Licensed Progeria Product or Licensed API reasonably acceptable to Eiger ("**PRF Second Source**"). Upon written request from PRF, Eiger agrees to: (i) work with such PRF Second Source in good faith; (ii) use commercially reasonable efforts to qualify such PRF Second Source for the manufacture of the Licensed Progeria Product and Licensed API; (iii) provide such PRF Second Source with all information and support necessary, and reasonable assistance, to enable such PRF Second Source to manufacture the Licensed Progeria Product and Licensed API for supply in accordance with this Agreement; and (iv) grant to such PRF Second Source a non-exclusive, world-wide, royalty-free, fully paid-up, non-sublicensable license under and to all Intellectual Property Controlled by Eiger necessary to manufacture the Licensed Progeria Product and Licensed API for supply in accordance with this Agreement. All costs and expenses with respect to the engagement, assessment, review and commitment of such PRF Second Source shall be the responsibility of PRF, provided that Eiger [*] from Eiger to such PRF Second Source.

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(h) Eiger agrees that, if, for any reason, Eiger Defaults (as defined below) on any of its obligations to supply any Licensed Progeria Product to PRF in accordance with this Agreement, and fails to cure such Default within [*] after its receipt from PRF of a written notice describing such Default, PRF has the right to obtain such Licensed Progeria Product or Licensed API from such PRF Second Source. Commencing on the [*] anniversary of the Effective Date, Eiger shall, at all times during the remainder of the Term, maintain an existing inventory of Licensed Progeria Product in an amount equal to the total amount of Licensed Progeria Product set forth in PRF's then-current monthly orders for the subsequent [*]. If, at any time during the Term, Eiger engages a second source to supply the Licensed Progeria Product or Licensed API, then Eiger shall identify to PRF in writing such alternative manufacturer and, at PRF's request, Eiger shall use commercially reasonable efforts to facilitate the manufacture of the Licensed Progeria Product or Licensed API for PRF by such alternative manufacturer [*] as the terms and conditions pursuant to which such alternative manufacturer agrees to manufacture the Licensed Progeria Product or Licensed API for Eiger. For purposes of this Section 9(h), "**Default**" means that Eiger fails to deliver to PRF at least [*] of the quantities of Licensed Progeria Product ordered under Section 9(a) (excluding all Non-Conforming Product for purposes of determining such failure level) in any [*] orders.

(i) In the event of (i) expiration or any termination of this Agreement (other than Eiger's termination of this Agreement in accordance with Section 22(b)(i) for an uncured, material breach of this Agreement by PRF), (ii) expiration or any termination of the Merck License Agreement, or (iii) the termination of development (including efforts to seek regulatory approval) or commercialization of Licensed Product by Eiger for any reason, Eiger shall: (A) upon PRF's written request, to the extent practicable, assign to PRF all manufacturing agreements and supply agreements that Eiger has not assigned to Merck pursuant to the Merck License Agreement relating to the manufacture or supply of Licensed Product then Controlled by Eiger and, to the extent Eiger has such rights, provide the necessary regulatory licenses and any other rights to PRF to enable continuity of supply of the Licensed Product (which manufacturing agreements and supply agreements assigned to PRF (**"Assigned Manufacturing Agreements**") may require payment by PRF for supply of the Licensed Product, it being understood that, with respect to any Assigned Manufacturing Agreement: (1) after the assignment of such Assigned Manufacturing Agreement by Eiger to PRF becomes effective ("**Assignment Effective Time**"), PRF shall be responsible for all ongoing obligations of Eiger under such Assigned Manufacturing Agreement, but only to the extent that such obligations: (w) arise after the Assignment Effective Time; (x) do not arise from or relate to any breach by Eiger of any provision of such Assigned Manufacturing Agreement; (y) are not the result of any event, circumstance or condition occurring or existing on or prior to the Assignment Effective Time; and (z) are ascertainable solely by reference to the express terms of such Assigned Manufacturing Agreement; provided, however, that (I) PRF shall not be obligated to assume, discharge or perform any obligation or liability under such Assigned Manufacturing Agreement if there shall not have been obtained prior to the assignment of such Assigned Manufacturing Agreement by Eiger to PRF any consent required to be obtained from any third party with respect to the assignment or delegation to PRF of any rights or obligations under such Assigned Manufacturing Agreement and (II) in no event shall PRF assume or be deemed to assume, pursuant to this Agreement or otherwise, any obligation or liability arising under such Assigned

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Manufacturing Agreement that accrued or arose prior to the Assignment Effective Time, unless expressly agreed upon by PRF and Eiger in the written assignment agreement effectuating such assignment; and (2) such Assigned Manufacturing Agreement shall, if agreed upon by the third party counter-party to such Assigned Manufacturing Agreement, be novated and assigned to PRF in its entirety (as may be modified by PRF and such counter-party)); (B) fulfill any outstanding orders for Licensed Progeria Product submitted by PRF pursuant to Section 22(c); and (C) except to the extent Eiger is obligated under the Merck License Agreement to deliver Eiger's remaining inventory of Licensed Progeria Product to Merck, deliver to PRF all of the safety stock maintained by Eiger pursuant to Section 9(h). With respect to any other remaining inventory of Licensed Progeria Product of Eiger, the Parties shall discuss in good faith Eiger (as may be permitted by Merck if Merck does not exercise its rights under the Merck License Agreement to the Licensed Progeria Product possessed by Eiger) making available any such remaining inventory of Licensed Progeria Product to PRF. For the avoidance of doubt, any such remaining inventory of Licensed Progeria Product assigned to PRF other than the safety stock maintained by Eiger pursuant to Section 9(h) shall be delivered on an "as is" basis without warranty of any kind, and PRF shall be responsible for requalification or other requirements for research use or use in humans under any applicable laws, rules and regulations with respect to such remaining inventory. In the event Eiger provides to PRF any such remaining inventory of Licensed Progeria Product other than such safety stock, Eiger shall provide to PRF [*].

10.Delivery. Eiger shall deliver the Licensed Progeria Product [*] to PRF or its designee (provided that all products in a single order will be delivered to a single place of destination in the U.S.) by PRF's requested delivery date, provided that with respect to Licensed Progeria Product, PRF supply orders are made in accordance with Section 9(a). Delivery of the Licensed Progeria Product intended to be used for Research Activities outside of the U.S. shall be [*] for PRF to undertake export, shipment and delivery outside of the U.S. For clarity, this Section 10 does not apply to, and Eiger remains solely responsible for, the delivery of all Licensed Progeria Product under the global patient support program described in Section 7 and the expanded access or other "named patient" programs described in Section 8.

11.Supply of Licensed API.

(a) Eiger shall supply and deliver to PRF an average quantity of [*] of Licensed API (or such higher quantity as reasonably agreed upon by the Parties) per calendar year (the "Applicable Calendar Year"), at no cost or expense to PRF, for inclusion in and distribution by PRF's Cell and Tissue Bank (information about which is located, as of the Effective Date, at https://www.progeriaresearch.org/cell-and-tissue-bank/). Eiger may supply and deliver such average quantity of Licensed API during such Applicable Calendar Year or the immediately subsequent calendar year (the "Subsequent Calendar Year"), but the supply and delivery of such average quantity of Licensed API for the Applicable Calendar Year during the Subsequent Calendar Year shall not decrease Eiger's obligation to supply and deliver such average quantity of Licensed API for the Subsequent Calendar Year. Eiger shall deliver such Licensed API to [*], unless the Parties otherwise agree in writing to an alternative delivery location, [*], by delivery dates reasonably agreed upon by the Parties in writing.

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(b) Eiger shall (i) retain a sample of each batch of the Licensed API supplied under or pursuant to this Agreement and (ii) maintain and provide to PRF reasonable access to records of the Licensed API in each shipment, including CoAs. As reasonably requested by PRF, Eiger shall promptly provide PRF (A) a copy of such CoAs and (B) access to a copy of any such other records described in subclause (ii) of the foregoing sentence and any records of testing performed on such Licensed API (as such testing records are required to be maintained by Eiger pursuant to any applicable law, statute, rule or regulation).

12.Rejection.

(a) For each shipment of the Licensed Progeria Product, Eiger shall provide PRF with a CoA no less than [*] days before shipping. PRF shall reasonably promptly review the CoA and notify Eiger in writing within [*] days after PRF's receipt of such CoA of any non-conformance PRF identifies in the CoA. If no notification is provided from PRF, then Eiger shall ship the Licensed Progeria Product as scheduled, and PRF (or its designee) shall inspect the Licensed Progeria Product upon its receipt thereof. Within ten [*] days after delivery of any Licensed Progeria Product, PRF may reject all or any portion of any shipment of the Licensed Progeria Product that (i) has been damaged or tampered with (or the container or packaging of which has been damaged or tampered with) prior to receipt of such Licensed Progeria Product by or on behalf of PRF or its designee, (ii) is not in conformance with the approved Eiger IND or NDA for such Licensed Progeria Product or (iii) is adulterated or misbranded within the meaning of such terms under the Federal Food, Drug and Cosmetic Act (each of such Licensed Progeria Product, a "**Non-Conforming Product**").

(b) In order to reject a shipment of the Licensed Progeria Product, PRF must provide Eiger with a written notice of rejection and the basis therefor within [*] days after PRF's receipt of such shipment, except that in the case of any Licensed Progeria Product having any latent defect which, upon reasonable examination by PRF or its designee, could not have been discovered within such [*] day period after receipt thereof, PRF must provide Eiger with a notice of rejection and the basis therefor within [*] days after PRF becomes aware of such defect. Any notice of rejection from PRF must contain reasonable documentation to allow Eiger to reasonably determine whether such rejected Licensed Progeria Product is a Non-Conforming Product. If no such notice of rejection is received by Eiger within the applicable [*] day period set forth above, PRF shall be deemed to have accepted such delivery of such Licensed Progeria Product, as the case may be.

(c) If in good faith Eiger does not accept PRF's basis for rejection of any Licensed Progeria Product, the Parties shall engage a mutually acceptable independent third party laboratory to test the putative Non-Conforming Product in question to determine if such Licensed Progeria Product is a Non-Conforming Product. The determination of such laboratory shall be binding upon the Parties, and the costs of such testing shall be shared equally by the Parties.

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(d) If Eiger accepts PRF's basis for rejection of any Licensed Progeria Product or if any such independent third party laboratory determines that the Licensed Progeria Product in question is a Non-Conforming Product, promptly upon receipt of such notice of rejection or such determination, Eiger shall, at PRF's request, use commercially reasonable efforts to promptly provide PRF with replacement Licensed Progeria Product in the same quantity as the Non-Conforming Product. Unless Eiger requests the return of a rejected batch of the Licensed Progeria Product within [*] after the later of the receipt of PRF's notice of rejection or, if applicable, the independent third party laboratory's determination that such Licensed Progeria Product is a Non-Conforming Product, PRF shall destroy such rejected batch of the Licensed Progeria Product and provide Eiger with written certification of such destruction. Within [*] after PRF's receipt of a written request from Eiger for the return of a rejected batch of the Licensed Progeria Product, PRF shall return such rejected batch to Eiger, at Eiger's cost and expense.

13.Recalls; Safety Reporting. Eiger shall have sole decision-making authority with respect to, and shall bear all costs and expenses relating to, issuing any recall, market withdrawal or correction of any Licensed Progeria Product provided by Eiger or with respect to issuing any advisory letter or other safety related communication with respect to any Licensed Progeria Product provided by Eiger. Eiger shall notify PRF in writing promptly (and in any event within (a) [*] after Eiger's receipt of any written notice or other communication from a regulatory agency that could reasonably be expected to result in any recall, market withdrawal, correction or suspension of distribution of any Licensed Progeria Product or (b) [*] after Eiger's receipt of any written notice or other communication from a regulatory agency that could reasonably be expected to result in any clinical hold of any Licensed Progeria Product) if any Licensed Progeria Product, or any Licensed API contained therein, is alleged or proven to be the subject of any recall, market withdrawal, correction, clinical hold or suspension of distribution. PRF will make available to Eiger, upon Eiger's written request, all of PRF's pertinent records in its Control relating to such Licensed Progeria Product that Eiger may reasonably request to assist in effecting any such recall, market withdrawal or correction. If either Party becomes aware of any information that reasonably suggests that a death or serious adverse reaction or injury will impact the Commercialization or development of the Licensed Progeria Product, such Party will (i) furnish such information to the other Party within [*] after such Party becomes aware of such information and (ii) make, maintain and retain records of such information.

14.Inventory Records. PRF shall keep Eiger reasonably informed of its use of all Licensed Progeria Product and shall keep full and accurate records of its receipt, use and inventory of any Licensed Progeria Product. Within [*] after the end of each [*], PRF shall provide Eiger with a written inventory report for the Licensed Progeria Product, documenting amounts of the Licensed Progeria Product being allocated to Research Activities and amounts otherwise being held in the possession of PRF, if any.

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15.Intellectual Property. Except as specifically set forth in this Agreement, Eiger retains all right, title, and interest in and to all Intellectual Property, information, know-how, Data and inventions that Eiger Controls as of the Effective Date ("**Pre-existing Eiger IP**") and all enhancements, modifications, extensions, improvements and derivatives of any Pre-existing Eiger IP developed independently by or for Eiger (either solely or jointly with any third party) and without use of the Confidential Information of PRF. Except as specifically set forth in this Agreement, PRF retains all right, title and interest in and to all Intellectual Property, information, know-how, Data and inventions that PRF Controls as of the Effective Date ("**Pre-existing PRF IP**") and all enhancements, modifications, extensions, improvements and derivatives of any Pre-existing PRF IP developed independently by or for PRF (either solely or jointly with any third party) and without use of the Confidential Information of Eiger (other than use of any Licensed Product in the Field).

16.Confidential Information.

(a) Obligations. Each Party (the "**Receiving Party**") will maintain in strict trust and confidence, and will not (i) use for any purpose other than the performance of its obligations and exercise of its rights under this Agreement, any Confidential Information (as defined below) received from the other Party in connection with this Agreement (the "**Disclosing Party**") or (ii) disclose any Confidential Information of the Disclosing Party to any persons or entities (other than the Receiving Party's employees, clinical site staff, contractors, consultants, agents or, in the case PRF is the Receiving Party, any person or entity to whom it provides any Licensed Progeria Product or Licensed API for any Research Activities, in each case who require such access for the purpose of this Agreement (including for the Receiving Party to perform its obligations or exercise its rights under this Agreement) and are obligated to keep the Disclosing Party's Confidential Information in confidence). "**Confidential Information**" of the Disclosing Party means (i) any information disclosed, directly or indirectly, by the Disclosing Party to the Receiving Party pursuant to this Agreement that (A) is in written, graphic, electronic or other tangible form (including documents, samples, know-how, data, product plans, research and development) and is marked "Confidential" or in a similar manner to indicate its confidential nature, (B) is disclosed orally, provided that such information is designated as confidential at the time of initial disclosure, or (C) otherwise should reasonably be considered confidential by the Receiving Party based on the circumstances of disclosure or the nature of the information itself or (ii) any Data owned or Controlled by the Disclosing Party. Confidential Information may include information of a third party disclosed by the Disclosing Party to the Receiving Party under this Agreement.

(b) Exceptions to Confidential Information. Obligations of non-disclosure and non-use will not apply to any information which: (i) is in the public domain or comes into the public domain through no breach of the confidentiality obligations set forth herein; (ii) is disclosed to the Receiving Party without restriction on disclosure and use by an independent third party having a legal right to make such disclosure without making such disclosure subject to confidentiality obligations; (iii) is already rightfully known by the Receiving Party without any confidentiality obligations at the time of receiving such information from the Disclosing

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Party, as evidenced by the Receiving Party's prior written records and other competent evidence; or (iv) is independently developed by the Receiving Party without any use of or reference to the Disclosing Party's Confidential Information, as evidenced by written records and other competent evidence. If the Receiving Party becomes legally compelled to disclose any Confidential Information, the Receiving Party shall provide the Disclosing Party prompt written notice, if legally permissible, and shall reasonably assist the Disclosing Party in seeking a protective order, confidential treatment or other appropriate restriction on disclosure or remedy. In any event, the Receiving Party shall disclose only that portion of such Confidential Information that the Receiving Party is legally required to disclose and shall maintain the confidentiality of such disclosed Confidential Information for all other purposes in accordance with this Agreement.

(c) Maintenance of Confidentiality. The Receiving Party shall protect the Disclosing Party's Confidential Information against unauthorized use and disclosure using at least the same degree of care and taking at least the same measures the Receiving Party uses and takes to protect its own confidential information of a similar nature, but in no event will the Receiving Party use or take less than reasonable care or reasonable measures. The Receiving Party shall promptly notify the Disclosing Party of any actual or suspected unauthorized use or disclosure of any of the Disclosing Party's Confidential Information, of which the Receiving Party becomes aware.

17.Publicity.

(a) Publications. If either Party desires to publish findings related to any Research Activities conducted after the Effective Date (such Party, the "**Publishing Party**"): (i) the Publishing Party shall provide a copy of the proposed publication to the other Party for review at least [*] prior to publication if reasonably possible and, if not, as soon as reasonably possible prior to submission for publication but in no event less than [*] prior to publication; (ii) such other Party shall provide the Publishing Party with any comments to such proposed publication at least [*] prior to the proposed publishing date; and (iii) the Publishing Party shall consider such comments in good faith. Upon such other Party's reasonable written request, the Publishing Party shall remove any Confidential Information of such other Party contained in such publication.

(b) Public Announcement. Other than as required by law or regulation, neither Party shall issue any press release or public announcement relating to this Agreement, or otherwise publicize the collaboration between the Parties under this Agreement, without the prior written approval of the other Party, which approval shall not be unreasonably withheld, conditioned or delayed, except that, once a press release or public announcement has been approved in writing by both Parties, a Party may make subsequent public disclosure of the information contained in such statement without any further approval of the other Party.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

18.Representations and Warranties.

(a) Eiger hereby represents, warrants, covenants and agrees that:

(i)as of the Effective Date, Eiger has all rights, approvals and authorities necessary to enter into, and perform all of its obligations under, this Agreement;

(ii) Eiger shall manufacture, package, handle, supply and ship the Licensed Progeria Product and Licensed API in compliance with (A) the approved Eiger IND, (B) all applicable laws, statutes, rules and regulations, and (C) all standards consistent with and necessary for products intended for use in humans;

(iii) Eiger shall manufacture the Licensed Progeria Product and Licensed API in compliance with the good manufacturing practices promulgated by the FDA and the quality assurance and quality control practices that are standard in the pharmaceutical industry;

(iv)neither the Licensed Progeria Product nor Licensed API will be adulterated or misbranded within the meaning of such terms under the Federal Food, Drug and Cosmetic Act;

(v)accompanying each shipment of the Licensed Progeria Product for use in humans, Eiger shall supply the CoA confirming that the Licensed Progeria Product meets all requirements and specifications set forth in the Eiger IND or NDA (including specifications of purity, stability, and composition), as applicable;

(vi) as of the Effective Date, Eiger has all rights necessary to grant to PRF all licenses, sublicenses, rights of access and rights of use (as applicable) to all Intellectual Property, know-how and Data pursuant to and accordance with the terms and conditions of this Agreement; and

(vii) Eiger has provided to PRF a true and complete copy of the Merck License Agreement in effect as of the Effective Date.

(b)PRF hereby represents, warrants, covenants and agrees that:

(i)as of the Effective Date, PRF has all rights, approvals and authorities necessary to enter into, and fulfill all of its obligations under, this Agreement;

(ii)PRF shall handle, store, and use the Licensed Progeria Product and Licensed API in accordance with all applicable laws and regulations and any written instructions provided by Eiger with respect to the proper handling, storage, and use of the Licensed Progeria Product and Licensed API;

(iii)PRF shall not take any action to adulterate or misbrand (within the meaning of such terms under the Federal Food, Drug and Cosmetic Act) the Licensed Progeria Product or Licensed API;

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(iv) the provisions of this Agreement cover, in addition to other matters, all covenants and obligations of Merck to PRF as of the Effective Date with respect to the supply of Licensed Progeria Product and Licensed API to PRF and the use of the Licensed Progeria Product and Licensed API in the Field; and

19. Warranty Disclaimer. EXCEPT FOR THE REPRESENTATIONS AND WARRANTIES PROVIDED BY THE PARTIES IN SECTION 18, (a) THE LICENSED PROGERIA PRODUCT AND LICENSED API ARE SUPPLIED BY EIGER TO PRF WITH NO WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, AND (b) BOTH PARTIES HEREBY DISCLAIM ALL WARRANTIES, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

20. Insurance; Indemnification.

(a) Each Party shall obtain and maintain insurance, including product liability insurance, in commercially reasonable and appropriate amounts at all times during the Term. Within [*] after a Party's written request, the other Party shall provide to the requesting Party copies of certificates of such insurance of such other Party. Each such insurance policy shall entitle the other Party to receive at least [*] prior written notice of any cancellation (including for nonrenewal) or change of any such insurance policy. All such insurance policies of Eiger will include PRF as an additional insured with respect to the Licensed Product. [*].

(b) Eiger shall indemnify, defend and hold harmless PRF and each of its officers, directors, employees and agents (collectively, "**PRF Indemnified Parties**") from and against any and all third party claims, losses, liabilities, damages, settlements, costs and expenses of any kind, as incurred, including reasonable attorneys' fees (collectively, "**Losses**") resulting from any suit, action, claim, demand or proceeding of any kind or nature arising from (i) Eiger's breach of any of its representations, warranties, covenants or agreements set forth in Section 18, (ii) any of Eiger's actions or failure to take action with respect to any Licensed Product in accordance with this Agreement or (iii) Eiger's gross negligence or willful misconduct, except in each case (i), (ii) and (iii) to the extent resulting from PRF's gross negligence or willful misconduct or to the extent such Losses would otherwise be subject to indemnification by PRF pursuant to Section 20(c) if such Losses were incurred or suffered by Eiger.

(c) PRF shall indemnify, defend and hold harmless Eiger and each of its officers, directors, employees and agents (collectively, "**Eiger Indemnified Parties**") from and against any and all third party Losses resulting from any suit, action, claim, demand or proceeding of any kind or nature arising from (i) PRF's use, handling, transfer or storage of the Licensed Progeria Product and Licensed API, in each case other than Losses in connection with any clinical trial agreement between PRF and an Additional Site that conducts, on behalf of, under the direction or supervision of, as instructed by or in collaboration with PRF, any clinical trial involving use in humans of the Licensed Progeria Product in the Field, (ii) PRF's breach of any of its representations and warranties set forth in Section 18 or (iii) PRF's gross negligence or willful misconduct, except in each case (i), (ii) and (iii) to the extent resulting from Eiger's gross negligence or willful misconduct or to the extent such Losses would otherwise be subject to indemnification by Eiger pursuant to Section 20(b) if such Losses were incurred or suffered by PRF.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(d) With respect to the indemnification obligations of each Party ("**Indemnifying Party**") set forth above in this Section 20: (a) the indemnified Party ("**Indemnified Party**") shall reasonably promptly notify the Indemnifying Party in writing of any claim for which the Indemnified Party seeks indemnification under this Section 20, provided, however, that the failure to reasonably promptly provide such notice will not relieve the Indemnifying Party from its liability or obligations under this Section 20, except to the extent the Indemnifying Party's defense of such claim is materially prejudiced by such failure; (b) the Indemnifying Party shall have sole control of the defense, settlement and negotiations for settlement (collectively, "**Defense**") of such claim at the Indemnifying Party's expense, provided, however, that the Indemnifying Party shall not, without the Indemnified Party's prior written consent, settle any such claim if such settlement (i) requires that any of the PRF Indemnified Parties (in the case PRF is the Indemnified Party) or any of the Eiger Indemnified Parties (in the case Eiger is the Indemnified Party) makes any payment or bears any other obligations (beyond those required under this Agreement), (ii) includes any admission of wrongdoing, fault or liability on the part of any of the PRF Indemnified Parties (in the case PRF is the Indemnified Party) or any of the Eiger Indemnified Parties (in the case Eiger is the Indemnified Party), (iii) does not include a full release of all PRF Indemnified Parties (in the case PRF is the Indemnified Party) or all Eiger Indemnified Parties (in the case Eiger is the Indemnified Party) or (iv) includes any injunctive or other equitable relief; and (c) the Indemnified Party shall, as reasonably requested by the Indemnifying Party, reasonably cooperate and provide reasonable assistance in connection with the Defense of such claim. The Indemnified Party shall have the right to participate in (but not control) such Defense through its own counsel and at its own cost and expense to monitor such Defense. The Indemnifying Party shall in good faith consult with such counsel for the Indemnified Party and keep such counsel reasonably advised of the status of such Defense.

21.Term. Unless earlier terminated in accordance with Section 22, this Agreement shall commence as of the Effective Date and continue in effect for an initial term of [*] ("**Initial Term**"), and shall thereafter automatically renew for subsequent renewal terms of two (2) years each (each a "**Renewal Term**"), unless either Party notifies the other Party in writing no later than [*] prior to the end of the then existing Initial Term or Renewal Term (as the case may be) that it does not intend to renew this Agreement for a subsequent Renewal Term. The Initial Term together with all Renewal Terms are referred to in this Agreement as the "**Term**."

22.Termination.

(a)PRF Termination. PRF may terminate this Agreement: (i) for any reason upon [*] prior written notice to Eiger; or (ii) [*]. The Parties agree that any termination pursuant to the foregoing clause (ii) in this Section 22(a) shall be deemed a termination for convenience by Eiger.

(b) Eiger Termination. Eiger may terminate this Agreement: (i) immediately upon PRF's material breach of this Agreement if PRF fails to cure such breach within [*] after its receipt from Eiger of a written notice reasonably describing such breach; or (ii) immediately upon written notice to PRF of the rightful termination or expiration of the Merck License Agreement pursuant to the terms and conditions thereof, provided that Eiger has notified PRF in writing immediately upon Eiger's receipt from Merck, or Eiger's sending to Merck, any notice of termination of the Merck License Agreement ("**Merck License Agreement Termination Notice**").

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(c) Orders Prior to Termination. In the event PRF terminates this Agreement for any reason or Eiger terminates this Agreement pursuant to Section 22(b)(ii), Eiger agrees that, subject to Eiger's obligation to continue to supply the Licensed Progeria Product as set forth in Section 9(f), PRF has the right (but not the obligation) to submit to Eiger prior to the effective date of termination, and Eiger will fulfill, any final orders in accordance with Section 9(a) for any Licensed Progeria Product in quantities specified by PRF (such quantities to be reasonable based on the then-current estimates pursuant to Section 9(a)(iii) as finally agreed upon by the Parties after conferring with each other in good faith), notwithstanding any prior forecasts by PRF for such Licensed Progeria Product.

(d) Effects of Termination. In the event of expiration or termination of this Agreement for any reason (other than (1) Eiger's termination of this Agreement in accordance with Section 22(b)(i) for PRF's uncured material breach or (2) PRF's termination of this Agreement in accordance with Section 22(a)(i) for convenience and not due to any breach of this Agreement by Eiger), Eiger shall, to the extent Eiger has rights or is permitted under the Merck License Agreement or Merck (or any successor of Merck or of Merck's rights in the Licensed Compound) otherwise agrees or permits in writing:

(i)[*] (A) [*] (B) *];

(ii)[*] (A) [*] and (B) [*];

(iii)provide PRF with complete and unredacted copies of all Data and all draft regulatory filings (it being understood that "draft" means documents reasonably available and in the possession or control of Eiger (or any of its Affiliates) as of the date of such expiration or termination), in each case to the extent Controlled by Eiger that may be necessary to (A) Commercialize the Licensed Product in the Field and (B) prepare, file or maintain any Progeria NDA, it being understood that with respect to access to Data and information regarding chemistry, manufacturing and controls such information may be provided solely by Right of Reference granted by Eiger to PRF (or its designee);

(iv)(A) [*] (B) [*];

(v)[*] (A) [*]; (B) [* ; and (C) [*]; and

(vi)[*] (A) [*] or (B) [*].

(e) Return or Destruction of Confidential Information. Upon the expiration or termination of all licenses granted by a Party ("Granting Party") to the other Party under or pursuant to this Agreement ("Former Licensee"), such Former Licensee shall (a) reasonably promptly return to such Granting Party or destroy all of such Granting Party's Confidential Information, and all copies, notes or extracts thereof, in the possession or control of such Former Licensee and (b) in the case of destruction, provide such Granting Party with written certification of such destruction signed by an officer of such Former Licensee.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(f) Survival. Upon the expiration or any termination of this Agreement, the following provisions shall survive: Sections 1, 3, 6, the last sentence of 9(c), 9(f), 9(i), 10, the last sentence of 11(b), 13, 15, 16, 17(a), 18, 19, 20(b), 20(c), 20(d), 22(c), 22(d), 22(e), 22(f), and 23 through and including 31. In addition, upon the expiration or termination of this Agreement for any reason (other than for Eiger's termination of this Agreement in accordance with Section 22(b) or PRF's termination of this Agreement in accordance with Section 22(a)(i) for convenience and not due to any breach of this Agreement by Eiger), Sections 2(c) and 2(d) shall survive so long as the Merck License Agreement is in effect.

23.Assignment. Neither Party may assign this Agreement, including by operation of law, without the prior written consent of the other Party, which consent will not be unreasonably withheld or delayed, except that either Party may assign this Agreement (i) to an Affiliate of such Party or (ii) as part of a merger, consolidation, corporate reorganization or sale of all or substantially all of such Party's assets, in each case (i) and (ii), without the prior written consent of the other Party provided that (A) the permitted assignee assumes in writing the performance of all of the assigning Party's obligations under this Agreement and (B) in the case Eiger is the assigning Party, Eiger simultaneously assigns the Merck License Agreement to the permitted assignee. Any attempted assignment in violation of the foregoing restriction will be void. Subject to the foregoing restriction, this Agreement will be binding upon, enforceable by, and inure to the benefit of the Parties and their respective successors and permitted assigns.

24.Entire Agreement. This Agreement sets forth the complete and final agreement of the Parties with respect to the subject matter hereof and supersedes and terminates all prior agreements and understandings, written or oral, between the Parties with respect to such subject matter, including the Non-Binding Term Sheet, dated July 14, 2017, by and between the Parties. This Agreement may be amended, and the observance of any provision of this Agreement may be waived, only by a writing signed by both Parties. The failure by either Party to enforce any provision of this Agreement will not constitute a waiver of future enforcement of that or any other provision.

25.Relationship of the Parties. PRF and Eiger are independent contractors, and nothing in this Agreement will be construed as making them partners or as creating the relationships of employer and employee, master and servant, or principal and agent between them, for any purpose whatsoever. Neither Party will make any contracts, warranties or representations or assume or create any other obligations, express or implied, in the other Party's name or on its behalf.

26.Governing Law. The validity, performance, construction, and effect of this Agreement shall be governed by and construed under the substantive laws of the State of New York, without regard to conflicts of law rules that would cause the application of the laws of another jurisdiction.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

27.Dispute Resolution.

(a) Resolution by Executives. If any unresolved dispute as to matters arising under or relating to this Agreement or either Party's rights or obligations hereunder arises, either Party may refer such dispute to the Executive Director (if referring the dispute to PRF) or the Chief Executive Officer (if referring the dispute to Eiger), who shall meet in person or by telephone within [*] after such referral to attempt in good faith to resolve such dispute. If such matter cannot be resolved by discussion of such officers within such [*] period (as may be extended by mutual written agreement of the Parties), such dispute shall be resolved in accordance with Section 27(b). The Parties acknowledge that discussions between the Parties in an attempt to resolve any disputes are settlement discussions under applicable rules of evidence and without prejudice to either Party's legal position.

(b) Arbitration. Any dispute that is not resolved pursuant to Section 27(a), except for any dispute, claim or controversy subject to Section 27(b)(vi), shall be settled by binding arbitration administered by federal arbitration before a single arbitrator having substantial experience with commercial transactions in the pharmaceutical industry. Such arbitration shall be governed by the U.S. Federal Arbitration Act, 9 U.S.C. §§ 1-16 (the "**Federal Arbitration Act**"), to the exclusion of any inconsistent state laws and conducted in accordance with the Arbitration Rules and Procedures of the Judicial Arbitration and Mediation Service, Inc. ("**JAMS**") then in effect. The arbitration will be conducted promptly in Boston, Massachusetts, and the Parties consent to the personal jurisdiction of the Federal District Court in the District of Massachusetts for any case arising out of or otherwise related to the arbitration, its conduct or its enforcement. Each Party shall have [*] to present its case, and the Parties shall jointly request that the arbitrator render a final decision within [*] following completion of each Party's presentation or as soon thereafter as is practicable.

(i) Any award shall be promptly paid free of any tax, deduction or offset, and any costs, fees or taxes incident to enforcing the award shall, to the maximum extent permitted by law, be charged against the Party resisting enforcement. The prevailing Party in the arbitration shall be entitled to receive reimbursement of its reasonable expenses (including reasonable attorneys' fees, expert witness fees and all other expenses) incurred in connection with such arbitration. Each Party agrees (A) to abide by the award rendered in any arbitration conducted pursuant to this Section 27(b) and (B) that, subject to the Federal Arbitration Act, judgment may be entered upon the final award in the Federal District Court in the District of Massachusetts and that other courts may award full faith and credit to such judgment in order to enforce such award. The award shall include interest from the date of any damages incurred for breach of this Agreement, and from the date of the award until paid in full, at a rate fixed by the arbitrator.

(ii) Except as set forth in Section 27(b)(i), each Party shall bear its own legal fees. The arbitrators shall have the authority to grant specific performance or to allocate between the Parties the costs of arbitration (including service fees, arbitrator fees and all other fees related to the arbitration) in such equitable manner as the arbitrator may determine.

(iii) Provided a Party has made a sufficient showing under the rules and standards set forth in the U.S. Federal Rules of Civil Procedure and applicable case law, the arbitrator shall have the freedom to invoke, and the Parties agree to abide by, injunctive

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measures after either Party submits in writing for arbitration claims requiring immediate relief. Additionally, nothing in this Section 27 will preclude either Party from seeking any injunctive relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction, permanent injunction or other equitable relief, concerning a dispute either prior to, during or after any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding.

(iv) The arbitration proceeding will be confidential and the arbitrator shall issue appropriate protective orders to safeguard each Party's Confidential Information.

(v) Any duty to arbitrate under this Agreement shall remain in effect and be enforceable after expiration or termination of this Agreement for any reason.

(vi) Any dispute, controversy or claim relating to the scope, validity, enforceability, infringement, violation, ownership, license or other rights of or with respect to any patents, trademarks or other intellectual property shall be submitted to a court of competent jurisdiction.

28.Notices. All notices required or permitted to be given under this Agreement will be in writing and will be sent by an overnight courier service with package tracking capabilities and costs prepaid, by registered or certified airmail, return receipt requested and postage prepaid, to the other Party at the addresses set forth in the preamble of this Agreement and to the attention of President and Executive Director (in the case of PRF) or the President and CEO (in the case of Eiger). Such notices will be deemed to have been given when received by the addressee. Any Party may give written notice of a change of address in accordance with this Section 28, whereupon any notice or request will thereafter be given to such Party as above provided at such changed address.

29.Severability. If any provision of this Agreement is held to be illegal or unenforceable, such provision will be limited or eliminated to the minimum extent necessary so that the remainder of this Agreement will continue in full force and effect and be enforceable, and the validity, legality and enforceability of the remaining provisions will not in any way be affected or impaired thereby. The Parties agree to negotiate in good faith an enforceable substitute provision for any invalid or unenforceable provision that most nearly achieves the Parties' intent of such provision.

30.Construction; Headings. No rule of construction that disfavors the drafting party will apply to this Agreement. As used in this Agreement, "including" and words of similar import mean "including but not limited to." The use of "or" will not be deemed to be exclusive. Headings and titles used in this Agreement are for convenience of reference only and shall not be used in interpreting this Agreement.

31.Counterparts. This Agreement may be executed in counterparts (including by facsimile or electronic transmission), each of which shall be deemed to be an original copy of this Agreement and all of which taken together shall be regarded as one and the same instrument.

[*SIGNATURE PAGE FOLLOWS.*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

In Witness Whereof, the Parties have executed this Agreement in duplicate originals by their respective authorized officers as of the Effective Date.

Eiger BioPharmaceuticals, Inc.		**The Progeria Research Foundation, Inc.**	
By:	/s/ David Cory	By:	/s/ Meryl Fink
Name:	David Cory	Name:	Meryl Fink
Title:	President, CEO	Title:	Executive Director, President

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Exhibit A

[*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Exhibit 10.31

Execution Version

ASSET PURCHASE AGREEMENT

BY AND BETWEEN

ABBVIE INC.

AND

EIGER BIOPHARMACEUTICALS, INC.

NOVEMBER 20, 2020

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List of Exhibits

ASSET PURCHASE AGREEMENT

This ASSET PURCHASE AGREEMENT (this "***Agreement***") is made and entered into as of November 20, 2020 (the "***Effective Date***"), by and between **ABBVIE INC**., a corporation organized under the laws of Delaware ("***Buyer***"), and **EIGER BIOPHARMACEUTICALS, INC.**, a corporation organized under the laws of Delaware ("***Seller***"). Buyer and Seller may hereinafter be referred to individually as a "***Party***" and collectively as the "***Parties.***"

RECITALS

WHEREAS, Seller and Buyer each (a) desire that Buyer purchase from Seller, and Seller sell, transfer and assign to Buyer, the Purchased Assets (as defined below), all on the terms set forth herein (such transaction, the "***Asset Purchase***") and (b) in furtherance thereof, have adopted and approved this Agreement and, upon the terms and subject to the conditions set forth in this Agreement, have adopted and approved the Asset Purchase as contemplated by this Agreement in accordance with all applicable Legal Requirements (as defined below).

WHEREAS, Seller and Buyer desire to make certain representations, warranties, covenants and other agreements as set forth herein in connection with the Asset Purchase contemplated by this Agreement.

NOW, THEREFORE, in consideration of the foregoing and their mutual undertakings hereinafter set forth, and intending to be legally bound, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

1.1 Certain Definitions. As used in this Agreement, the following capitalized terms shall have the meanings indicated below:

(a) "***Action***" means any claim, audit, examination, action, cause of action or suit (whether in contract or tort or otherwise), litigation (whether at law or in equity, whether civil or criminal), assessment, arbitration, mediation, investigation, hearing, charge, complaint, demand, notice or proceeding.

(b) "***Adverse Claim***" means (a) a claim asserted by any Third Party that Seller does not have the right to sell and transfer the Priority Review Voucher to Buyer, (b) a Judgment of a Governmental Entity that prohibits Buyer from using the Priority Review Voucher, or (c) a Judgment involving a Third Party that would prevent Buyer from using the Priority Review Voucher.

(c) "***Affiliate***" means any Person which, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with, a Party to this Agreement, for so long as such control exists, whether such Person is or becomes an Affiliate on or after the Effective Date. A Person shall be deemed to "***control***" another Person if it: (i) owns, directly or indirectly, beneficially or legally, at least fifty percent (50%) of the outstanding capital stock, voting securities or other ownership interest (or such lesser percentage which is the

maximum allowed to be owned by such Person in a particular jurisdiction) of such other Person (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity); or (ii) has the power, whether pursuant to Contract, ownership of securities or otherwise, to direct the management and policies of such other Person.

(d) "***Alternative Transaction***" means, other than the transactions contemplated by this Agreement, any proposal or offer from any Person or group of Persons (other than Buyer or its Affiliates or their respective Representatives) for any acquisition by, or transfer, license or other grant of rights to, such Person or group of Persons of any right, title or interest in or to the Purchased Assets; provided, that "***Alternative Transaction***" shall not include any acquisition of substantially all of Seller's assets (whether through a stock purchase, merger, sale of all or substantially all assets or otherwise) so long as such acquisition provides that this Agreement continues to be binding, enforceable and in full force and effect on the same terms in effect as of the Effective Date.

(e) "***Approval Letter***" means the letter, dated November 20, 2020, from the FDA to Seller, issuing the FDA Approval and granting the Priority Review Voucher, attached hereto as Exhibit A.

(f) "***Asset Purchase***" has the meaning set forth in the Recitals.

(g) "***Business Day***" means a day (i) other than Saturday or Sunday and (ii) on which commercial banks are open for business in New York, New York, United States.

(h) "***Consent***" means any and all filings, authorizations, consents, approvals, notices, permits, orders, registrations or declarations.

(i) "***Contract***" means any written or oral legally binding contract, agreement, instrument, commitment or undertaking (including leases, licenses, mortgages, notes, guarantees, sublicenses, subcontracts and purchase orders).

(j) "***DOJ***" means the United States Department of Justice.

(k) "***Encumbrance***" means any lien, pledge, charge, mortgage, owner's mortgage, easement, encroachment, imperfection of title, title exception, title defect, right of possession, right of negotiation or refusal, leasehold interest, security interest, encumbrance, adverse claim, interference, or other restriction on transfer, ownership or use.

(l) "***FDA***" means the U.S. Food and Drug Administration.

(m) "***FDA Approval***" means commercial marketing authorization issued by FDA to the Seller relating to NDA 213969 for lonafarnib in accordance with Section 505(b)(1) of the FFDCA on November 20, 2020.

(n) "***FFDCA***" means the United States Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

(o) "***FTC***" means the United States Federal Trade Commission.

(p) "***Fundamental Representations***" means the representations and warranties contained in Section 3.1 (Organization; Standing and Power), Section 3.2 (Due Authority), Section

3.3(b)(i) (No Contravention), Section 3.5 (Title to Purchased Assets), Section 3.8 (Regulatory Compliance), Section 3.11 (Revocation; Use of Purchased Assets), Section 3.12 (Marketed Product), Section 3.13 (Brokers) and Section 3.14 (Solvency).

(q) "***Governmental Entity***" means any supranational, national, state, municipal, local or foreign government, any court, tribunal, arbitrator, administrative agency, commission or other governmental official, authority or instrumentality, in each case whether domestic or foreign, any stock exchange or similar self-regulatory organization or any quasi-governmental, private body or arbitral body exercising any executive, legislative, judicial, quasi-judicial, regulatory, taxing, importing, administrative or other governmental or quasi-governmental authority.

(r) "***HSR Act***" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended from time to time.

(s) "***Indemnified Party***" means any of the Buyer Indemnified Parties or Seller Indemnified Parties, as applicable.

(t) "***Indemnifying Party***" means any Person against whom a claim for indemnification is being asserted under any provision of Article 8.

(u) "***Judgment***" means any orders, writs, injunctions, awards, judgments, settlements, stipulations, determinations and decrees entered by or with any Governmental Entity.

(v) "***Knowledge***" means, with respect to Seller, the actual knowledge of the facts and information of any director or officer of Seller, after performing a reasonable inquiry with respect to such facts and information.

(w) "***Law***" means any federal, state, foreign, local, municipal or other law, statute, constitution, principle of common law, resolution, ordinance, code, edict, decree, rule, regulation, ruling or requirement issued, enacted, adopted, promulgated, implemented or otherwise put into effect by or under the authority of any Governmental Entity.

(x) "***Legal Requirement***" means any Law, or any Judgment, or any license, franchise, authorization of any Governmental Entity or similar right granted under any of the forgoing, or any similar provision having the force or effect of Law applicable to a Party or to any of its assets, properties or businesses. Legal Requirements shall include, with respect to Seller or its Affiliates, any requirements, conditions or obligations relating to the Priority Review Voucher set forth in the FFDCA or the Approval Letter or in any other correspondence received by Seller or its Affiliates from the FDA regarding the Priority Review Voucher.

(y) "***Lender Consent***" means that certain Consent Agreement between Seller and Oxford Finance, LLC, attached hereto as Exhibit B.

(z) "***Liabilities***" means all debts, liabilities and obligations, whether presently in existence or arising hereafter, accrued or fixed, absolute or contingent, matured or unmatured, determined or determinable, asserted or unasserted, known or unknown, including those arising under any Law, action or governmental order and those arising under any Contract.

(aa) "***Losses***" means all losses, Liabilities, damages, claims, causes of action, judgments, awards, suits, Taxes, fines, penalties, costs or expenses (including reasonable attorneys' and experts' fees and expenses).

(bb) "***Market***" or "***Marketing***" means to market a drug within the meaning of Section 529(e)(1) of the FFDCA.

(cc) "***Mutual Confidential Disclosure Agreement***" means that certain bilateral confidential disclosure agreement by and between the Parties, dated August 21, 2020.

(dd) "***Person***" means any natural person, company, corporation, limited liability company, general partnership, limited partnership, trust, proprietorship, joint venture, business organization or Governmental Entity.

(ee) "***PRF Agreement***" means that certain Collaboration and Supply Agreement, by and between Seller and The Progeria Research Foundation, Inc. dated May 15, 2018, as amended from time to time.

(ff) "***PRF Consent***" means that certain Consent Agreement between Seller and The Progeria Research Foundation, Inc., attached hereto as Exhibit C.

(gg) "***Priority Review***" means a priority review of and action upon a human drug application, which is submitted under Section 505(b)(1) or 505(b)(2) of the FFDCA or under Section 351 of the Public Health Service Act, by the FDA not later than six (6) months after the filing of such application by the FDA, as defined in the FFDCA.

(hh) "***Priority Review Voucher***" means the priority review voucher issued by the Secretary of the Department of Health and Human Services pursuant to section 529(b)(1) of the FFDCA to Seller as evidenced by the Approval Letter, and assigned tracking number PRV NDA 213969.

(ii) "***Proceeding***" means any action, arbitration, audit, hearing, investigation, litigation or suit (whether civil, criminal, administrative, judicial or investigative, whether formal or informal, whether public or private) commenced, brought, conducted or heard by or before, or otherwise involving, any Governmental Entity or arbitrator.

(jj) "***Purchased Assets***" means (i) the Priority Review Voucher and (ii) any and all rights, benefits and entitlements with respect thereto afforded to the holder of the Priority Review Voucher.

(kk) "***Rare Pediatric Disease***" means rare pediatric disease as defined in Section 529(a)(3) of the FFDCA.

(ll) "***Regulatory Change***" means any (i) changed or additional Legal Requirement, amendment, supplement or interpretation to any then-existing Legal Requirement, or (ii) additional, amended or supplemented term or condition that is not set forth in the Approval Letter imposed on the Priority Review Voucher or a party seeking to use or transfer the Priority Review Voucher, that in either case of (i) or (ii) has been enacted, adopted, approved, or imposed by a Governmental Entity with appropriate jurisdiction over the matter between the Effective Date and the Closing Date and materially adversely impacts or limits the manner in which Buyer may use, receive, hold, transfer or otherwise exploit the Priority Review Voucher.

(mm) "***Representative***" means, with respect to a particular Person, any director, officer, manager, employee, agent, consultant, advisor, accountant, financial advisor, legal counsel or other representative of that Person.

(nn) "***Tax***" or "***Taxes***" means any net income, alternative or add-on minimum tax, gross income, gross receipts, sales, use, value added tax, ad valorem, transfer, franchise, profits, license, withholding, payroll, employment, excise, severance, stamp, occupation, municipal tax, municipal surcharge premium, property, environmental or windfall profit tax, social security contribution or other tax of any kind whatsoever, together with any interest or any penalty, addition to tax or additional amount in the nature of a tax imposed by any Governmental Entity responsible for the imposition of any such tax (domestic or foreign), whether disputed or not and including (i) the tax liability of any other Person imposed pursuant to Treasury Regulations Section 1.1502-6 or any similar provision of other tax Law, and (ii) the obligation to indemnify or assume or otherwise succeed to the tax liability of any other Person, by contract or pursuant to any Law.

(oo) "***Third Party***" means any Person other than a Party and such Party's Affiliates.

(pp) Other capitalized terms defined elsewhere in this Agreement and not defined in this Section 1.1 shall have the meanings assigned to such terms in this Agreement.

ARTICLE 2
PURCHASE AND SALE; CLOSING

2.1 Purchase and Sale of Purchased Assets.

(a) Upon the terms and subject to the conditions of this Agreement, at and as of the Closing (as defined in Section 2.3), Buyer shall purchase from Seller and Seller shall sell, transfer, convey, assign and deliver to Buyer all of Seller's right, title and interest in and to the Purchased Assets free and clear of all Encumbrances. Seller shall perform all actions necessary to facilitate the transfer of the Purchased Assets to Buyer.

(b) Buyer shall not assume, nor shall it be liable for, or otherwise be obligated to pay, perform or discharge, any Liabilities of Seller or its Affiliates, including any Liabilities arising from or related to Seller's ownership prior to the Closing of any rights with respect to the Purchased Assets (such Liabilities, the "***Excluded Liabilities***"). Seller shall be solely responsible for all such Excluded Liabilities.

2.2 Purchase Price. The total consideration to be paid by Buyer for all of the Purchased Assets shall be NINETY FIVE MILLION U.S. DOLLARS (U.S. $95,000,000) (the "***Purchase Price***"). Buyer shall pay the Purchase Price to Seller on the Closing Date in United States dollars by wire transfer of immediately available funds to a bank account of Seller in accordance with the wire instructions provided by the Seller to the Buyer at least fourteen (14) Business Days prior to the Closing Date.

2.3 Closing. The closing of the transactions contemplated hereby (the "***Closing***") shall take place remotely via the exchange of documents and signatures, at 10:00 a.m. Eastern time on the third (3rd) Business Day following the date on which all of the conditions precedent set forth in Article 6 have been satisfied or waived (other than conditions to be satisfied only by the delivery of certificates or other documents at the Closing, but subject to the satisfaction or waiver of such conditions at the Closing), or at such other time and place as the Parties may mutually agree in writing. The date on which the Closing actually takes place is referred to in this Agreement as the "***Closing Date.***"

2.4 Title Passage; Delivery of Purchased Assets.

(a) *Title Passage*. Upon the Closing, all of the right, title and interest in and to the Purchased Assets shall pass to Buyer free and clear of all Encumbrances.

(b) *Method of Delivery of Assets*. On a date mutually agreed upon by the Parties, but in no event later than five (5) Business Days following the Closing Date, Seller will submit to FDA the separate notifications referred to in Section 2.5(b) and Section 2.6(c), respectively, as a submission to NDA 213969 through FDA's Electronic Submissions Gateway under the cover letter substantially in the form attached as Exhibit 2.4(b), and Buyer will submit to FDA a paper copy of such separate notifications and cover letter. Seller shall provide to Buyer confirmation from FDA of successful electronic submission and a complete copy of such submission. Notwithstanding anything to the contrary set forth herein, the Parties acknowledge and agree that Seller is not making any representation or warranty regarding, and shall not be liable to Buyer or any other Buyer Indemnified Party hereunder with respect to, the adequacy of the requirements set forth in this Section 2.4(b) to comply with Legal Requirements applicable to the transfer of the Priority Review Voucher as contemplated by this Agreement; provided, however, that the foregoing shall not limit the obligations of the Seller pursuant to Section 5.5.

(c) *Filings; Notifications*. Buyer and Seller agree to cooperate and assist each other with respect to all filings or notifications to FDA related to the transfer and assignment of the Purchased Assets.

2.5 Closing Deliveries by Seller. At the Closing, Seller shall deliver to Buyer the following:

(a) an executed Bill of Sale substantially in the form attached hereto as Exhibit 2.5(a);

(b) a copy of the notification of the purchase and sale of the Priority Review Voucher pursuant to this Agreement to be submitted to the FDA pursuant to Section 2.4(b), which

notification shall be substantially in the form of Exhibit 2.5(b) or such other form as the FDA may require as of the Closing Date;

(c) a certificate of Seller dated as of the Closing Date, in the form set forth in Exhibit 2.5(c), duly executed by Seller, certifying as to the satisfaction of the conditions set forth in Sections 6.2(a) and 6.2(b);

(d) a certificate of Seller dated as of the Closing Date, in the form set forth in Exhibit 2.5(d), duly executed by Seller, certifying as to the resolutions of the Board of Directors of Seller authorizing the execution, delivery and performance of this Agreement, the transactions contemplated hereunder and authorizing the person or persons executing this Agreement on behalf of Seller or any instrument delivered, or to be delivered, hereunder to so execute and deliver such instrument; and

(e) such other documents and instruments as may be required to be delivered by Seller by any other provision of this Agreement or as may be reasonably required to consummate the transactions contemplated by this Agreement.

2.6 Closing Deliveries by Buyer. At the Closing, Buyer shall deliver to Seller the following:

(a) payment of the Purchase Price in accordance with Section 2.2;

(b) an executed Bill of Sale substantially in the form attached hereto as Exhibit 2.5(a);

(c) a copy of the notification of the purchase and sale of the Priority Review Voucher pursuant to this Agreement to be submitted to the FDA pursuant to Section 2.4(b), which notification shall be substantially in the form of Exhibit 2.6(c) or such other form as the FDA may require as of the Closing Date;

(d) a certificate of Buyer dated as of the Closing Date, in the form set forth in Exhibit 2.6(d), duly executed by Buyer, certifying as to the satisfaction of the conditions set forth in Sections 6.1(a) and 6.1(b); and

(e) such other documents and instruments as may be required to be delivered by Buyer by any other provision of this Agreement or as may be reasonably required to consummate the transactions contemplated by this Agreement.

2.7 Withholding. Any payments by Buyer to Seller shall be made without any deduction or withholding for or on account of any Taxes, levies, duties, deductions, withholdings, assessments, fees or other charges imposed by any Governmental Entity (collectively, "***Withholding Taxes***"), other than as required for taxes imposed on Seller's net income; provided, however, that if Buyer assigns its rights under this Agreement to any Person pursuant to Section 9.5 on or prior to the Closing Date, any such payment to Seller shall be increased such that the amount received by Seller after any deduction or withholding (including such deductions and withholdings applicable to additional sums payable under this Section 2.7) is equal to the amount Seller would have received in the absence of such assignment. Where any sum due to be paid to

either Party hereunder is subject to any Withholding Taxes, the Parties shall use their commercially reasonable efforts to do all such acts and things and to sign all such documents as will enable them to take advantage of any applicable double taxation agreement or treaty. If a Governmental Entity retroactively determines that a payment made by Buyer to Seller should have been subject to Withholding Taxes (or to additional Withholding Taxes) (including any penalties, interest and additions thereto), Seller shall cooperate as reasonably requested by Buyer, at Buyer's sole cost and expense, in preparing and filing any tax returns or other filings required in respect of any Withholding Taxes. At Buyer's reasonable request, Seller shall use commercially reasonable efforts to assist Buyer in mitigating, reducing or eliminating any such Withholding Taxes, at Buyer's sole cost and expense. For clarity, nothing in this provision or elsewhere in this Agreement shall make Buyer liable for any taxes imposed on Seller's net income.

2.8 Transfer Taxes. Notwithstanding any other provision in this Agreement to the contrary, Buyer shall bear and pay any and all sales Taxes, value added Taxes, use Taxes, transfer Taxes, documentary charges, recording fees or similar Taxes, charges or fees (including any penalties, interest and additions thereto) that may become payable by either Party or its Affiliates in connection with the sale of the Purchased Assets to Buyer (collectively, "***Transfer Taxes***"). Seller shall cooperate as reasonably requested by Buyer, at Buyer's sole cost and expense, in timely paying any Transfer Taxes to the applicable Governmental Entity and preparing and timely filing any tax returns required to be filed in respect of any Transfer Taxes. At Buyer's reasonable request, Seller shall use commercially reasonable efforts to assist Buyer in mitigating, reducing or eliminating any such Transfer Taxes, at Buyer's sole cost and expense. For clarity, nothing in this provision or elsewhere in this Agreement shall make Buyer liable for any taxes imposed on Seller's net income.

2.9 Broker Fees. Notwithstanding any other provision in this Agreement to the contrary, Seller shall bear and pay any and all fees and expenses that may become payable by either Party or its Affiliates in connection with any arrangement made by Seller or its Affiliates with any broker, finder or investment banker in connection with the purchase and sale of the Purchased Assets hereunder or any of the other transactions contemplated by this Agreement.

ARTICLE 3
REPRESENTATIONS AND WARRANTIES OF SELLER

Seller hereby represents and warrants to Buyer, as of the Effective Date and the Closing Date (or in the case of representations and warranties that are made as of a specified date, as of such specified date) as follows:

3.1 Organization, Standing and Power. Seller is a corporation duly organized, validly existing and in good standing under the laws of Delaware. Seller has the requisite corporate power and authority to own, operate and lease its properties and to carry on its business as presently conducted and is duly qualified or licensed to do business and is in good standing in each jurisdiction where the character of its properties owned or leased or the nature of its activities make such qualification or licensing necessary, except where the failure to be so qualified or licensed would not, individually or in the aggregate, reasonably be expected to materially adversely affect any of the Purchased Assets, Seller's ability to consummate the transactions contemplated by this

Agreement, or Buyer's ownership and rights with respect to any of the Purchased Assets after the Closing. Seller is not in violation of its organizational documents, as amended to date.

3.2 Due Authority. Seller has all requisite corporate power and authority to execute and deliver, perform its obligations under, and consummate the transactions contemplated by, this Agreement. The execution, delivery and performance of this Agreement, and the consummation of the Asset Purchase, have been duly and validly authorized by all necessary corporate action on the part of Seller. This Agreement has been duly executed and delivered by Seller. This Agreement, upon due execution and delivery by the Parties, will constitute a valid and binding obligation of Seller enforceable against Seller in accordance with its terms, subject only to the effect, if any, of (a) applicable bankruptcy and other similar Laws affecting the rights of creditors generally and (b) rules of Law governing specific performance, injunctive relief and other equitable remedies (whether considered in an action at Law or in equity).

3.3 No Contravention. The execution and delivery by Seller of this Agreement does not, and the consummation of the transactions contemplated hereby, including the transfer of title to, ownership in, and possession of the Purchased Assets, will not, (a) result in the creation of any Encumbrance on the Purchased Assets or (b) conflict with, or result in any violation of or default under (with or without notice or lapse of time, or both), or give rise to a right of termination, revocation, suspension, cancellation or acceleration of any obligation or loss of any benefit under, or require any consent (other than the Lender Consent and the PRF Consent), approval or waiver from any Person pursuant to, (i) any provision of the organizational or governing documents of Seller, in each case as amended to date, (ii) the Priority Review Voucher, the Approval Letter or any Contract to which Seller or any Affiliate of Seller is a party or bound which involves or affects in any way any of the Purchased Assets or (iii) except as may be required to comply with the HSR Act, any Legal Requirements applicable to Seller or any Affiliate of Seller or any of the Purchased Assets, except, in the case of clause (b)(ii) with respect to the Contracts referenced therein but expressly excluding the Priority Review Voucher, or in the case of clause (b)(iii), for any such conflicts, violations or other occurrences that would not, individually or in the aggregate, reasonably be expected to (A) have a material adverse effect on the ability of Seller to consummate the sale of the Purchased Assets at Closing or (B) delay, restrict, limit, preclude or otherwise negatively impact, in a material manner, the transfer to Buyer of, or ownership or use by Buyer of, the Purchased Assets.

3.4 No Consents. Except for (a) any Antitrust Approvals (as defined in Section 5.3(b)) required by the HSR Act, (b) the Lender Consent, (c) the PRF Consent and (d) the letters referenced in Section 2.4(b), no Consent of a Governmental Entity or any other Person, is necessary or required in connection with the execution, delivery and performance by Seller of this Agreement, and the consummation by Seller or its Affiliates of the transactions contemplated hereby. Each of the Lender Consent and the PRF Consent has been duly executed and delivered by Seller to Buyer on the Effective Date and has been duly and validly approved and authorized by Seller and, to Seller's Knowledge, the other parties thereto, and necessary corporation action by Seller and, to Seller's Knowledge, the other parties thereto, and constitutes a valid and binding obligation of Seller, and to Seller's Knowledge, the other parties thereto, enforceable against Seller and, to Seller's Knowledge, the other parties thereto, in accordance with their respective terms.

3.5 Title to Purchased Assets. Seller is the sole and exclusive owner of all right, title and interest in and to the Purchased Assets (subject, prior to the Closing, to the Encumbrances in favor of PRF pursuant to the PRF Agreement and Oxford Finance, LLC pursuant to the credit documents described in the Lender Consent, which Encumbrances will be released at or prior to Closing), owns good title to the Purchased Assets and at the Closing will transfer to Buyer good and transferable title to the Purchased Assets free and clear of any Encumbrances. Seller has performed all actions necessary to perfect its ownership of, and its ability to transfer, the Purchased Assets. Seller has the full right to sell, transfer, convey, assign and deliver the Purchased Assets to Buyer at the Closing free and clear of all Encumbrances. The right, title and interest in and to the Purchased Assets that are to be sold, transferred, conveyed, assigned and delivered by Seller to Buyer at the Closing in accordance with this Agreement collectively constitutes the entire right, title and interest in and to the Purchased Assets and immediately following the Closing, Buyer shall have all right, title and interest in and to the Purchased Assets free and clear of all Encumbrances. In addition to the foregoing, there are no Adverse Claims with respect to any of the Purchased Assets.

3.6 Contracts. Except for this Agreement, the PRF Agreement, the Loan Agreement (as defined in the Lender Consent), there is no Contract to which Seller or any of its Affiliates is a party to or bound by that involves or affects (or may involve or affect) the issuance of, ownership of, transfer or licensing of, title to, or use of any of the Purchased Assets, or that otherwise assigned, transferred, licensed, conveyed or encumbered, or granted or allowed to exist any Encumbrance with respect to, any of Seller's right, title or interest in, to or under the Purchased Assets.

3.7 Compliance with Legal Requirements. Seller and its Affiliates are, and at all times have been, in compliance with all Legal Requirements that are or were applicable to the Purchased Assets. None of Seller or any of its Affiliates has received any written notice or other written communication from any Person regarding any actual or alleged violation of, or failure to comply with, any such Legal Requirement.

3.8 Regulatory Compliance. Since the three (3) year period prior to the Effective Date and as it relates to the FDA Approval, the Approval Letter, the Priority Review Voucher or the activities giving rise to such FDA Approval, the Approval Letter or the Priority Review Voucher, neither Seller, any Affiliate of Seller, nor to the Knowledge of Seller, any Representative of Seller or any Affiliate of Seller, has made an untrue statement of material fact or a fraudulent statement to the FDA or any other Governmental Entity, failed to disclose a material fact or a fraudulent statement to the FDA or any other Governmental Entity or committed an act, made a statement or failed to make a statement that, at the time such disclosure was made, would reasonably be expected to provide a basis for the FDA to invoke its policy respecting "***Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities,***" set forth in 56 Fed. Reg. 46191 (September 10, 1991) or for any other Governmental Entity to invoke any similar policy, or for the FDA to withdraw, suspend or revoke the FDA Approval or Priority Review Voucher.

3.9 Legal Proceedings. There is no pending, or to Seller's Knowledge, threatened, Action involving Seller or any of its Affiliates, nor has there been an Action involving Seller or any of its Affiliates, and neither Seller nor any of its Affiliates are a party or subject to the provisions of any Judgment, (a) that involves or affects the issuance of, continued validity of,

ownership of, transfer or license of, title to, or use of any of the Purchased Assets, including, but not limited to, any such Action or Judgment that seeks to prohibit or limit in any respect, or place any conditions on, the ownership or use by Buyer or its Affiliates of any of the Purchased Assets, in each case as a result of the transactions contemplated by this Agreement (b) that otherwise challenges or seeks to restrain, prohibit, prevent, enjoin, alter or delay the consummation the transactions contemplated by this Agreement, or (c) that seeks to obtain from Buyer or any of its Affiliates in connection with the transactions contemplated by this Agreement any damages or which would result in the transactions contemplated hereby being rescinded following consummation. To the Knowledge of Seller, there is no fact or circumstance that would reasonably be expected to serve as a basis for any of the foregoing Actions.

3.10 Governmental Authorizations. Neither Seller nor any of its Affiliates is required to hold any license, registration, or permit issued by any Governmental Entity to own, use or transfer the Purchased Assets, other than such licenses, registrations or permits that have already been obtained.

3.11 Revocation; Use of Purchased Assets. The Priority Review Voucher was awarded to Seller by the FDA in respect of Seller's sponsorship of a Rare Pediatric Disease product application pursuant to Section 529(b)(1) of the FFDCA. The Priority Review Voucher has been duly granted and issued and has not been terminated, redeemed, transferred, suspended, cancelled or revoked and to Seller's Knowledge there are no facts or circumstances that could reasonably be expected to (with or without notice or lapse of time, or both) result in the termination, suspension, cancellation or revocation of the Priority Review Voucher by a Governmental Entity, give rise to a right of FDA to revoke the Priority Review Voucher, result in the redemption or transfer of the Priority Review Voucher (other than pursuant to the transactions contemplated by this Agreement), or that could reasonably be expected to preclude or interfere with the sale and transfer of the Purchased Assets to Buyer or Buyer's use of the Purchased Assets following the Closing to obtain Priority Review or any other benefits associated with the Purchased Assets. There is no term or condition imposed by the FDA on the Priority Review Voucher as of the date hereof that is not set forth in the Approval Letter. Seller has provided to Buyer true and complete copies of the Approval Letter and all other correspondence submitted or received by Seller or any of its respective Affiliates regarding the Priority Review Voucher. Neither Seller nor any of its Affiliates has notified FDA of intent to use the Priority Review Voucher.

3.12 Marketed Product. Seller has initiated or will initiate, and subsequently continue, Marketing in the United States of the Rare Pediatric Disease product for which the Priority Review Voucher was awarded within the three hundred and sixty five (365) day period beginning on the date of the FDA approval of such Rare Pediatric Disease product.

3.13 Brokers. No broker, finder or investment banker is entitled to any brokerage or finder's fee in connection with the purchase and sale of the Purchased Assets hereunder or any of the other transactions contemplated by this Agreement based upon arrangements made by or on behalf of Seller or its Affiliates.

3.14 Solvency. Seller is not entering into this Agreement with the actual intent to hinder, delay, or defraud any creditor of Seller or any Affiliate of Seller. The remaining assets of Seller after the Closing will not be unreasonably small in relation to the business in which Seller will

engage after the Closing. After the Closing, Seller will not be insolvent and will have the ability to pay its debts as they become due.

3.15 No Other Representations. Neither Seller nor any of its Affiliates or their respective Representatives is making any representation or warranty of any kind or nature whatsoever, oral or written, express or implied, except as otherwise expressly set forth in this ARTICLE 3.

ARTICLE 4
REPRESENTATIONS AND WARRANTIES OF BUYER

Buyer hereby represents and warrants to Seller as of the Effective Date and as of the Closing Date as follows:

4.1 Organization, Standing and Power. Buyer is a company duly organized, validly existing and in good standing under the laws of Delaware.

4.2 Authority. Buyer has all requisite corporate power and authority to execute and deliver, perform its obligations under, and consummate the transactions contemplated by, this Agreement. The execution, delivery and performance of, and the consummation of the transactions contemplated by, this Agreement have been duly and validly approved and authorized by all necessary corporation action. This Agreement has been duly executed and delivered by Buyer.

This Agreement, upon due execution and delivery by the Parties, will constitute a valid and binding obligation of Buyer, enforceable against Buyer in accordance with its terms, subject only to the effect, if any, of (a) applicable bankruptcy and other similar Laws affecting the rights of creditors generally and (b) rules of Law governing specific performance, injunctive relief and other equitable remedies (whether considered in an action at Law or in equity).

4.3 No Contravention. The execution and delivery by Buyer of this Agreement does not, and the consummation of the transactions contemplated hereby will not, conflict with, or result in any violation of or default under (with or without notice or lapse of time, or both), or give rise to a right of termination, cancellation or acceleration of any obligation or loss of any benefit under, or require any consent, approval or waiver from any Person pursuant to, (a) any provision of the organizational or governing documents of Buyer, in each case as amended to date, (b) any Contract to which Buyer or any Affiliate of Buyer is a party or bound by or by which it or its assets or properties are bound or under which Buyer or any Affiliate of Buyer has material rights or benefits, or (c) except as may be required to comply with the HSR Act, any Legal Requirements applicable to Buyer.

4.4 No Consents. Except for (a) any Antitrust Approvals (as defined in Section 5.3(b)) required by the HSR Act and (b) the letters referenced in Section 2.5(b), no Consent of any Governmental Entity or any other Person is necessary or required in connection with the execution, delivery and performance by Buyer of this Agreement or the consummation by Buyer of the transactions contemplated hereby.

4.5 Brokers. No broker, finder or investment banker is entitled to any brokerage or finder’s fee in connection with the purchase and sale of the Purchased Assets hereunder or any of

the other transactions contemplated by this Agreement based upon arrangements made by or on behalf of Buyer or its Affiliates.

4.6 Non-Reliance. Except for the representations and warranties expressly set forth in ARTICLE 3 or in any other certificate or document delivered by or on behalf of the Seller or any of its Affiliates pursuant to this Agreement, neither Seller nor any of its Affiliates or their respective Representatives makes, or has made any representation or warranty, oral or written, express or implied, relating to Seller, the Purchased Assets or otherwise in connection with the Asset Purchase, and Seller and its Affiliates and their respective Representatives expressly disclaim any liability with respect thereto. Except for the representations and warranties expressly set forth in ARTICLE 3 or in any other certificate or document delivered by or on behalf of the Seller or any of its Affiliates pursuant to this Agreement, Buyer has not relied, and is not relying, on any representation or warranty of the Seller or any of its Affiliates relating to Seller, the Purchased Assets or otherwise in connection with the Asset Purchase.

ARTICLE 5
COVENANTS

5.1 Efforts. During the period from the Effective Date and continuing until the earlier of the termination of this Agreement or the Closing Date (the "***Pre-Closing Period***"), except as otherwise expressly contemplated by this Agreement or with such other Party's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed, each Party shall not, and shall cause its Affiliates not to, knowingly take or permit any action that, or omit to take any action the absence of which, could reasonably be expected to prevent the satisfaction of the conditions set forth in Article 6.

5.2 No Solicitation.

(a) During the Pre-Closing Period, Seller shall not, nor shall it authorize, instruct or permit any of its Affiliates or its or their Representatives to (i) solicit, initiate, facilitate or encourage any inquiries, proposals or offers with respect to, or the submission of, any Alternative Transaction by any Person (other than Buyer or its Affiliates or their respective Representatives) or any inquiry, proposal or offer that is reasonably likely to lead to an Alternative Transaction, (ii) engage, continue or participate in any discussions or negotiations regarding, or take any other action intended or reasonably expected to facilitate the making of any inquiry, proposal or offer to Seller that constitutes, or may reasonably be expected to lead to, any Alternative Transaction by any Person (other than Buyer or its Affiliates or their respective Representatives) other than to state that they are not permitted to have discussions, (iii) accept any inquiry, proposal or offer from any Person (other than Buyer) in respect of an Alternative Transaction, or (iv) resolve to propose or agree to do any of the foregoing.

(b) Upon execution of this Agreement, Seller and its Affiliates shall immediately cease and cause to be terminated any existing discussions with any Person (other than Buyer) that are in respect of an Alternative Transaction.

(c) Without limiting Section 5.2(a), it is understood that any violation of the restrictions set forth in Section 5.2(a) by any Person covered by Section 5.2(a), whether or not

such Person is purporting to act on behalf of Seller, shall be deemed to be a breach of Section 5.2(a) by Seller.

5.3 Antitrust Notification.

(a) Unless this Agreement shall have been validly terminated in accordance with Section 7.1, Buyer and Seller shall, within fifteen (15) Business Days after the Effective Date. file with the FTC and the DOJ the premerger notification and report form required as a result of the contemplated purchase and sale of the Purchased Assets and the other transactions contemplated hereby, and shall include any supplemental information requested in connection therewith, pursuant to the HSR Act. Any such filing, notification and report form and supplemental information shall be in substantial compliance with the requirements of the HSR Act. The Parties shall work together and shall furnish to one another such necessary information and reasonable assistance as the other may request in connection with its preparation of any filing or submission which is necessary under the HSR Act. The Parties shall (i) cooperate with one another and promptly inform the other Party of any communications with, and any inquiries or requests for additional information from, the FTC, the DOJ or any other applicable Governmental Entity, (ii) comply promptly with any such reasonable inquiry or request, (iii) not participate, or permit its Affiliates to participate, in any substantive meeting or discussion with any Governmental Entity in respect of any filings, investigation or inquiry concerning this Agreement unless it consults with the other Party in advance and, to the extent permitted by such Governmental Entity, gives the other Party the opportunity to attend and participate thereat, and (iv) with the exception of business documents deemed highly confidential by the possessing Party (including documents submitted as attachments to the Party's notification and report form under the HSR Act), furnish the other Party or the other Party's outside counsel with copies of all correspondence, filings, and communications (and memoranda setting forth the substance thereof) between a Party or its Affiliates, on the one hand, and any Governmental Entity, on the other hand, with respect to the transactions contemplated hereunder or any investigation with respect to the transactions contemplated hereunder. Buyer shall pay all filing fees for the filing under the HSR Act.

(b) From and after the date on which the filings are made pursuant to Section 5.3(a), Buyer and Seller shall use reasonable best efforts to obtain any clearance required under the HSR Act (the "***Antitrust Approval***"), including replying at the earliest practicable date to any requests for information received from the FTC or DOJ pursuant to the HSR Act and requesting early expiration or termination of the applicable waiting periods under the HSR Act as soon as possible. Notwithstanding the foregoing, in connection with and as a result of any Antitrust Approval granted during the Pre-Closing Period, nothing in this Agreement shall require, or be construed to require, Buyer or any of its respective Affiliates to offer or agree to (i)(A) sell, hold, separate, divest, license, discontinue, or limit any assets, businesses, equity, holdings, intellectual property, or other interests or (B) any conditions relating to, or changes or restrictions in, the operation or use of any such assets, businesses, equity holdings, intellectual property or interests (including but not limited to any requirements to enter into new contracts or modify or terminate existing contracts), including with respect to the Purchased Assets and use of the Priority Review Voucher to obtain Priority Review of a product candidate of Buyer or its Affiliates or any other benefit associated with the Purchased Assets or (ii) any modification or waiver of the terms and conditions of this Agreement (any item set forth in clauses (i) or (ii), a "***Burdensome Condition***").

5.4 Expenses. Whether or not the purchase and sale of the Purchased Assets and the other transactions contemplated by this Agreement are consummated, and except as otherwise set forth in this Agreement, each of the Parties shall bear its own fees and expenses incurred or owed in connection with the purchase and sale of the Purchased Assets, this Agreement and the transactions contemplated hereby.

5.5 Further Assurances. During the Pre-Closing Period, and from and after the Closing, the Parties shall cooperate reasonably with each other in connection with any steps required to be taken as part of their respective obligations under this Agreement, including without limitation any notifications or filings required to be made to the FDA in connection with the transfer of the Purchased Assets, and shall, at no expense to the other Party, (a) furnish upon request to each other such further information, (b) execute and deliver to each other such other documents, and (c) do such other acts and things, all as the other Party may reasonably request for the purpose of carrying out the intent of this Agreement and the transactions contemplated by this Agreement, including the use of the Purchased Assets to obtain Priority Review. The Parties agree that the user fees to be paid in connection with the use of the Priority Review Voucher by Buyer or any transferee of the Priority Review Voucher, and all other user fees under the FFDCA applicable to the human drug application for which the Priority Review Voucher is redeemed, shall be borne exclusively by the Buyer or any transferee of the Priority Review Voucher. In any such event, Seller shall have no liability or obligation for any such fees.

5.6 Public Announcements. Forthwith upon execution of this Agreement, Seller will issue the public announcement set forth in Exhibit 5.6. Except as may be required by applicable Law or as may be required to comply with the requirements of any applicable stock exchange or any Governmental Entity, including the U.S. Securities and Exchange Commission, neither Party shall (i) other than the public announcement contemplated by the first sentence of this Section 5.6, disclose the existence or terms of this Agreement (other than disclosures to Representatives on a need-to-know basis and who are bound by confidentiality terms substantially no less stringent than the terms of the Mutual Confidential Disclosure Agreement) or (ii) issue any press release, publication, or other public announcement relating to this Agreement, the performance of this Agreement, or that otherwise identifies the other Party as a party to this Agreement. To the extent practicable, the disclosing Party shall give at least three (3) Business Days' advance notice of any legally required disclosure to the non-disclosing Party, and the non-disclosing Party may provide any comments on the proposed legally required disclosure during the foregoing time period; provided, that such disclosing Party shall be under no obligation to accept any such comments provided by the non-disclosing Party.

5.7 Use of Name. Except as expressly provided herein, neither Party shall mention or otherwise use the name, logo, or trademark of the other Party or any of its Affiliates (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material, or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Section 5.7 shall not prohibit either Party from making any disclosure identifying the other Party that, in the opinion of the disclosing Party's counsel, is required by applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed; *provided*, that such disclosing Party shall submit the proposed disclosure identifying the other Party in writing to the other Party as far in advance as reasonably

practicable (and in no event less than two (2) Business Days prior to the anticipated date of disclosure) so as to provide a reasonable opportunity to comment thereon.

5.8 Compliance with Legal Requirements. Seller shall, and shall cause its Affiliates and each of their respective successors in interest and assigns to the Rare Pediatric Disease product for which the Priority Review Voucher was awarded, to materially comply with all Legal Requirements applicable to such Persons (as the sponsor of such Rare Pediatric Disease product and, through the Closing, as the owner of the Priority Review Voucher), in any case relating to the Priority Review Voucher, including, but not limited to, any Legal Requirements applicable to such Persons that would impact the validity, maintenance, use or transfer of the Priority Review Voucher. Seller shall promptly forward to Buyer any written communications or notices it or its Affiliates receive from any Governmental Entity to the extent relating to or otherwise materially impacting the Priority Review Voucher; provided that Seller may redact any portion of such written communications or other notices that is not relevant to the Priority Review Voucher. Without limiting the generality of the foregoing, to the extent required, now or in the future, under applicable Legal Requirements or otherwise by the FDA for the use or transfer of the Priority Review Voucher, or to avoid revocation of the Priority Review Voucher, Seller shall, and shall cause its Affiliates and each of their respective successors in interest and assigns to the Rare Pediatric Disease product for which the Priority Review Voucher was awarded, to submit a post-approval production report to the FDA not later than five (5) years after the approval of such Rare Pediatric Disease product in accordance with section 529(e)(2) of the FFDCA.

5.9 Marketing. Seller shall, and shall cause its Affiliates and each of their respective successors in interest and assigns (if any) to, within the 365-day period beginning on the date of FDA approval of the Rare Pediatric Disease product for which the Priority Review Voucher was awarded, Market in the United States such Rare Pediatric Disease product to the extent and in a manner required under applicable Legal Requirements or otherwise by FDA to preclude FDA from exercising its authority to revoke the Priority Review Voucher pursuant to Section 529(e)(1) of the FFDCA.

5.10 Other Covenants. During the Pre-Closing Period, (i) Seller shall, and shall cause each of its Affiliates to, provide Buyer with prompt written notice of the occurrence of any Regulatory Change and maintain the Priority Review Voucher in full force and effect, (ii) Seller shall not, and shall cause each of its Affiliates not to, (A) enter into any Contract with respect to the Purchased Assets or (B) take or permit, or omit to take any action that would reasonably be expected to (x) prevent the satisfaction of the conditions set forth in Article 6 or (y) adversely affect any of the Purchased Assets, Seller's or any of its Affiliates' ability to consummate the transactions contemplated by this Agreement or Buyer's ownership and rights with respect to any of the Purchased Assets after the Closing and (iii) Seller shall, and shall cause each of its Affiliates to, provide Buyer with prompt written notice of the occurrence or non-occurrence of any event the occurrence or non-occurrence of which has caused or would reasonably be expected to cause any condition to the obligations of Seller to effect the Closing or the failure of Seller to comply with or satisfy in any material respect any covenant to be complied with or satisfied by Seller following the Closing pursuant to this Agreement; provided the failure by Seller to give notice of any such occurrence as required pursuant to this Section 5.10 with respect to a breach of or inaccuracy in a representation or warranty contained herein shall not, in and of itself, render such breach or inaccuracy to become a failure to comply with a covenant. Such notices provided pursuant to this

Section 5.10 shall not be deemed to amend, modify or supplement any representation or warranty provided by Seller in this Agreement or any certificate or document delivered hereunder and shall not operate as a waiver or otherwise affect or impair any of Buyer's rights under this Agreement (including with respect to Article 7 and Article 8).

ARTICLE 6
CONDITIONS PRECEDENT TO CLOSING

6.1 Conditions Precedent to Seller's Obligation. The obligation of Seller to consummate the transactions contemplated by this Agreement is subject to the satisfaction or waiver on or prior to the Closing Date of the following conditions:

(a) Representations and Warranties of Buyer. Each of the representations and warranties of Buyer made in Article 4 shall be true and correct (without giving effect to any limitation or qualification as to "***materiality***" (including the word "***material***") or "***material adverse effect***" set forth therein) in all material respects as of the Effective Date and as of the Closing Date (or in the case of representations and warranties that are made as of a specified date, such representations and warranties shall be true and correct as of such specified date).

(b) Compliance with Agreements and Covenants. Buyer and its Affiliates shall have performed in all material respects all obligations and agreements and complied in all material respects with all covenants and conditions required by this Agreement to be performed or complied with by Buyer or any such Affiliate on or before the Closing Date.

(c) Antitrust. Any waiting period (or extension thereof) applicable to the transactions contemplated by this Agreement under the HSR Act shall have been terminated or shall have expired, in each case, without the imposition of a Burdensome Condition.

(d) No Injunction or Legal Restraint. No Governmental Entity shall have enacted, issued, promulgated, enforced or entered any Law nor shall any temporary restraining order, preliminary or permanent injunction or other order or decree have been issued or be pending by any court of competent jurisdiction that is in effect and which has the effect of, or that if in effect would have the effect of, making the transactions contemplated by this Agreement illegal or otherwise preventing, prohibiting or restraining the consummation of the transactions contemplated by this Agreement.

(e) Closing Deliveries. Buyer shall have made the deliveries contemplated under Section 2.6.

6.2 Conditions Precedent to Buyer's Obligation. The obligation of Buyer to consummate the transactions contemplated by this Agreement is subject to the satisfaction or waiver on or prior to the Closing Date of the following conditions:

(a) Representations and Warranties of Seller. Each of the representations and warranties of Seller made in Article 3, other than the Fundamental Representations, shall be true and correct (without giving effect to any limitation or qualification as to "***materiality***" (including the word "***material***") or "***material adverse effect***" set forth therein) in all material respects as of the Effective Date and as of the Closing Date (or in the case of representations and warranties that are made as of a specified date, such representations and warranties shall be true and correct as of such specified date); *provided*, that any such failure of such representations and warranties to be true and correct shall be disregarded if it would not, individually or in the aggregate, reasonably be expected to delay, restrict, limit, preclude or otherwise negatively impact in a material manner the transfer to Buyer of, or ownership or use by Buyer of, the Purchased Assets. The Fundamental Representations shall be true and correct in all respects as of the Effective Date and as of the Closing Date (or in the case of representations and warranties that

are made as of a specified date, such representations and warranties shall be true and correct as of such specified date).

(b) Compliance with Agreements and Covenants. Seller and its Affiliates shall have performed in all material respects all obligations and agreements and complied in all material respects with all covenants and conditions required by this Agreement to be performed or complied with by Seller or any such Affiliate on or before the Closing Date.

(c) Antitrust. Any waiting period (or extension thereof) applicable to the transactions contemplated by this Agreement under the HSR Act shall have been terminated or shall have expired, in each case, without the imposition of a Burdensome Condition.

(d) No Injunction or Legal Restraint. No Governmental Entity shall have enacted, issued, promulgated, enforced or entered any Law nor shall any temporary restraining order, preliminary or permanent injunction or other order or decree have been issued or be pending by any court of competent jurisdiction that is in effect and which has the effect of, or that if in effect would have the effect of, making the transactions contemplated by this Agreement illegal or otherwise preventing, prohibiting or restraining the consummation of the transactions contemplated by this Agreement.

(e) Consents. Each of the Lender Consent and the PRF Consent has been executed and has not been terminated or rescinded at or before the Closing and otherwise remains in effect on and after the Closing.

(f) Closing Deliveries. Seller shall have made the deliveries contemplated under Section 2.5.

(g) No Regulatory Change. There shall not have occurred and remain in effect any Regulatory Change.

ARTICLE 7
TERMINATION

7.1 Termination. This Agreement may be terminated, and the transactions contemplated hereby may be abandoned, at any time prior to Closing:

(a) by mutual written consent of Buyer and Seller;

(b) by Buyer or Seller, if the Closing has not occurred by 11:59 p.m. Eastern time on the date that is ninety (90) days following the Effective Date (the "***Outside Date***"); provided, that neither Party may terminate this Agreement pursuant to this clause (b) if such Party is in breach of this Agreement;

(c) by Buyer or Seller, if (i) any Law having the effect referred to in Section 6.2(d) or Section 6.1(d), as applicable, has been enacted, issued, promulgated, enforced or entered, or (ii) any order, injunction or decree having the effect referred to in Section 6.2(d) or Section 6.1(d), as applicable, is in effect and has become final and non-appealable;

(d) by Buyer, if Buyer is not in material breach of its obligations under this Agreement and there has been a violation or breach by Seller of any of its representations, warranties, covenants or other agreements contained in this Agreement, which has prevented or would prevent the satisfaction of any condition to the obligations of Buyer at the Closing set forth in Section 6.2, and (i) such violation or breach has not been waived by Buyer, (ii) Buyer has provided written notice to Seller of such violation or breach setting forth the allegations of violation or breach in reasonable detail, and (iii) such violation or breach cannot be or has not been cured by Seller within twenty (20) Business Days after receiving written notice thereof from Buyer (provided that in no event shall such twenty (20) Business Day extend beyond the Outside Date); or

(e) by Seller, if Seller is not in material breach of its obligations under this Agreement and there has been a violation or breach by Buyer of any of its representations, warranties, covenants or other agreements contained in this Agreement, which has prevented or would prevent the satisfaction of any condition to the obligations of Seller at the Closing set forth in Section 6.1 and (i) such violation or breach has not been waived by Seller, (ii) Seller has provided written notice to Buyer of such violation or breach setting forth the allegations of violation or breach in reasonable detail, and (iii) such violation or breach cannot be or has not been cured by Buyer within twenty (20) Business Days after receiving written notice thereof from Seller (provided that in no event shall such twenty (20) Business Day extend beyond the Outside Date).

7.2 Effect of Termination. If this Agreement is terminated and the transactions contemplated hereby are abandoned as described in this Article 7, this Agreement shall become void and of no further force or effect and there shall be no liability on the part of Buyer or Seller, except for Losses resulting from any willful and intentional breach prior to termination of this Agreement by Buyer or Seller, as applicable, except that (i) the provisions of this Section 7.2, Sections 5.4, 5.6, 5.7, and Article 1 and Article 9 shall survive the termination of this Agreement and shall remain in full force and effect and (ii) the Mutual Confidential Disclosure Agreement shall survive termination in accordance with its terms.

ARTICLE 8
INDEMNIFICATION

8.1 Indemnification.

(a) Indemnification by Seller. From and after the Closing, Seller shall indemnify, defend and hold Buyer and its Affiliates and its and their respective directors, officers, employees, shareholders, partners, members, agents, Representatives, successors and assigns (each, a "***Buyer Indemnified Party***") harmless for, from and against any and all Losses, whether or not arising from, relating to or otherwise in connection with a claim of a Third Party (each, a "***Third Party Claim***"), which any Buyer Indemnified Party may suffer, incur, sustain or become subject to, to the extent arising from, relating to or otherwise in connection with (i) any breach of

or inaccuracy in any representations and warranties of Seller made under this Agreement or any certificate or document delivered hereunder; (ii) any breach of or failure to perform any covenants or obligations of Seller made under this Agreement or any certificate or document delivered hereunder; and (iii) all Excluded Liabilities.

(b) Indemnification by Buyer. From and after the Closing, Buyer shall indemnify, defend and hold harmless Seller and its Affiliates, and its and their respective directors, officers, employees, agents, Representatives, successors and assigns (each, a "***Seller Indemnified Party***") from and against any and all Losses, whether or not arising from, relating to or otherwise in connection with a Third Party Claim, which any Seller Indemnified Party may suffer, incur, sustain or become subject to, to the extent arising from, relating to or otherwise in connection with (i) any breach of or inaccuracy in any representations and warranties of Buyer made under this Agreement or any certificate or document delivered hereunder; and (ii) any breach of or failure to perform any covenants or obligations of Buyer made under this Agreement or any certificate or document delivered hereunder.

8.2 Notice of Loss; Third Party Claims.

(a) (a) A claim for indemnification for any matter not involving a Third Party Claim may be asserted by written notice to the Party from whom indemnification is sought. Such notice shall be made, or caused to be made, promptly by the Indemnified Party and shall include the facts constituting the basis for such claim for indemnification, the Sections of this Agreement upon which such claim for indemnification is then based and an estimate, if possible, of the amount of Losses suffered or reasonably expected to be suffered by the Indemnified Party; *provided*, that the failure to give such notification or any deficiency in such notification will not relieve such Indemnifying Party from any obligation under this Article 8, except (i) to the extent such failure to give such notification or any deficiency in such notification actually and materially prejudices such Indemnifying Party or (ii) as provided in Section 8.3.

(b) In the event of any instituted or asserted Third Party Claim against an Indemnified Party, the Indemnified Party shall promptly cause written notice of the assertion of any Third Party Claim of which it has knowledge which is covered by the provisions of Section 8.1(a) or Section 8.1(b), as applicable, to be forwarded to the Indemnifying Party. The failure to give such notification or any deficiency in such notification will not relieve such Indemnifying Party from any obligation under this Article 8, except (i) to the extent such failure to give such notification or any deficiency in such notification actually and materially prejudices such Indemnifying Party or (ii) as provided in Section 8.3. The Indemnifying Party shall have the right, at its sole option and expense, to be represented by counsel reasonably acceptable to the Indemnified Party and to defend against, negotiate, settle or otherwise deal with any Third Party Claim which relates to any Losses indemnified by it hereunder, subject to the provisions below; *provided*, *however*, that the Indemnifying Party may not assume control of defense to a Third Party Claim (i) unless it provides written notice within twenty (20) Business Days after the Indemnified Party has given notice of the Third Party Claim to the Indemnifying Party that the Indemnifying Party elects to assume the defense and that the Indemnifying Party will be liable to indemnify the Indemnified Party with respect to all Losses relating to such Third Party Claim, (ii) in which equitable relief other than monetary damages is sought, (iii) if such Third Party Claim is brought by a Governmental Entity or is otherwise related to or arises in connection with any FDA, tax or

criminal or regulatory enforcement matter, (iv) if the Indemnified Party has been advised in writing by outside counsel that a legal conflict exists between the Indemnified Party and the Indemnifying Party in connection with conducting the defense of the Third Party Claim, or (v) the Indemnifying Party fails to diligently and in good faith conduct the defense of the Third Party Claim.

(c) If the Indemnifying Party elects to defend against, negotiate, settle or otherwise deal with any Third Party Claim which relates to any Losses indemnified by it hereunder, it shall within thirty (30) days (or sooner, if the nature of the Third Party Claim so requires) notify the Indemnified Party of its intent to do so. If the Indemnifying Party elects not to defend against, negotiate, settle or otherwise deal with any Third Party Claim which relates to any Losses indemnified against hereunder, or is not permitted to assume the defense of a Third Party Claim pursuant to the proviso to the third sentence of Section 8.2(b), the Indemnified Party may defend against, negotiate, settle or otherwise deal with such Third Party Claim, subject to the provisions below. If the Indemnifying Party shall assume the defense of any Third Party Claim pursuant to the terms of this Agreement, the Indemnified Party may participate, at its own expense, in the defense of such Third Party Claim. The Parties agree to reasonably cooperate with each other in connection with the defense, negotiation or settlement of any such Third Party Claim. Notwithstanding anything in this Section 8.2 to the contrary, the Indemnifying Party shall not, without the prior written consent of the Indemnified Party, settle or compromise any Third Party Claim or permit a default or consent to entry of any judgment unless (1) the claimant provides to the Indemnified Party a full and unqualified release of the Indemnified Parties and their respective Affiliates and Representatives from all liability in respect of such Third Party Claim, (2) such settlement does not involve any injunctive relief binding upon the Indemnified Party or any of its Affiliates or Representatives, (3) such settlement does not create an Encumbrance upon any of the assets of any Indemnified Party or impose any restriction or condition that would apply to or materially affect any Indemnified Party or the conduct of any Indemnified Party's business, and (4) such settlement does not involve any admission of liability or wrongdoing by any Indemnified Party or any of its Affiliates or Representatives.

(d) In the event that the Indemnified Party conducts the defense of the Third Party Claim pursuant to this Section 8.2, the Indemnifying Party will (i) advance the Indemnified Party promptly and periodically for the reasonable costs of defending against the Third Party Claim (including reasonable attorneys' and experts' fees and expenses) and (ii) remain responsible for any and all other Losses that the Indemnified Party may incur or suffer resulting from, arising out of, relating to, in the nature of or caused by the Third Party Claim to the fullest extent provided in this Article 8.

8.3 Survival. The representations and warranties of Seller and Buyer under this Agreement, and liability for the breach thereof, shall survive the Closing Date and shall remain in full force and effect for a period of eighteen (18) months following the Closing Date; provided, however, that all covenants, and the Fundamental Representations shall survive the Closing Date and shall remain in full force and effect for a period of six (6) years following the Closing Date. No claim for breach of any representation, warranty, covenant or agreement may be brought after expiration of the survival periods set forth in this Section 8.3. Notwithstanding the foregoing, if written notice of a claim has been given in the manner required by Section 8.2 prior to the expiration of the applicable survival period by the Party seeking indemnification for such claim,

then the relevant covenants, representations and warranties of the other Party shall survive as to such claim until such claim has been finally resolved pursuant to this Article 8.

8.4 Additional Indemnification Matters. The right of indemnification provided under this Article 8 shall not be affected by any knowledge acquired (or capable of being acquired) at any time, whether before or after the Effective Date, with respect to the accuracy or inaccuracy of, or compliance or noncompliance with, any representation, warranty, covenant or agreement contained herein. If, following the Closing, the Priority Review Voucher is terminated, revoked or cancelled by FDA as a result of the failure by Seller and its Affiliates to comply with the requirements set forth in Section 5.9, Seller shall indemnify Buyer for Losses in an amount equal to the Purchase Price paid by Buyer. Amounts paid pursuant to this Section 8.4 shall be deemed indemnifiable Losses for purposes of Section 8.6.

8.5 Adjustments. Any amount paid under this Article 8 shall be treated as an adjustment to the Purchase Price for all Tax purposes unless otherwise required by applicable Law.

8.6 Limits on Indemnification. Notwithstanding anything to the contrary contained in this Agreement, the maximum aggregate amount of indemnifiable Losses that may be recovered from (a) Seller by Buyer Indemnified Parties pursuant to Section 8.1(a) shall equal the Purchase Price and (b) Buyer by Seller Indemnified Parties pursuant to Section 8.1(b) shall equal the Purchase Price. Notwithstanding anything to the contrary set forth herein, except to the extent actually awarded against an Indemnified Party pursuant to a Judgment with respect to (i) a Third Party Claim, or (ii) a claim for fraud, no Party hereto shall have any liability under any provision of this Agreement (including this Article VIII) for any punitive, incidental, special or indirect damages or damages for or otherwise based on business interruption, diminution of value, loss of future revenue, profits or income, or loss of business reputation or opportunity relating to the breach or alleged breach of this Agreement.

8.7 Exclusivity. From and after the Closing, this ARTICLE 8 will provide the exclusive remedy against either Party for any breach of any representation, warranty, covenant or other claim arising out of or relating to this Agreement and/or the transactions contemplated hereby, except nothing in this Agreement will prevent or otherwise limit either Party from seeking or obtaining injunctive or other equitable relief for any breach of any covenant or agreement set forth herein or making any claim in the event of fraud. The Parties hereto agree that the provisions in this Agreement relating to indemnification, and the limits imposed on Buyer's remedies with respect to this Agreement and the transactions contemplated hereby, were specifically bargained for between sophisticated parties and were specifically taken into account in the determination of the amounts to be paid to Seller hereunder.

ARTICLE 9
GENERAL PROVISIONS

9.1 Notice Requirements. Any notice, request, demand, waiver, consent, approval, or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if (a) delivered by hand, or (b) sent by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in this Section 9.1 or to such other

address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 9.1. Such notice shall be deemed to have been given as of the date delivered by hand or on the second Business Day (at the place of delivery) after deposit with an internationally recognized overnight delivery service. Any notice delivered by facsimile shall be confirmed by a hard copy delivered as soon as practicable thereafter.

If to Buyer, to:

AbbVie Inc.
1 North Waukegan Road North
Chicago, IL 60064
Attention: Vice Chairman, External Affairs, Chief Legal Officer and Corporate Secretary
Facsimile: 1-847- 935-3294

with a copy (which shall not constitute notice) to:

Ropes & Gray LLP
Prudential Tower
800 Boylston Street
Boston, MA 02199
Attention: Patrick O'Brien
Facsimile: 617-235-0392

If to Seller, to:

Eiger BioPharmaceuticals, Inc.
2155 Park Blvd
Palo Alto, CA 94306
Attention: General Counsel
Email: legal@eigerbio.com

with a copy (which shall not constitute notice) to:

Covington & Burling LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018
Attention: Stephen A. Infante
Facsimile: 646-441-9039

9.2 Construction. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe,

extend, or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including," "include," or "includes" as used herein shall mean "including, but not limited to," and shall not limit the generality of any description preceding such term. The words "will" and "shall" have the same meaning. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party hereto. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions.

9.3 References. Unless otherwise specified, (a) references in this Agreement to any Article, Section, Schedule or Exhibit shall mean references to such Article, Section, Schedule or Exhibit of this Agreement, (b) references in any Section to any clause are references to such clause of such Section, and (c) references to any agreement, instrument, or other document in this Agreement refer to such agreement, instrument, or other document as originally executed or, if subsequently amended, replaced, or supplemented from time to time, as so amended, replaced, or supplemented and in effect at the relevant time of reference thereto.

9.4 Entire Agreement; Amendments. This Agreement, the documents, Exhibits and Schedules referred to herein, and the Mutual Confidential Disclosure Agreement sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understandings, promises, and representations, whether written or oral, with respect thereto are superseded hereby. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Agreement. No amendment, modification, release, or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

9.5 Assignment. Without the prior written consent of the other Party neither Party shall sell, transfer, assign, delegate, pledge, or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder; provided, that (a) either Party may make such an assignment without the other Party's consent to any of its Affiliates, and (b) Buyer may make such an assignment, in whole or in part, without Seller's consent, to any Affiliate, purchaser, transferee, or assignee of the Purchased Assets. With respect to any permitted assignment, the assigning Party shall remain responsible for the performance by such permitted assignee of the assigning Party's duties and obligations hereunder. Any attempted assignment or delegation in violation of this Section 9.5 shall be void and of no effect. All validly assigned and delegated rights and obligations of the Parties hereunder shall be binding upon and inure to the benefit of and be enforceable by and against the successors and permitted assigns of Buyer or Seller, as the case may be. For the avoidance of doubt, no assignment made pursuant to this Section 9.5 shall relieve the assigning Party of any of its obligations under this Agreement.

9.6 Severability. If any provision of this Agreement is held to be illegal, invalid, or unenforceable under any present or future law, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable; (b) this Agreement shall be construed and enforced as if such illegal, invalid, or unenforceable provision had never comprised a part hereof; (c) the remaining provisions of this

Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid, or unenforceable provision or by its severance herefrom; and (d) in lieu of such illegal, invalid, or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid, and enforceable provision as similar in terms to such illegal, invalid, or unenforceable provision as may be possible and reasonably acceptable to the Parties. To the fullest extent permitted by applicable Law, each Party hereby waives any provision of Law that would render any provision hereof illegal, invalid, or unenforceable in any respect.

9.7 Governing Law. This Agreement or the performance, enforcement, breach or termination hereof shall be interpreted, governed by and construed in accordance with the laws of the State of New York, United States ("***New York***"), excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

9.8 Submission to Jurisdiction.

Each Party irrevocably agrees that any legal action or proceeding arising out of or relating to this Agreement brought by such Party or its successors or assigns shall be brought and determined in any New York state or federal court, and each Party hereby irrevocably (a) submits to the exclusive jurisdiction of the aforesaid courts with regard to any such action or proceeding arising out of or relating to this Agreement and the transactions contemplated hereby and (b) agrees that service of any court paper may be made in the manner provided for in Section 9.1 or such other as may be provided under applicable Laws or court rules governing service of process

. Each Party agrees not to commence any action, suit or proceeding relating thereto except in the courts described above in New York, other than actions in any court of competent jurisdiction to enforce any judgment, decree or award rendered by any such court in New York as described herein. Each Party hereby irrevocably and unconditionally waives, and agrees not to assert, by way of motion or as a defense, counterclaim or otherwise, in any action or proceeding arising out of or relating to this Agreement or the transactions contemplated hereby, (a) any claim that it is not personally subject to the jurisdiction of the courts in New York as described herein for any reason, (b) that it or its property is exempt or immune from jurisdiction of any such court or from any legal process commenced in such courts (whether through service of notice, attachment prior to judgment, attachment in aid of execution of judgment, execution of judgment or otherwise) and (c) that (i) the suit, action or proceeding in any such court is brought in an inconvenient forum, (ii) the venue of such suit, action or proceeding is improper or (iii) this Agreement, or the subject matter hereof, may not be enforced in or by such courts.

9.9 WAIVER OF JURY TRIAL. EACH PARTY, TO THE EXTENT PERMITTED BY LAW, KNOWINGLY, VOLUNTARILY, AND INTENTIONALLY WAIVES ITS RIGHT TO A TRIAL BY JURY IN ANY ACTION OR OTHER LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT AND THE TRANSACTIONS IT CONTEMPLATES. THIS WAIVER APPLIES TO ANY ACTION OR LEGAL PROCEEDING, WHETHER SOUNDING IN CONTRACT, TORT, OR OTHERWISE.

9.10 Waiver and Non-Exclusion of Remedies.

(a) Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party hereto of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise, and nothing in this Agreement shall be deemed a waiver by any Party of any right to specific performance or injunctive relief. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by applicable Law or otherwise available except as expressly set forth herein.

(b) The Parties agree that irreparable harm would occur in the event that the Closing is not consummated in accordance with the terms of this Agreement, and that money damages or other legal remedies would not be an adequate remedy for any such harm. Accordingly, the Parties acknowledge and hereby covenant and agree that in the event of any breach or threatened breach of the covenants, agreements or obligations set forth in this Agreement, then in addition to any other remedy available at law or in equity, the non-breaching Party will be entitled to seek an injunction or injunctions to prevent or restrain any breaches or threatened breaches of this Agreement, and to specifically enforce the terms and provisions of this Agreement to enforce compliance with the covenants, agreements and obligations under this Agreement. Each Party hereby covenants and agrees not to raise, and irrevocably waives, any objections to the availability of such relief that a remedy at law would be adequate and that a bond or other security will be required.

9.11 No Benefit to Third Parties. Except as provided in Article 8, the covenants and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they shall not be construed as conferring any rights on any other Persons.

9.12 Counterparts; Facsimile Execution. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one (1) and the same instrument. This Agreement may be executed by facsimile or electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, each of Buyer and Seller has caused this Agreement to be executed and delivered by their respective officers thereunto duly authorized, all as of the date first written above.

ABBVIE, INC.

By: */s/ Henry Gosebrud*

Name: Henry Gosebrud

Title: EVP, Chief Strategy Officer

IN WITNESS WHEREOF, each of Buyer and Seller has caused this Agreement to be executed and delivered by their respective officers thereunto duly authorized, all as of the date first written above.

EIGER BIOPHARMACEUTICALS, INC.

By:	/s/ Sriram Ryali
Name:	Sriram Ryali
Title:	CFO

Omitted Attachments

Exhibits to Asset Purchase Agreement

Exhibit A	Approval Letter
Exhibit B	Lender Consent
Exhibit C	PRF Consent
Exhibit 2.4(b)	Form of Seller Cover Letter
Exhibit 2.5(a)	Form of Bill of Sale
Exhibit 2.5(b)	Form of Seller PRV Transfer Letter
Exhibit 2.5(c)	Form of Seller Closing Certificate
Exhibit 2.5(d)	Form of Seller Secretary's Certificate
Exhibit 2.6(c)	Form of Buyer PRV Transfer Letter
Exhibit 2.6(d)	Form of Buyer Closing Certificate
Exhibit 5.6	Form of Public Announcement

Pursuant to Item 601(a)(5) of Regulation S-K, the registrant hereby undertakes to furnish supplementally a copy of any of the above-listed attachments to the Commission upon request.

Exhibit 10.32

AMENDMENT #7 TO LICENSE AGREEMENT

This Amendment #7 to License Agreement ("Amendment #7") is entered into as of the date of last signature below ("Amendment #7 Effective Date") by and between Merck Sharp & Dohme Corp. (formerly known as Schering Corporation), a New Jersey corporation having a place of business at 2000 Galloping Hill Road, Kenilworth, NJ 07033 ("Merck") and Eiger BioPharmaceuticals, Inc., a Delaware corporation having a place of business at 2155 Park Boulevard, CA 94306 ("Licensee") (each of Merck and Licensee, a "Party", and together, the "Parties") to amend that certain License Agreement between the Parties dated September 3, 2010, as amended on January 18, 2011 and subsequently first amended June 11, 2013, as second amended November 20, 2014, as third amended March 6, 2015, as fourth amended June 9, 2015, as fifth amended December 15, 2015, as sixth amended on May 15, 2018 (collectively, the "Agreement").

IN CONSIDERATION OF the mutual promises and covenants contained herein, the parties agree as follows:

1. Definitions

   a. The following definition in Article I is hereby deleted and replaced with the following:

   "Progeria" shall mean Hutchinson-Gilford Progeria Syndrome and Progeroid Laminopathies.

2. Except as set forth herein, all capitalized terms not defined in this Amendment #7 shall have the meaning given to them in the Agreement.

3. In the event of any inconsistency between the terms of this Amendment #7 and the terms of the Agreement, the terms of this Amendment #7 shall govern.

4. Except as expressly amended hereby, all of the terms and conditions of the Agreement remain in full force and effect.

IN WITNESS WHEREOF, the Parties have executed this Amendment #7 by their duly authorized representatives as of the Amendment #7 Effective Date.

Eiger BioPharmaceuticals, Inc.		**Merck Sharp & Dohme Corp.**	
By:	*/s/ Sriram Ryali*	By:	*/s/ Benjamin Thorner*
Name:	Sriram Ryali	Name:	Benjamin Thorner
Title:	Chief Financial Officer	Title:	SVP & Head of BD&L, MRL
Date:	November 3, 2020	Date:	November 3, 2020

FIFTH AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS **FIFTH AMENDMENT** to Loan and Security Agreement (this "**Amendment**") is entered into as of February [__], 2021, by and between **OXFORD FINANCE LLC**, a Delaware limited liability company with an office located at 115 South Union Street, Suite 300, Alexandria, Virginia 22314 ("**Oxford**"), as collateral agent (in such capacity, "**Collateral Agent**"), the Lenders listed on Schedule 1.1 of the Loan Agreement (as defined below) or otherwise party thereto from time to time including Oxford in its capacity as a Lender (each a "**Lender**" and collectively, the "**Lenders**"), and EIGER BIOPHARMACEUTICALS, INC., a Delaware corporation ("**Parent**"), EB Pharma, LLC, a Delaware limited liability company ("**EB Pharma**") and EBPI Merger, Inc., a Delaware corporation ("**EBPI**"), each with offices located at 2155 Park Blvd., Palo Alto, CA 94306 (Parent, EB Pharma and EBPI, individually and collectively, jointly and severally, "**Borrower**").

RECITALS

A. Collateral Agent, Lenders and Borrower have entered into that certain Loan and Security Agreement dated as of December 30, 2016 (as amended from time to time, including by that certain First Amendment to Loan and Security Agreement dated as of April 24, 2017, that certain Second Amendment to Loan and Security Agreement dated as of May 11, 2018, that certain Second Amendment to Loan and Security Agreement dated as of May 11, 2018, that certain Third Amendment to Loan and Security Agreement dated as of March 5, 2019 and that certain Default Waiver and Fourth Amendment to Loan and Security Agreement dated as of March 10, 2020, the "**Loan Agreement**"). Lenders have extended credit to Borrower for the purposes permitted in the Loan Agreement.

B. Borrower has requested that Collateral Agent and Lenders (i) modify the repayment schedule and (ii) make certain other revisions to the Loan Agreement as more fully set forth herein. Collateral Agent and the Lenders have agreed to so amend certain provisions of the Loan Agreement, but only to the extent, in accordance with the terms, subject to the conditions and in reliance upon the representations and warranties set forth below

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing recitals and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

1. Definitions. Capitalized terms used but not defined in this Amendment shall have the meanings given to them in the Loan Agreement.

2. Amendments to Loan Agreement.

2.1 Section 2.2(b) (Term Loans). Section 2.2(b) of the Loan Agreement hereby is amended and restated in its entirety to read as follows:

"(b) Repayment. Borrower shall make monthly payments of interest only commencing on the first (1st) Payment Date following the Funding Date of each Term Loan, and continuing on the Payment Date of each successive month thereafter through and including the Payment Date immediately preceding the Amortization Date. Borrower agrees to pay, on the Funding Date of each Term Loan, any initial partial monthly interest payment otherwise due for the period between the Funding Date of such Term Loan and the first Payment Date thereof. Commencing on the Amortization Date, and continuing on the Payment Date of each month thereafter, Borrower shall make consecutive equal monthly payments of principal, together with applicable interest, in arrears, to each Lender, as calculated by Collateral Agent (which calculations shall be deemed correct absent manifest error) based upon: (1) the amount of such Lender's Term Loan then outstanding, (2) the effective rate of interest, as determined in Section 2.3(a), and (3) a repayment schedule equal to (i) if the Amortization Date is September 1, 2022, nineteen (19) months and (ii) if the Amortization Date is March 1, 2023, thirteen (13) months. All unpaid principal

and accrued and unpaid interest with respect to each Term Loan is due and payable in full on the Maturity Date. Each Term Loan may only be prepaid in accordance with Sections 2.2(c) and 2.2(d)."

2.2 Section 2.5 (Fees). New Section 2.5(f) of the Loan Agreement hereby is added to the Loan Agreement to read as follows:

"(f) Fifth Amendment Fee. A fully-earned, non-refundable final payment, due in connection with the Term Loans, in the aggregate amount of One Hundred Seventy-Five Thousand Dollars ($175,000.00) (the "Fifth Amendment Fee"), payable to the Lenders in accordance with their respective Pro Rata Shares and due on the Fifth Amendment Effective Date; and"

2.3 Section 10 (Notices). The notice information for Collateral Agent in Section 10 of the Loan Agreement hereby is amended and restated as follows:

"If to Collateral Agent: OXFORD FINANCE LLC
115 South Union Street, Suite 300
Alexandria, Virginia 22314
Attention: Legal Department
Fax: (703) 519-5225
Email: LegalDepartment@oxfordfinance.com"

2.4 Section 13 (Definitions). The following terms and their respective definitions hereby are added, in appropriate alphabetical order, or amended and restated in their entirety, as applicable, to Section 13.1 of the Loan Agreement as follows:

"**Amortization Date**" is September 1, 2022; provided that, if Borrower achieves the Second Draw Period Milestone, the Amortization Date shall automatically be extended to March 1, 2023.

"**Fifth Amendment Effective Date**" is February [__], 2021.

"**Second Draw Period**" is the period commencing on the on the latest of (a) the date of the occurrence of the Second Draw Milestone, and (b) January 1, 2021, and ending on the earliest of (x) thirty (30) days from the occurrence of the Second Draw Period Milestone, (y) August 31, 2022, and (z) the occurrence of any Event of Default; provided, however, that the Second Draw Period shall not commence if on the date of the occurrence of the Second Draw Period Milestone an Event of Default has occurred and is continuing.

3. Limitation of Amendment.

3.1 The amendments set forth in **Section 2** are effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right or remedy which Collateral Agent or any Lender may now have or may have in the future under or in connection with any Loan Document.

3.2 This Amendment shall be construed in connection with and as part of the Loan Documents and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents, except as herein amended, are hereby ratified and confirmed and shall remain in full force and effect.

4. Representations and Warranties. To induce Collateral Agent and Lenders to enter into this Amendment, Borrower hereby represents and warrants to Collateral Agent and Lenders as follows:

4.1 Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct as of such date), and (b) no Event of Default has occurred and is continuing;

4.2 Borrower has the power and authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;

4.3 The organizational documents of Borrower delivered to Collateral Agent and Lenders on the Effective Date, or subsequent thereto, remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;

4.4 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, have been duly authorized;

4.5 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not and will not contravene (a) any law or regulation binding on or affecting Borrower, (b) any contractual restriction with a Person binding on Borrower, (c) any order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrower, or (d) the organizational documents of Borrower;

4.6 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on Borrower; and

4.7 This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.

5. Prior Agreement. The Loan Documents are hereby ratified and reaffirmed and shall remain in full force and effect. This Amendment is not a novation and the terms and conditions of this Amendment shall be in addition to and supplemental to all terms and conditions set forth in the Loan Documents. In the event of any conflict or inconsistency between this Amendment and the terms of such documents, the terms of this Amendment shall be controlling, but such document shall not otherwise be affected or the rights therein impaired.

6. Miscellaneous.

6.1 This Amendment shall constitute a Loan Document under the Loan Agreement; the failure to comply with the covenants contained herein shall constitute an Event of Default under the Loan Agreement; and all obligations included in this Amendment (including, without limitation, all obligations for the payment of principal, interest, fees, and other amounts and expenses) shall constitute obligations under the Loan Agreement and secured by the Collateral.

6.2 Each provision of this Amendment is severable from every other provision in determining the enforceability of any provision.

7. Counterparts. This Amendment may be executed in any number of counterparts and all of such counterparts taken together shall be deemed to constitute one and the same instrument.

8. Effectiveness. This Amendment shall be deemed effective upon (a) the due execution and delivery to Collateral Agent and Lenders of (i) this Amendment by each party hereto, and (ii) the Corporate Borrowing Certificate for each Borrower, the form of which is attached hereto, and (b) Borrower's payment of (i) the Fifth Amendment Fee due as specified in Section 2.5(f) of the Loan Agreement, and (ii) all Lenders' Expenses incurred through the date of this Amendment.

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In Witness Whereof, the parties hereto have caused this Amendment to be duly executed and delivered as of the date first written above.

BORROWER:

EIGER BIOPHARMACEUTICALS, INC.

By:
Name:
Title:

EB PHARMA, LLC

By:
Name:
Title:

EBPI MERGER, INC.

By:
Name:
Title:

COLLATERAL AGENT AND LENDER:

OXFORD FINANCE LLC

By:
Name:
Title:

CORPORATE BORROWING CERTIFICATE

BORROWER: EIGER BIOPHARMACEUTICALS, INC. **DATE**: February [__], 2021
LENDER: OXFORD FINANCE LLC, as Collateral Agent and Lender

I hereby certify as follows, as of the date set forth above:

1. I am the Secretary, Assistant Secretary or other officer of Borrower. My title is as set forth below.

2. Borrower's exact legal name is set forth above. Borrower is a corporation existing under the laws of the State of Delaware.

3. Attached hereto as Exhibit A and Exhibit B, respectively, are true, correct and complete copies of (i) Borrower's Certificate of Incorporation (including amendments), as filed with the Secretary of State of the state in which Borrower is incorporated as set forth in paragraph 2 above; and (ii) Borrower's Bylaws. Neither such Certificate of Incorporation nor such Bylaws have been amended, annulled, rescinded, revoked or supplemented, and such Certificate of Incorporation and such Bylaws remain in full force and effect as of the date hereof.

4. The following resolutions were duly and validly adopted by Borrower's Board of Directors at a duly held meeting of such directors (or pursuant to a unanimous written consent or other authorized corporate action). Such resolutions are in full force and effect as of the date hereof and have not been in any way modified, repealed, rescinded, amended or revoked, and the Lenders may rely on them until each Lender receives written notice of revocation from Borrower.

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RESOLVED, that **any one** of the following officers or employees of Borrower, whose names, titles and signatures are below, may act on behalf of Borrower:

Name	Title	Signature

RESOLVED FURTHER, that **any one** of the persons designated above with a checked box beside his or her name may, from time to time, add or remove any individuals to and from the above list of persons authorized to act on behalf of Borrower.

RESOLVED FURTHER, that such individuals may, on behalf of Borrower:

Borrow Money. Borrow money from the Lenders.
Execute Loan Documents. Execute any loan documents any Lender requires.
Grant Security. Grant Collateral Agent a security interest in any of Borrower's assets.
Negotiate Items. Negotiate or discount all drafts, trade acceptances, promissory notes, or other indebtedness in which Borrower has an interest and receive cash or otherwise use the proceeds.
Further Acts. Designate other individuals to request advances, pay fees and costs and execute other documents or agreements (including documents or agreement that waive Borrower's right to a jury trial) they believe to be necessary to effectuate such resolutions.

RESOLVED FURTHER, that all acts authorized by the above resolutions and any prior acts relating thereto are ratified.

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5. The persons listed above are Borrower's officers or employees with their titles and signatures shown next to their names.

By:

Name:

Title:

**** If the Secretary, Assistant Secretary or other certifying officer executing above is designated by the resolutions set forth in paragraph 4 as one of the authorized signing officers, this Certificate must also be signed by a second authorized officer or director of Borrower.*

I, the _____ of Borrower, hereby certify as to paragraphs 1 through 5 above, as
[print title]
of the date set forth above.

By:

Name:

Title:

**[*Signature Page to Corporate Borrowing Certificate*
EIGER BIOPHARMACEUTICALS, INC.]

EXHIBIT A

Certificate of Incorporation (including amendments)

[see attached]

EXHIBIT B

Bylaws

[see attached]

CORPORATE BORROWING CERTIFICATE

BORROWER: EB PHARMA, LLC **DATE**: February [__], 2021
LENDER: OXFORD FINANCE LLC, as Collateral Agent and Lender

I hereby certify as follows, as of the date set forth above:

1. I am the Secretary, Assistant Secretary or other officer of Borrower. My title is as set forth below.

2. Borrower's exact legal name is set forth above. Borrower is a limited liability company existing under the laws of the State of Delaware.

3. Attached hereto as Exhibit A and Exhibit B, respectively, are true, correct and complete copies of (i) Borrower's Certificate of Formation (including amendments), as filed with the Secretary of State of the state in which Borrower is incorporated as set forth in paragraph 2 above; and (ii) Borrower's operating agreement. Neither such Certificate of Formation nor such operating agreement have been amended, annulled, rescinded, revoked or supplemented, and such Certificate of Formation and such operating agreement remain in full force and effect as of the date hereof.

4. The following resolutions were duly and validly adopted by Borrower's Board of Directors at a duly held meeting of such directors (or pursuant to a unanimous written consent or other authorized corporate action). Such resolutions are in full force and effect as of the date hereof and have not been in any way modified, repealed, rescinded, amended or revoked, and the Lenders may rely on them until each Lender receives written notice of revocation from Borrower.

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RESOLVED, that **any one** of the following officers or employees of Borrower, whose names, titles and signatures are below, may act on behalf of Borrower:

Name	Title	Signature

RESOLVED FURTHER, that **any one** of the persons designated above with a checked box beside his or her name may, from time to time, add or remove any individuals to and from the above list of persons authorized to act on behalf of Borrower.

RESOLVED FURTHER, that such individuals may, on behalf of Borrower:

Borrow Money. Borrow money from the Lenders.
Execute Loan Documents. Execute any loan documents any Lender requires.
Grant Security. Grant Collateral Agent a security interest in any of Borrower's assets.
Negotiate Items. Negotiate or discount all drafts, trade acceptances, promissory notes, or other indebtedness in which Borrower has an interest and receive cash or otherwise use the proceeds.
Further Acts. Designate other individuals to request advances, pay fees and costs and execute other documents or agreements (including documents or agreement that waive Borrower's right to a jury trial) they believe to be necessary to effectuate such resolutions.

RESOLVED FURTHER, that all acts authorized by the above resolutions and any prior acts relating thereto are ratified.

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5. The persons listed above are Borrower's officers or employees with their titles and signatures shown next to their names.

By:

Name:

Title:

**** If the Secretary, Assistant Secretary or other certifying officer executing above is designated by the resolutions set forth in paragraph 4 as one of the authorized signing officers, this Certificate must also be signed by a second authorized officer or director of Borrower.*

I, the _____ of Borrower, hereby certify as to paragraphs 1 through 5 above, as
[print title]
of the date set forth above.

By:

Name:

Title:

**[*Signature Page to Corporate Borrowing Certificate*
EB PHARMA, LLC]

EXHIBIT A

Certificate of Formation (including amendments)

[see attached]

EXHIBIT B

Operating Agreement

[see attached]

CORPORATE BORROWING CERTIFICATE

BORROWER: EBPI MERGER, INC. **DATE**: February [__], 2021
LENDER: OXFORD FINANCE LLC, as Collateral Agent and Lender

I hereby certify as follows, as of the date set forth above:

1. I am the Secretary, Assistant Secretary or other officer of Borrower. My title is as set forth below.

2. Borrower's exact legal name is set forth above. Borrower is a corporation existing under the laws of the State of Delaware.

3. Attached hereto as Exhibit A and Exhibit B, respectively, are true, correct and complete copies of (i) Borrower's Certificate of Incorporation (including amendments), as filed with the Secretary of State of the state in which Borrower is incorporated as set forth in paragraph 2 above; and (ii) Borrower's Bylaws. Neither such Certificate of Incorporation nor such Bylaws have been amended, annulled, rescinded, revoked or supplemented, and such Certificate of Incorporation and such Bylaws remain in full force and effect as of the date hereof.

4. The following resolutions were duly and validly adopted by Borrower's Board of Directors at a duly held meeting of such directors (or pursuant to a unanimous written consent or other authorized corporate action). Such resolutions are in full force and effect as of the date hereof and have not been in any way modified, repealed, rescinded, amended or revoked, and the Lenders may rely on them until each Lender receives written notice of revocation from Borrower.

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RESOLVED, that **any one** of the following officers or employees of Borrower, whose names, titles and signatures are below, may act on behalf of Borrower:

Name	Title	Signature

RESOLVED FURTHER, that **any one** of the persons designated above with a checked box beside his or her name may, from time to time, add or remove any individuals to and from the above list of persons authorized to act on behalf of Borrower.

RESOLVED FURTHER, that such individuals may, on behalf of Borrower:

Borrow Money. Borrow money from the Lenders.
Execute Loan Documents. Execute any loan documents any Lender requires.
Grant Security. Grant Collateral Agent a security interest in any of Borrower's assets.
Negotiate Items. Negotiate or discount all drafts, trade acceptances, promissory notes, or other indebtedness in which Borrower has an interest and receive cash or otherwise use the proceeds.
Further Acts. Designate other individuals to request advances, pay fees and costs and execute other documents or agreements (including documents or agreement that waive Borrower's right to a jury trial) they believe to be necessary to effectuate such resolutions.

RESOLVED FURTHER, that all acts authorized by the above resolutions and any prior acts relating thereto are ratified.

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5. The persons listed above are Borrower's officers or employees with their titles and signatures shown next to their names.

By:

Name:

Title:

**** If the Secretary, Assistant Secretary or other certifying officer executing above is designated by the resolutions set forth in paragraph 4 as one of the authorized signing officers, this Certificate must also be signed by a second authorized officer or director of Borrower.*

I, the _____ of Borrower, hereby certify as to paragraphs 1 through 5 above, as
[print title]
of the date set forth above.

By:

Name:

Title:

**[*Signature Page to Corporate Borrowing Certificate*
EBPI MERGER, INC.]

EXHIBIT A

Certificate of Incorporation (including amendments)

[see attached]

EXHIBIT B

Bylaws

[see attached]

Exhibit 21.1

Subsidiaries of Registrant

Name of Subsidiary	Jurisdiction of Incorporation
EBPI Merger, Inc.	Delaware
EB Pharma LLC	Delaware
Eiger BioPharmaceuticals Europe Limited	England and Wales
EigerBio Europe Limited	Ireland

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Eiger BioPharmaceuticals, Inc.:

We consent to the incorporation by reference in the registration statements (Nos. 333-251497, 333-235655, 333-221972, 333-212114, and 333-203153) on Form S-3 and the registration statements (Nos. 333-237156, 333-230287, 333-224872, 333-219936, 333-211009, 333-203154, and 333-193662) on Form S-8 of Eiger BioPharmaceuticals, Inc. of our report dated March 9, 2021, with respect to the consolidated balance sheets of Eiger BioPharmaceuticals, Inc. as of December 31, 2020 and 2019, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2020, and the related notes, which report appears in the December 31, 2020 annual report on Form 10-K of Eiger BioPharmaceuticals, Inc.

/s/ KPMG LLP

San Francisco, California
March 9, 2021

Exhibit 31.1

Certification of the Chief Executive Officer
Pursuant to
Securities Exchange Act Rules 13A-14(A) and 15D-14(A)

I, David A. Cory, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 9, 2021

/s/ David A. Cory
David A. Cory
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Chief Financial Officer
Pursuant to
Securities Exchange Act Rules 13A-14(A) and 15D-14(A)

I, Sriram Ryali, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 9, 2021

/s/ Sriram Ryali
Sriram Ryali
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

Certification Pursuant to
18 U.S.C. Section 1350,
As Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), David A. Cory, Chief Executive Officer of Eiger BioPharmaceuticals, Inc. (the "Company"), and Sriram Ryali, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2020, to which this Certification is attached as Exhibit 32.1 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

In Witness Whereof, the undersigned have set their hands hereto as of the 9th day of March, 2021.

Date: March 9, 2021

/s/ David A. Cory
David A. Cory
President and Chief Executive Officer (Principal Executive Officer)

/s/ Sriram Ryali
Sriram Ryali
Chief Financial Officer (Principal Financial and Accounting Officer)

"This certification accompanies the Annual Report on Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Eiger BioPharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing."